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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2014

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

Commission File No. 001-34186

VANDA PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	**03-0491827**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

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 ☑

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

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

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

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

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

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

As of June 30, 2014, 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 $380.6 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 March 6, 2015 was 41,641,005.

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 2015 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, 2014, 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, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in our forward-looking statements include, among others:

- our ability to successfully commercialize HETLIOZ® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the U.S.;
- uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ®;
- our ability to generate U.S. sales of Fanapt® (iloperidone) for the treatment of schizophrenia;
- the timing and costs of our establishment of a sales and marketing, supply chain, distribution, pharmacovigilance, compliance and safety infrastructure to promote Fanapt® in the U.S.;
- our dependence on third-party manufacturers to manufacture HETLIOZ® and Fanapt® in sufficient quantities and quality;
- our limited sales and marketing infrastructure;
- the regulatory status of HETLIOZ® and Fanapt® in Europe;
- our ability to successfully commercialize HETLIOZ® and Fanapt® outside of the U.S.;
- 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 or to comply with ongoing regulatory requirements;
- the timing and costs of complying with the remaining post-marketing commitments and post-marketing requirements established in connection with the U.S. Food and Drug Administration (FDA) approval of Fanapt®;
- the timing and success of preclinical studies and clinical trials conducted by us and our development partners;
- the ability to obtain and maintain regulatory approval of our products, and the labeling for any approved products;
- the scope, progress, expansion, and costs of developing and commercializing our products;
- the size and growth of the potential markets for our products and the ability to serve those markets;
- 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;
- our ability to prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights;

- the cost and effects of potential litigation;
- losses incurred from product liability claims made against us; and
- use of our existing cash, cash equivalents and marketable securities.

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 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. Our product portfolio includes:

- HETLIOZ® (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) for which a New Drug Application (NDA) was approved by the U.S. Food and Drug Administration (FDA) in January 2014 and launched commercially in the U.S. in April 2014. Additionally, a Marketing Authorization Application (MAA) in the European Union was accepted by the European Medicines Agency (EMA) for review in June 2014 and a regulatory decision is expected in the third quarter of 2015. HETLIOZ® has potential utility in a number of circadian rhythm disorders. Ongoing HETLIOZ® life cycle management activities include an observation study in Smith-Magenis Syndrome (SMS) and a clinical development plan is being developed for pediatric Non-24. In addition, we are exploring the creation of a new liquid formulation of HETLIOZ®.
- Fanapt® (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which was being marketed and sold in the U.S. by Novartis Pharma AG (together with its affiliates, Novartis) until December 31, 2014. On December 31, 2014, Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt® franchise to Vanda. See *Settlement Agreement with Novartis* footnote to the consolidated financial statements included in Part II of this annual report on Form 10-K for information. Additionally, our distribution partners launched Fanapt® in Israel and Mexico in 2014.
- Tradipitant (VLY-686), a small molecule neurokinin-1 receptor (NK-1R) antagonist, which is presently in clinical development for the treatment of chronic pruritus in atopic dermatitis. Results from a Phase II study for the treatment of chronic pruritus in atopic dermatitis were announced in March 2015. Clinical evaluation is ongoing to assess potential future development activities.
- Trichostatin A, a small molecule histone deacetylase (HDAC) inhibitor.
- AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

In May 2014, we commenced arbitration proceedings against Novartis relating to the license of Fanapt® (the Fanapt® Arbitration). In December 2014, we entered into a settlement agreement with Novartis and certain of its affiliates (the Settlement Agreement). Pursuant to the terms of the Settlement Agreement, Vanda and Novartis dismissed the Fanapt® Arbitration and released each other from any related claims. In addition, in connection with the Settlement Agreement, Novartis (i) transferred all U.S. and Canadian rights in the Fanapt® franchise to Vanda, (ii) purchased $25.0 million of our common stock at a price per share equal to $13.82, and (iii) granted to Vanda an exclusive worldwide license to AQW051. In connection with the Settlement Agreement, the 2009 Amended Sublicense Agreement was terminated.

Since we began operations in March 2003, we have devoted substantially all of our resources to the in-licensing, clinical development and commercialization 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, and our ability to successfully commercialize HETLIOZ® for the treatment of Non-24 and Fanapt® for the treatment of schizophrenia. 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 entitled *Risk Factors* and Item 7 of Part II entitled *Management's Discussion and Analysis of Financial Condition and Results of Operations* of this annual report on Form 10-K.

Our activities will necessitate significant uses of working capital throughout 2015 and beyond. We are currently concentrating our efforts on the continued U.S. commercial launch of HETLIOZ® and selling Fanapt® commercially in the U.S. Additionally, we continue to pursue market approval of HETLIOZ® and Fanapt® in Europe and other regions. We will continue to work with our distribution partners who launched Fanapt® in Mexico and Israel during 2014. We see opportunities to grow our commercial products through life cycle management strategies that include the addition of new indications and formulations. Our pipeline includes novel programs that could address largely unmet medical needs.

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® and Fanapt®;*
- *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.*

Products

We have the following products on the market or under regulatory review:

Product	Indication	Country	Select Milestones
HETLIOZ® (tasimelteon)	Non-24	United States	FDA approval in January 2014; Commercial launch in April 2014
		Europe	EMA accepted for evaluation our MAA in June 2014; Expect EMA opinion in the third quarter of 2015
		Canada	Plan to file a marketing application with Health Canada in the second half of 2015
Fanapt® (Oral) (iloperidone)	Schizophrenia	United States	FDA approval in May 2009; Commercial launch in January 2010; U.S. and Canada rights sublicensed to Novartis in October 2009; Reacquired by Vanda in December 2014

Product	Indication	Country	Select Milestones
		Europe	Plan to file MAA with EMA in 2015
		Mexico	Market approval in October 2013; Commercial launch in the fourth quarter of 2014 by our local distribution partner, Probiomed S.A. de C.V.
		Israel	Market approval August 2012; Commercial launch in the fourth quarter of 2014 by our local distribution partner, Megapharm Ltd.

We have the following products in clinical development:

Product	Target Indication	Select Milestones
HETLIOZ® (tasimelteon)	Pediatric Non-24	Discussion ongoing regarding development plan; Plan to initiate a pharmacokinetic study in the second half of 2015
	SMS	Initiated observational study in patients with SMS; Results of this study are expected in the first half of 2015
	Liquid Formulation	Under development with potential utilization for multiple indications
Fanapt® (Oral) (iloperidone)	Schizophrenia	Planning to submit results of REPRIEVE, a Phase III long term maintenance study that was conducted by Novartis; Depot formulation under evaluation
Tradipitant (VLY-686)	Pruritus in patients with Atopic Dermatitis	Results from a Phase II study for the treatment of chronic pruritus in atopic dermatitis were announced in March 2015; Clinical evaluation is ongoing to assess potential future development activities
Trichostatin A	Oncology	Plan to file an IND in 2016
AQW051	CNS Disorders	Transferring clinical data from Novartis; Indication is under strategic evaluation for cognitive impairment

HETLIOZ®

Commercial opportunity: Non-24

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. HETLIOZ® was launched commercially in the U.S. in April 2014. In addition, the EMA accepted for evaluation our MAA for oral HETLIOZ® capsules for the treatment of Non-24 in June 2014. We expect a decision from the EMA regarding our HETLIOZ® MAA in the third quarter of 2015. During the second half of 2015, we plan to file a HETLIOZ® marketing application with Health Canada for the treatment of Non-24.

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.

Non-24 is a serious, rare and chronic circadian rhythm disorder characterized by the inability to 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 synchronize 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 Non-24, other than HETLIOZ®, there are a number of drugs approved and prescribed for patients with sleep disorders. The most commonly prescribed drugs are hypnotics. Please see *Competition* below for a discussion of commonly prescribed drugs for patients with sleep disorders.

Therapeutic opportunity: Circadian Rhythm Sleep Disorders

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 delayed sleep phase disorder, shift work sleep disorder and Non-24.

Therapeutic opportunity: Other

We have initiated an observational study in patients with SMS in order to further characterize the circadian rhythm defect and its association with clinical symptoms. SMS is a rare genetic disorder caused by a deletion on chromosome 17. The U.S. National Institute of Health estimates that SMS affects approximately one in 20,000 people.

We are planning to develop HETLIOZ® for the treatment of pediatric Non-24 and are presently in discussions with regulatory agencies regarding the appropriate studies to enable regulatory approval. We expect to initiate a pediatric pharmacokinetic study in the second half of 2015.

We are in the process of developing a liquid formulation of HETLIOZ® to potentially be utilized in multiple indications.

Fanapt®

Commercial Opportunity: Schizophrenia

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 had exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. In January 2010, Novartis launched Fanapt® in the U.S. On December 31, 2014, Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt® franchise to Vanda as part of the Settlement Agreement. See *Settlement Agreement with Novartis* footnote to the consolidated financial statements included in Part II of this annual report on Form 10-K for further information.

We continue to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. In December 2012, the EMA's Committee for Medicinal Products for Human Use (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. In 2015, we plan to have the results from REPRIEVE, a Phase III long term maintenances study that was conducted by Novartis. In addition, we plan to refile a MAA for Fanaptum™ with the EMA in 2015.

We have entered into agreements with the following partners for the commercialization of Fanapt® in the countries set forth below:

Country	Partner	Market Approval Date
Mexico	Probiomed S.A. de C.V.	October 2013
Israel	Megapharm Ltd.	August 2012

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. Please see *Competition* below for a discussion of commonly prescribed atypical antipsychotics in addition to Fanapt®.

Vanda will complete the close out activities for the REPREIVE long term maintenance study for the treatment of Schizophrenia that was initially conducted by Novartis. REPREIVE study close out activities are expected to be completed in 2015. Pursuant to the Settlement Agreement with Novartis, we reacquired the U.S. and Canadian rights to the long-acting injectable (depot) formulation of Fanapt®. We are evaluating the commercial opportunity around the depot formulation.

Tradipitant (VLY-686)

Tradipitant is a small molecule 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 commenced a Phase II clinical study of tradipitant in the treatment of chronic pruritus in patients with atopic dermatitis in 2014. Results from a Phase II study for the treatment of chronic pruritus in atopic dermatitis were announced in March 2015. This study showed no significant difference from placebo on the pre-specified primary endpoint. Vanda believes this proof of concept study was informative, in that through subsequent analyses, it revealed significant and clinically meaningful responses across multiple outcomes evaluated in individuals with higher blood plasma levels of tradipitant at the time of their pruritus assessments. Clinical evaluation is ongoing to assess potential future development activities.

Trichostatin A

Trichostatin A is a small molecule HDAC inhibitor with potential use as a treatment for several oncology indications. We plan to file an IND in the first half of 2016.

AQW051

AQW051 is a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist that we licensed from Novartis on December 31, 2014 pursuant to the Settlement Agreement. We are currently in the process of transferring clinical data from Novartis and evaluating potential indications, including cognitive impairment.

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 Company (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. We made developmental milestone payments to BMS totaling $12.0 million under the license agreement, including an $8.0 million milestone payment in the first quarter of 2014 as a result of the FDA's approval of our HETLIOZ® NDA. The $8.0 million milestone payment was capitalized as an intangible asset and is being amortized over the expected HETLIOZ® patent life in the U.S. We are obligated to make a future milestone payment to BMS of $25.0 million in the event that cumulative worldwide sales of HETLIOZ® reach $250.0 million. Additionally, we are obligated to make royalty payments on HETLIOZ® net sales to BMS in any territory where we commercialize HETLIOZ® for a period equal to the greater of 10 years post the first commercial sale in the territory or the expiry of the new chemical entity patent in that territory. During the period prior to the expiry of the new chemical entity patent in a territory, we are obligated to pay a 10% royalty on net sales in that territory. The royalty rate is decreased by half for countries in which no new chemical entity patent existed or for the remainder of the 10 years after the expiry of the new chemical entity patent. 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®

Pursuant to the terms of the Settlement Agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to Vanda on December 31, 2014.

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 partial consideration for this sublicense, we paid Novartis an initial license fee of $0.5 million and were obligated to make future milestone payments to Novartis of less than $100.0 million in the aggregate (the majority of which were tied to sales milestones), as well as royalty payments to Novartis at a rate which, as a percentage of net sales, was in the mid-twenties. As a result of the FDA's approval of the NDA for Fanapt® in May 2009, we met a milestone under the sublicense agreement, which required us to make a payment of $12.0 million to Novartis.

In October 2009, we 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 had 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 was responsible for the further clinical development activities in the U.S. and Canada. Pursuant to the amended and restated sublicense agreement, we received an upfront payment of $200.0 million and was 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. We also received royalties, which, as a percentage of net sales, were in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. We retained exclusive rights to Fanapt® outside the U.S. and Canada and are obligated to make royalty payments to Sanofi S.A. on Fanapt® sales outside the U.S. and Canada.

Pursuant to the terms of the Settlement Agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us on December 31, 2014. We are obligated to make royalty payments to Sanofi, S.A. and Titan, at a percentage rate equal to 23% on annual U.S. net sales of Fanapt® up to $200 million, and at a percentage in the mid-twenties on sales over $200.0 million through November 2016. After the expiration of the new chemical entity patent in major markets (U.S., United Kingdom, Germany, France, Italy, Spain and Japan) and some non-major markets, we will have a fixed royalty obligation to Sanofi on Fanapt® net sales of up to 9%. See *Settlement Agreement with Novartis* footnote to the consolidated financial statements included in Part II of this annual report on Form 10-K for further information.

Tradipitant (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, tradipitant, 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 tradipitant. 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 tradipitant.

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 tradipitant.

Trichostatin A

Trichostatin A is a small molecule HDAC inhibitor with potential use as a treatment for several oncology indications. We plan to file an IND in the first half of 2016.

AQW051

In December 2014, we entered into a license agreement with Novartis 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 alpha-7 nicotinic acetylcholine receptor partial agonist, AQW051, for all human indications.

Pursuant to the agreement, we will be responsible for all development costs for AQW051. Novartis is eligible to receive tiered royalties on net sales at percentage rates up to the low double digits. We have agreed to use commercially reasonable efforts to develop and commercialize AQW051.

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 Novartis 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 Novartis on an exclusive basis, subject to payment by Novartis to us of a royalty on net sales of products that contain AQW051.

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 and Mexico, 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 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 the U.S. Federal Food, Drug, and Cosmetic 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 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. The U.S. Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the "Hatch-Waxman Act," 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®, tradipitant and AQW051 are covered by new chemical entity and other patents and patent applications. The 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.

The table below is a summary of select patents for our commercial products.

	Number	Type	Country
HETLIOZ®	US 5,856,529	NCE	Issued in 39 countries including US, EU and Japan
	US 8,785,492	Method of treatment	US issued, pending in 15 countries and EU
	US 7,754,902	Synthesis	US
	US 8,097,738	Synthesis	US
	US 8,558,017	Synthesis	US
Fanapt®	RE 39198	NCE	US
	US 8,586,610	Method of treatment	US, pending in Japan, Canada, EU, Australia
	PCT/EP2002/012073	Iloperidone microparticle depot formulation	US, EU & Japan, issued in 29 countries
	PCT/EP2003/007619	Iloperidone aq. crystal depot formulation	US, EU & Japan, issued in 34 countries
	PCT/EP2002/013937	Method of treatment	US & EU, issued in 30 countries

HETLIOZ®

Our rights to the new chemical entity patent covering HETLIOZ® and related intellectual property have been acquired through a license with BMS. HETLIOZ® and its formulations, genetic markers and uses are covered by a total of 14 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. 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. An application for the five year patent term extension has been filed and is being processed by the U.S. Patent and Trademark Office. In July 2014, a new method of use patent was issued to the Company by the U.S. Patent and Trademark Office for HETLIOZ® in the treatment of Non-24. The method of use patent is expected to expire in 2033, potentially further extending the exclusivity protection of HETLIOZ®. Both the new chemical entity patent and the method of use patent are listed in the FDA's Orange Book.

In Europe, the law provides 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. It is also possible that the term of the new chemical entity patent in Europe could be extended by issuance of a supplementary protection certificate (SPC). The European Patent Office has issued a Decision to Grant the Company's patent application directed to the 20 mg/day dose. This patent will expire normally in 2027. Patent applications directed to the treatment of Non-24, if granted, would provide exclusivity in Europe for this indication until at least 2033.

Outside the U.S. and Europe, data exclusivity will protect HETLIOZ® from generic competition for varying numbers of years depending on the country.

Additional patent applications directed to specific sleep disorders and to methods of treating patients with HETLIOZ®, if issued, would provide exclusivity for such indications and methods of treatment, potentially extending the effective patent protection period in the U.S., Europe, and other major markets.

Fanapt®

The new chemical entity patent for Fanapt® is owned by Sanofi, and other patents and patent applications relating to Fanapt® previously owned by Novartis are now owned by Vanda. We originally obtained exclusive worldwide rights to develop and commercialize the products covered by these patents through license and sublicense arrangements. Then, pursuant to an amended sublicense agreement with Novartis, Novartis retained exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. However, as of December 2014, pursuant to an asset transfer agreement, we acquired all rights in Fanapt®, including in the U.S. and Canada.

Fanapt® and its metabolites, formulations, genetic markers and uses are covered by a total of 17 patent and patent application families in the U.S., Europe, and other markets. 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. In November 2013, a patent directed to a method of treating patients with Fanapt® based on genotype was issued to the Company by the U.S. Patent and Trademark Office. This patent, which was listed in the FDA's Orange Book in January 2015, is set to expire in 2027, potentially further extending the exclusivity protection of Fanapt®. The Company has asserted its patents against Roxane Laboratories. See *Legal Matters* footnote to the consolidated financial statements included in Part II of this annual report on Form 10-K for information.

In Europe, the law provides 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 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. The patent family for the microsphere depot formulation of Fanapt® expires in 2024 in the U.S. and 2022 in most of the major markets in Europe. The patent family for the aqueous microcrystals depot formulation of Fanapt® expires in 2023 in the U.S and in most of the major markets in Europe.

Tradipitant

Lilly owns a new chemical entity patent as well as patent applications directed to polymorphic forms of, and methods of making tradipitant. Thus, tradipitant is covered by a total of three patent and patent application families worldwide, which have been licensed to the Company. The new chemical entity patent covering tradipitant expires in 2023, except in the U.S., where it expires normally in 2024 subject to any extension that may be received under Hatch-Waxman.

AQW051

Novartis owns a new chemical entity patent as well as patent applications directed to methods of using AQW051, AQW051 formulations, and combinations of AQW051 with other active pharmaceutical ingredients. The new chemical entity patent expires normally in 2023 in the U.S., Europe, and other markets.

Other Patents

Aside from the new chemical entity patents and other in-licensed patents relating to Fanapt®, HETLIOZ®, tradipitant, and AQW051, as of December 31, 2014 we had approximately 33 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 application families 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, has changed and is expected to further 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. We cannot predict the

complete impact of the ACA on pharmaceutical companies because many of the ACA's reforms require the promulgation of detailed regulations to implement the statutory provisions, which has not yet occurred. While we cannot predict the complete 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

HETLIOZ® was approved in the U.S. for the treatment of Non- 24 in January 2014 and commercially launched in the U.S. in April 2014.

The EMA accepted for evaluation our MAA for oral HETLIOZ® capsules for the treatment of Non-24 in June 2014. We expect a decision from the EMA regarding our HETLIOZ® MAA in the third quarter of 2015. 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. Pursuant to the terms of the Settlement Agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to Vanda on December 31, 2014. In 2014, Fanapt® was launched in Israel and Mexico by our distribution partners. We continue to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. and Canada.

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, all of which could negatively impact our operation and our financial results.

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 at Patheon's Cincinnati, Ohio manufacturing site. Under the HETLIOZ® manufacturing 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 HETLIOZ® manufacturing 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 HETLIOZ® manufacturing agreement under certain circumstances upon specified written notice to the other party.

As part of the Settlement Agreement, we assumed Novartis' manufacturing agreement with Patheon for the manufacture of commercial supplies of Fanapt®. Under the Fanapt® manufacturing agreement, we may procure bulk, partially packaged and finished supplies of various dosages of Fanapt® for sale worldwide. We are responsible for sourcing the supply of the active pharmaceutical ingredient (iloperidone), and Patheon will manufacture 1, 2, 4, 6, 8, 10 and 12 mg tablets pursuant to orders placed by us. The Fanapt® manufacturing agreement contains specific forecasting, order lead time, minimum order quantities, yield requirements, delivery terms and alternative manufacturing provisions. Generally, all product shipped to us must have a remaining shelf life of more than four-fifths of its total shelf life, but no less than one year of shelf life remaining for certain products. The Fanapt® manufacturing agreement continues on a year-to-year basis, and can be terminated by either party on at least 12 months prior notice, or prior to the end of the then current term for uncured breach, insolvency/bankruptcy, or by us if a regulatory action prevents the supply of iloperidone to Patheon or otherwise the purchase or sale of Fanapt®.

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 $19.2 million, $28.5 million and $45.8 million in research and development expenses in the years ended December 31, 2014, 2013 and 2012, 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 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. Shift work and excessive sleepiness disorder treatments include Nuvigil® (armodafinil) and Provigil® (modafinil) both by Teva Pharmaceutical Industries Ltd.
- For Fanapt® in the treatment of schizophrenia, the atypical antipsychotics competitors are 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™, each by Eli Lilly and Company, Seroquel® (quetiapine) by AstraZeneca PLC, Abilify® (aripiprazole) by BMS/Otsuka America Pharmaceutical Inc., Abilify® Maintena® (the depot formulation of Abilify®) by Lundbeck/Otsuka America Pharmaceutical Inc., Geodon® (ziprasidone) by Pfizer Inc., Saphris® (asenapine) by Actavis plc, 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, 2014, we had 64 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.

ITEM 1A. RISK FACTORS

An investment 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-Hour Sleep-Wake Disorder (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 initiated the U.S. commercialization of HETLIOZ® in 2014, 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 market acceptance of HETLIOZ® or our strategy to commercialize the product.

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 continue the commercialization 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 received marketing authorization and was commercially launched in the U.S. in 2014, 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 substantially dependent upon the commercial success of HETLIOZ® for the treatment of Non-24 in the U.S. In January 2014, the U.S. Food and Drug Administration (FDA) approved our New Drug Application (NDA) for HETLIOZ® for the treatment of Non-24 and in April 2014, we commenced the U.S. commercial launch of HETLIOZ®. Our future success is also 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. In June 2014, the European Medicines Agency (EMA) accepted for evaluation our Marketing Authorization Application (MAA) for oral HETLIOZ® capsules for the treatment of Non-24.

We have incurred and expect to continue to incur significant expenses as we seek the approval of HETLIOZ® in other jurisdictions. This represents a significant investment in the regulatory success of HETLIOZ®, which is uncertain. 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, results of operations and prospects.

If we do not successfully commercialize HETLIOZ® in other countries in which HETLIOZ® may be approved for sale, our ability to generate increased product sales revenue may be jeopardized and, consequently, our business may be seriously harmed.

We recently acquired further rights to Fanapt® in the United States, and began selling, marketing and distributing Fanapt® in the United States in the first quarter of 2015, and our ability to generate meaningful product sales from Fanapt® will depend on the success of this product in the marketplace.

Our ability to generate meaningful product sales from Fanapt® will depend on many factors, including the following:

- Disruptions in the commercialization of Fanapt® in the U.S. caused by the transfer of Fanapt® from Novartis to Vanda;
- the effectiveness of our sales and marketing efforts in support 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 payors;
- a satisfactory efficacy and safety profile as demonstrated in a broad patient population;
- the size of the market for Fanapt®;
- the ability of our manufacturing partners to successfully expand and sustain 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 additional countries; and
- the unfavorable outcome or other negative effects of any potential litigation relating to Fanapt®.

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.

As a company, we have minimal experience selling, marketing or distributing products, which may make commercializing our products difficult.

At present, we as a company have minimal marketing experience. Therefore, in order for us to successfully commercialize HETLIOZ®, Fanapt® or our other products, we must either acquire or continue to 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 the commercialization of HETLIOZ®, Fanapt® or our other products, we may not be able to establish additional sales, marketing and distribution capabilities or 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. 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 growing our own sales and marketing team or with entering into a partnering agreement with an independent sales and marketing organization.

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

We may enter into third party collaborations from time to time in order to commercialize our products. If we are unable to identify or enter into an agreement with any material third-party collaborator, if our collaborations with any such third-party are not commercially successful or if our agreement with any such third-party is terminated or allowed to expire, we could be adversely affected financially or our business reputation could be harmed.

Our business strategy includes entering into collaborations with corporate collaborators for the commercialization of HETLIOZ®, Fanapt® and our other products. Areas in which we may potentially enter into third-party collaboration arrangements include joint sales and marketing arrangements for sales and marketing in certain European Union countries and elsewhere outside of the U.S., and future product development arrangements. If we are unable to identify or enter into an agreement with any material third-party collaborator we could be adversely affected financially or our business reputation could be harmed. Any arrangements we do enter into may not be scientifically or commercially successful. The termination of any of these arrangements might adversely affect our ability to develop, commercialize and market our products.

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations. We expect that the risks which we face in connection with these future collaborations will include the following:

- our collaboration agreements are expected to be for fixed terms and subject to termination under various circumstances, including, in many cases, on short notice without cause;
- our collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with our products which are the subject of their collaboration with us; and
- our collaborators may change the focus of their commercialization efforts. In recent years there have been a significant number of mergers and consolidations in the pharmaceutical and biotechnology industries, some of which have resulted in the participant companies reevaluating and shifting the focus of their business following the completion of these transactions. The ability of our products to reach their potential could be limited if any of our future collaborators decreases or fails to increase spending relating to such products.

Collaborations with pharmaceutical companies and other third-parties often are terminated or allowed to expire by the other party. With respect to our future collaborations, any such termination or expiration could adversely affect us financially as well as harm our business reputation.

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

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.

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

As of December 31, 2014, we had 64 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 distribution, clinical research, data collection and analysis, manufacturing, 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® or Fanapt® supply chains could materially affect our ability to successfully commercialize HETLIOZ® or Fanapt®, thereby reducing our future earnings and prospects.

A loss or disruption with any one of our manufacturers or suppliers could disrupt supply of HETLIOZ® or Fanapt®, 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® or Fanapt® 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. 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.

Following marketing approval of a product, we and our partners will continue to face heavy governmental regulation. 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.

If we or our partners become subject to any of these foregoing items, our business, results of operations and financial condition could be materially adversely affected.

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.

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.

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 2015 and beyond. It is uncertain whether our existing funds will be sufficient to meet our operating needs. As of December 31, 2014, our total cash and cash equivalents and marketable securities were $129.8 million. Our long term capital requirements are expected to depend on many factors, including, among others:

- our ability to successfully commercialize HETLIOZ® and Fanapt® 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, if any, received from our commercial partners;
- 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.

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, obtain a bank credit facility, or enter into partnerships or other collaboration agreements. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders and may also result in a lower price for our common stock. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that could restrict our operations. However, we may not be able to raise additional funds on acceptable terms, or at all. If we are unable to secure sufficient capital to fund our planned activities, we may not be able to continue operations, or we may have to enter into partnerships or other collaboration agreements that could require us to share commercial rights to our products to a greater extent or at earlier stages in the drug development process than is currently intended. These partnerships or collaborations, if consummated prior to proof-of-efficacy or safety of a given product, could impair our ability to realize value from that product. If additional financing is not available when required or is not available on acceptable terms, we may be unable to fund our operations and planned growth, develop or enhance our technologies or products, take advantage of business opportunities or respond to competitive market pressures, any of which would materially harm our business, financial condition and results of operations.

We rely on a limited number of specialty pharmacies for distribution of HETLIOZ® in the U.S., and the loss of one or more of these specialty pharmacies or their failure to distribute HETLIOZ® effectively would materially harm our business.

HETLIOZ® is only available for distribution through a limited number of specialty pharmacies in the U.S. A specialty pharmacy is a pharmacy that specializes in the dispensing of medications for complex or chronic

conditions, which often require a high level of patient education and ongoing management. The use of specialty pharmacies involves certain risks, including, but not limited to, risks that these specialty pharmacies will:

- not provide us accurate or timely information regarding their inventories, the number of patients who are using HETLIOZ® or complaints about HETLIOZ®;
- reduce their efforts or discontinue to sell or support or otherwise not effectively sell or support HETLIOZ®;
- not devote the resources necessary to sell HETLIOZ® in the volumes and within the time frames that we expect;
- be unable to satisfy financial obligations to us or others; or
- cease operations.

In addition if one or more of our specialty pharmacies do not fulfill their contractual obligations to us, or refuse or fail to adequately serve patients, or their agreements are terminated without adequate notice, shipments of HETLIOZ®, and associated revenues, would be adversely affected. We expect that it would take a significant amount of time if we were required to replace one or more of our specialty pharmacies.

Our revenues from Fanapt® are substantially dependent on sales through a limited number of wholesalers, and such revenues may fluctuate from quarter to quarter.

We sell Fanapt® primarily through a limited number of pharmaceutical wholesalers in the U.S. The use of pharmaceutical wholesalers involves certain risks, including, but not limited to, risks that these pharmaceutical wholesalers will:

- not provide us accurate or timely information regarding their inventories, demand from wholesaler customers buying Fanapt® or complaints about Fanapt®;
- reduce their efforts or discontinue to sell or support or otherwise not effectively sell or support Fanapt®;
- not devote the resources necessary to sell Fanapt® in the volumes and within the time frames that we expect;
- be unable to satisfy financial obligations to us or others; or
- cease operations.

Additionally, our reliance on a small number of wholesalers could cause revenues to fluctuate from quarter to quarter based on the buying patterns of these wholesalers. In addition, if any of these wholesalers fails to pay on a timely basis or at all, our business, financial condition and results of operations could be materially adversely affected.

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. 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. Shift work and excessive sleepiness disorder treatments include Nuvigil® (armodafinil) and Provigil® (modafinil) both by Teva Pharmaceutical Industries Ltd.
- For Fanapt® in the treatment of schizophrenia, the atypical antipsychotics competitors are 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™, each by Eli Lilly and Company, Seroquel® (quetiapine) by AstraZeneca PLC, Abilify® (aripiprazole) by BMS/Otsuka America Pharmaceutical Inc., Abilify® Maintena® (the depot formulation of Abilify®) by Lundbeck/Otsuka America Pharmaceutical Inc., Geodon® (ziprasidone) by Pfizer Inc., Saphris® (asenapine) by Actavis plc, 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.

We previously filed suit against Roxane Laboratories, Inc. (Roxane) seeking an adjudication that Roxane has infringed one or more claims of one of our patents relating to Fanapt® by submitting to the FDA an ANDA for generic versions of iloperidone oral tablets in 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths. The relief requested by us in this suit includes a request for a permanent injunction preventing Roxane from infringing the asserted claims of the patent by engaging in the manufacture, use, offer to sell, sale, importation or distribution of generic versions of iloperidone before the expiration of the patent in 2027. The adjudication of this suit in favor of Roxane could have a material adverse effect on our business, results of operations, prospects and financial condition.

In November 2013, Novartis brought a patent infringement action against Roxane. The suit alleges that Roxane’s filing of an ANDA for generic iloperidone with a paragraph IV certification infringes Sanofi’s new chemical entity patent. Roxane is defending on the grounds that the patent claims are invalid or unenforceable or

that certain patent claims are not infringed. Roxane also filed a motion to dismiss on the grounds that the court lacks jurisdiction. At present, approval of Roxane's ANDA is stayed for 30 months from the end of the data exclusivity period for iloperidone, i.e., until November 6, 2016. Upon our acquisition of Novartis' rights in Fanapt®, we assumed responsibility for this litigation. In addition to the risk that Roxane will prevail on its defenses or on its motion to dismiss, the litigation may divert substantial financial and employee resources from our business. It is also possible that a counterclaim will expose us to financial liability. If Roxane prevails on its defenses or on its motion to dismiss, Roxane could be allowed to launch a generic iloperidone product prior to expiration of the 30 months stay.

FDA regulatory approval of our products is uncertain.

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 (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.

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 and Israel, 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.

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.

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 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 commercialization of HETLIOZ® and Fanapt® will require substantial additional expenditures.

As of December 31, 2014, we had an accumulated deficit of $288.0 million and we cannot estimate with precision the extent of our future losses. In April 2014, we commercially launched HETLIOZ® in the U.S. for the treatment of Non-24. In the fourth quarter of 2014, we acquired all further rights to Fanapt® from Novartis. The continued commercialization of HETLIOZ® and generating U.S. sales of Fanapt® on our own will require substantial additional expenditures. In addition, we may not succeed in commercializing HETLIOZ®, Fanapt® or any other products. Novartis launched Fanapt® in the U.S. in the first quarter of 2010 and we began selling Fanapt® on our own in the first quarter of 2015. We may not succeed in gaining additional market acceptance of Fanapt® in the U.S. and we may not succeed in commercializing HETLIOZ® or Fanapt® outside of the U.S. 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 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;
- 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;
- our ability to successfully market and sell Fanapt® in the U.S. and our or our partners' ability to successfully market and sell Fanapt® in other jurisdictions in which we may receive regulatory approval, if any;
- 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 (NOLs) and certain other tax assets (tax attributes) 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. Ownership changes did occur as of December 31, 2014 and December 31, 2008. However, our management believes that we had sufficient "Built-In-Gain" to offset the Section 382 of the Code limitation generated by the ownership changes. Any future ownership changes may cause our existing tax attributes to have additional limitations.

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 (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. In addition, we assumed Novartis' agreement with Patheon for the manufacture of Fanapt® in the fourth quarter of 2014. We do not have exclusive long-term agreements with any other third party manufacturers of our products. If Patheon, or any other third party manufacturer, is unable or unwilling to perform its obligations under our manufacturing agreements 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, 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.

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 $20.0 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.

European Union and European Union Member States tend to impose strict price controls, which may adversely affect our future profitability.

In the European Union**,** prescription drug pricing and reimbursement is subject to governmental control and reimbursement mechanisms used by private and public health insurers in the European Union vary by Member State. For the public systems, reimbursement is determined by guidelines established by the legislator or responsible national authority. As elsewhere, inclusion in reimbursement catalogues focuses on the medical usefulness, need, quality and economic benefits to patients and the health care system. Acceptance for reimbursement comes with cost, use and often volume restrictions, which can vary by member state. In those member states that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing

approval in some member states, we or our partners may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies.

Some member states require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some member states, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our partners might obtain marketing approval for a product in a particular member state, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues that are generated from the sale of the product in that country. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross-border sales, our profitability will be negatively affected.

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, (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 PPACA 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 ability to commercialize approved products successfully may be hindered, and our business may be harmed as a result.

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 due to a number of factors which make our future results difficult to predict and could cause our operating results to fall below expectations or our guidance.

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:

- product sales;
- cost of product sales;
- marketing and other expenses;
- manufacturing or supply issues;
- the timing and amount of royalties or milestone payments;
- our addition or termination of development programs;
- variations in the level of expenses related to our products or future development programs;
- regulatory developments affecting our products or those of our competitors; our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- any intellectual property infringement 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 or below any guidance we may provide, 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® is based in part on patents and other intellectual property owned by Sanofi. 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. We acquired all of Novartis' rights to Fanapt® in the fourth quarter of 2014 pursuant to an asset transfer agreement and related agreements with Novartis. We may lose our rights to develop and commercialize Fanapt® if we fail to comply with certain requirements in the Titan license agreement regarding our financial condition, or if we fail to comply with certain diligence obligations regarding our development or commercialization activities. Our loss of rights in Fanapt® would have a material adverse effect on our business, financial condition and results of operations.

Tradipitant is based in part on patents that we have licensed on an exclusive basis and other intellectual property licensed from Eli Lilly and Company (Lilly). Lilly may terminate our license if we fail to use our commercially reasonable efforts to develop and commercialize tradipitant 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 tradipitant (including any intellectual property we develop with respect to tradipitant) will revert back to Lilly, subject to payment by Lilly to us of a royalty on net sales of products that contain tradipitant.

AQW051, to which we acquired rights from Novartis in the fourth quarter of 2014, is based on patents and other intellectual property that we have licensed on an exclusive basis from Novartis. Novartis may terminate our license if we materially breach the agreement, which includes an obligation to use commercially reasonable efforts to develop and commercialize AQW051, and fail to cure that breach. In the event that Novartis terminates our license for the reasons stated above, all of our rights to AQW051 (including any intellectual property we develop with respect to AQW051) will revert back to Novartis without compensation.

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.

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. HETLIOZ®'s U.S. "method of use" patent (the patent covering the method of treatment as described in the HETLIOZ® label approved by the FDA) expires normally in 2033. 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. In November 2013, a patent directed to a method of treating patients with Fanapt® based on genotype was issued to us by the U.S. Patent and Trademark Office. This patent, which was listed in the FDA's Orange Book in January 2015, is set to expire in 2027, potentially further extending the exclusivity protection of Fanapt® under the Hatch-Waxman Act.

Method-of-use patents protect the use of a product for the method specified in the patent claims. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for a use that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, such infringement may be difficult to prevent.

Our patents and 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 and HETLIOZ®'s U.S. "method of use" patent (the patent covering the method of treatment as described in the HETLIOZ® label approved by the FDA) until 2033. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

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 tradipitant, and that we continue to have rights under our license agreement with respect to this product, we would have exclusive rights to tradipitant's U.S. new chemical entity patent until 2029. Assuming we gain a five-year patent term restoration for AQW051, and that we continue to have rights under our license agreement with respect to this product, we would have exclusive rights to AQW051's U.S. new chemical entity patent until 2028.

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.

In November 2013, Novartis brought a patent infringement action against Roxane. The suit alleges that Roxane's filing of an ANDA for generic iloperidone with a paragraph IV certification infringes Sanofi's new chemical entity patent. Roxane is defending on the grounds that the patent claims are invalid or unenforceable or that certain patent claims are not infringed. Roxane also filed a motion to dismiss on the grounds that the court lacks jurisdiction. At present, approval of Roxane's ANDA is stayed for 30 months from the end of the data exclusivity period for iloperidone, i.e., until November 2016. If Roxane prevails on its defenses or on its motion to dismiss, Roxane could be allowed to launch a generic iloperidone product prior to expiration of the 30 months stay.

Upon acquisition of Novartis' rights in Fanapt®, we assumed responsibility for this litigation. In addition to the risk that Roxane will prevail on its defenses or on its motion to dismiss, the litigation may divert substantial financial and employee resources from our business. It is also possible that a counterclaim will expose us to financial liability.

In June 2014, we brought a patent infringement action against Roxane for infringement of a Vanda patent, U.S. Patent No. 8,586,610, which, in general terms, relates to altering the dose of iloperidone based on a patient's CYP2D6 genotype. Roxane filed a motion to dismiss on the grounds that the claims are directed to a law of nature and are therefore patent ineligible. The law with respect to patent eligibility of methods of use that rely on genotype or other biomarker is evolving and uncertain.

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, 2014 and December 31, 2014, the high and low sales prices of our common stock as reported on The NASDAQ Global Market varied between $8.34 and $19.25 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:

- our or our partners' ability to successfully commercialize our products;
- our ability to successfully execute our commercialization strategies;

- 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;
- 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;
- financial guidance or business updates we may provide;
- announcements about our earnings that are not in line with analyst expectations or guidance we may provide;
- 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 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, 2014, there were a total of 7,905,883 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 previous 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 previous 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 previous offerings.

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 several 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.

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 use third parties for sales, distribution, medical affairs and clinical research, 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 30,260 square feet of office space. Our lease and a subsequent amendment for additional space for this facility expire in 2023 and 2027, respectively, subject to five year renewal options. 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

In May 2014, we commenced arbitration proceedings against Novartis relating to the license of Fanapt® (the Fanapt® Arbitration). In December 2014, we entered into a settlement agreement with Novartis and certain of its affiliates (the Settlement Agreement).

Pursuant to the terms of the Settlement Agreement, we and Novartis dismissed the Fanapt® Arbitration and released each other from any related claims. In addition, in connection with the Settlement Agreement, Novartis (i) transferred all U.S. and Canadian rights in the Fanapt® franchise to us, (ii) made a $25.0 million equity investment in us at a price per share equal to $13.82, and (iii) granted to us an exclusive worldwide license to AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

In June 2014, we filed suit against Roxane Laboratories, Inc. (Roxane) in the U.S. District Court for the District of Delaware. The suit seeks an adjudication that Roxane has infringed one or more claims of our U.S. Patent No. 8,586,610 (the Patent) by submitting to the FDA an Abbreviated New Drug Application for generic versions of Fanapt® oral tablets in 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths. The relief requested by us includes a request for a permanent injunction preventing Roxane from infringing the asserted claims of the Patent by engaging in the manufacture, use, offer to sell, sale, importation or distribution of generic versions of Fanapt® before the expiration of the Patent in 2027.

Pursuant to the Settlement Agreement with Novartis, we assumed Novartis' patent infringement action against Roxane in the U.S. District Court for the District of Delaware. The suit alleges that Roxane's filing of an ANDA for generic iloperidone with a paragraph IV certification infringes Sanofi's new chemical entity patent. Roxane is defending on the grounds that the patent claims are invalid or unenforceable or that certain patent claims are not infringed. Roxane also filed a motion to dismiss on the grounds that the court lacks jurisdiction.

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, 2014	High	Low
First quarter	$19.25	$10.00
Second quarter	17.69	9.27
Third quarter	16.48	10.33
Fourth quarter	15.51	8.34

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

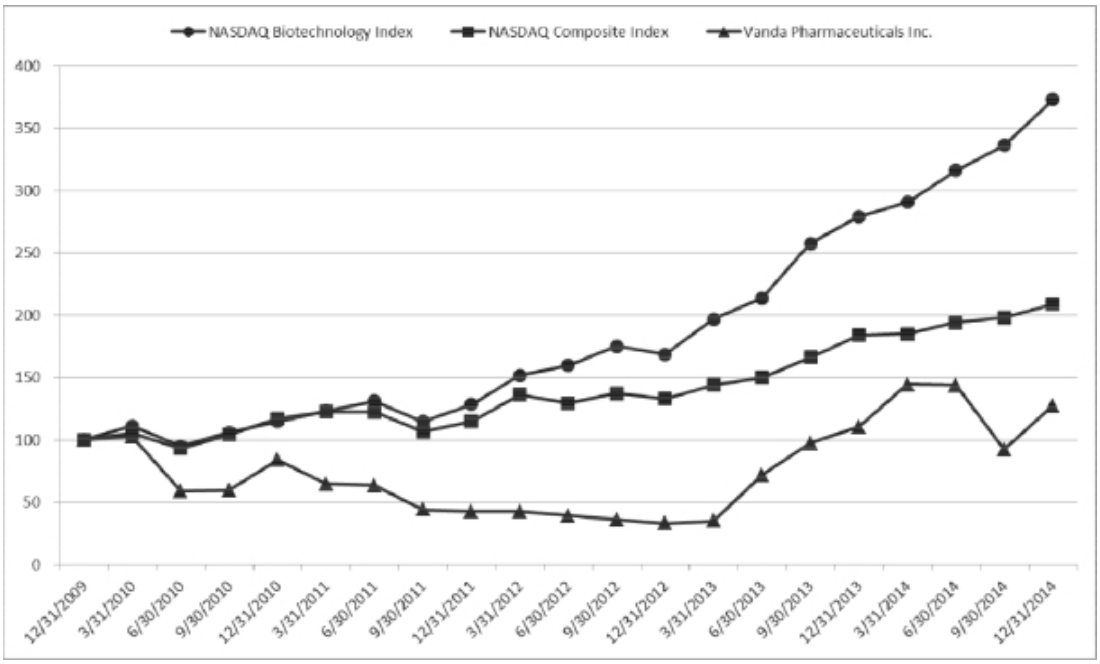
As of March 6, 2015, there were 10 holders of record of our common stock. The number of holders of record of our common stock does not reflect the number of beneficial holders whose shares are held by depositors, brokers or other nominees.

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.

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, 2009 and its relative performance is tracked through December 31, 2014. 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, 2014, 2013 and 2012 and the consolidated balance sheet data as of December 31, 2014 and 2013 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, 2011 and 2010, and the consolidated balance sheet data as of December 31, 2012, 2011 and 2010 are each derived from our audited consolidated financial statements not included herein. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

The following data should be read together with our consolidated financial statements and accompanying notes and the section entitled *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in this annual report on Form 10-K.

(in thousands, except for share and and per share amounts)	Year Ended December 31, 2014	2013 (1)	2012 (1)	2011 (1)	2010 (1)
Statements of operations data					
Total revenues	$ 50,157	$ 33,879	$ 32,727	$ 31,270	$ 35,709
Operating expenses:					
Cost of goods sold	1,583	—	129	—	2,891
Research and development	19,230	28,502	45,764	28,857	13,982
Selling, general and administrative	84,644	25,082	14,517	11,294	11,704
Intangible asset amortization	2,254	1,495	1,495	1,495	1,495
Gain on arbitration settlement	(77,616)	—	—	—	—
Total operating expenses	30,095	55,079	61,905	41,646	30,072
Income (loss) from operations	20,062	(21,200)	(29,178)	(10,376)	5,637
Other income	124	145	561	461	431
Income (loss) before taxes	20,186	(21,055)	(28,617)	(9,915)	6,068
Tax provision (benefit)	—	—	—	(444)	2,077
Net income (loss)	$ 20,186	$ (21,055)	$ (28,617)	$ (9,471)	$ 3,991
Net income (loss) per share:					
Basic	$ 0.58	$ (0.69)	$ (1.01)	$ (0.34)	$ 0.14
Diluted	$ 0.55	$ (0.69)	$ (1.01)	$ (0.34)	$ 0.14
Weighted average shares outstanding:					
Basic	34,774,163	30,351,353	28,228,409	28,106,831	27,916,388
Diluted	36,686,723	30,351,353	28,228,409	28,106,831	28,702,261

	Year Ended December 31, 2014	2013	2012	2011	2010
Balance sheet data					
Cash and cash equivalents	$ 60,901	$ 64,764	$ 88,772	$ 87,923	$ 42,559
Marketable securities, current	68,921	65,586	31,631	60,961	155,478
Marketable securities, non-current	—	—	—	19,012	—
Working capital	133,944	102,763	93,705	121,882	169,546
Total assets	171,704	143,349	135,448	182,618	213,101
Total liabilities	10,887	99,225	125,543	149,144	175,370
Accumulated deficit (1)	(287,984)	(308,170)	(287,115)	(258,498)	(249,027)
Total stockholders' equity	160,817	44,124	9,905	33,474	37,731

(1) In the first quarter of 2014, we elected to change our method of accounting for stock-based compensation from the accelerated attribution method to the straight-line method. The consolidated financial data above for the years ended 2013, 2012, 2011 and 2010 have been adjusted to reflect this change. Refer to *Change in Method of Accounting for Stock-based Compensation* footnote to the consolidated financial statements included in Part II of this annual report on Form 10-K for further information.

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 commenced operations in 2003 and our product portfolio includes:

- HETLIOZ®, a product for the treatment of Non-24 for which a NDA was approved by the FDA in January 2014 and launched commercially in the U.S. in April 2014.
- Fanapt®, a product for the treatment of schizophrenia, the oral formulation of which was being marketed and sold in the U.S. by Novartis until December 31, 2014. On December 31, 2014, Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt® franchise to Vanda. See *Settlement Agreement with Novartis* footnote to the consolidated financial statements included in Part II of this annual report on Form 10-K for information. Additionally, our distribution partners launched Fanapt® in Israel and Mexico in 2014.
- Tradipitant, a small molecule neurokinin-1 receptor (NK-1R) antagonist, which is presently in clinical development the treatment of chronic pruritus in atopic dermatitis. Results from a Phase II study for the treatment of chronic pruritus in atopic dermatitis were announced in March 2015. Clinical evaluation is ongoing to assess potential future development activities.
- Trichostatin A, a small molecule histone deacetylase (HDAC) inhibitor.
- AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

Operational Highlights

HETLIOZ® net product sales in the U.S. grew to $6.0 million in the fourth quarter of 2014, a 15% increase, compared to $5.2 million in the third quarter of 2014. HETLIOZ® net product sales were $12.8 million for the full year 2014.

Since the U.S. commercial launch of HETLIOZ® in April 2014, over 760 new patient prescriptions have been written for HETLIOZ®, including over 220 in the fourth quarter of 2014. As of December 31, 2014, over 470 patients had initiated HETLIOZ® treatment and over 330 patients were on active treatment, reflecting a cumulative persistence rate of approximately 70%.

The HETLIOZ® MAA in the European Union (EU) is under review with a regulatory decision expected in the third quarter of 2015.

Tasimelteon life cycle management activities are ongoing and include a SMS observational study with results expected in the first half of 2015 and preparations for a clinical development program for pediatric Non-24.

Pursuant to the terms of the Settlement Agreement with Novartis on December 31, 2014, Vanda and Novartis dismissed the Fanapt® Arbitration and released each other from any related claims. In addition, Novartis (i) transferred all U.S. and Canadian rights in the Fanapt® franchise to us, (ii) purchased $25.0 million of our common stock at a price per share equal to $13.82, and (iii) granted to us an exclusive worldwide license to AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist. In connection with the Settlement Agreement, the 2009 Amended Sublicense Agreement was terminated.

Results of the Phase II study (2101) of tradipitant for the treatment of chronic pruritus in atopic dermatitis were announced in March 2015. This study showed no significant difference from placebo on the pre-specified primary endpoint. Vanda believes this proof of concept study was informative, in that through subsequent analyses, it revealed significant and clinically meaningful responses at the time of their pruritus assessments across multiple outcomes evaluated in individuals with higher blood plasma levels of tradipitant. Clinical evaluation is ongoing to assess potential future development activities.

Since we began operations in March 2003, we have devoted substantially all of our resources to the in-licensing, clinical development and commercialization of our products. Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ® and Fanapt® and 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. 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.

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, 2014 included in this annual report on Form 10-K. However, we believe that the following accounting policies are important to understanding and evaluating our reported financial results, and we have accordingly included them in this discussion.

Inventory. Inventory, which is recorded at the lower of cost or market, includes the cost of third-party manufacturing and other direct and indirect costs and is valued using the first-in, first-out method. We capitalize inventory costs associated with our products upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. Inventory is evaluated for impairment by consideration of factors such as lower of cost or market, net realizable value, obsolescence or expiry.

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.

Net Product Sales. Our 2014 net product sales consists of U.S. sales of HETLIOZ® for the treatment of Non-24 and sales of Fanapt® in Israel. We apply the revenue recognition guidance in accordance with Financial

Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Subtopic 605-15, *Revenue Recognition—Products*. We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collectability is reasonably assured and we have no further performance obligations.

In the U.S., HETLIOZ® is only available for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. We invoice and record revenue when the specialty pharmacies receive HETLIOZ® from our third-party logistics warehouse.

We have entered into distribution agreements with Probiomed S.A.de C.V. (Probiomed) for the commercialization of Fanapt® in Mexico and Megapharm Ltd. for the commercialization of Fanapt® in Israel. With the exception of sales to Probiomed, we invoice and record revenue upon delivery of Fanapt® to our distribution partner. The Probiomed distribution agreement contains a contracted delivery price plus a revenue sharing provision based on Probiomed's sales of Fanapt®. As a result, the selling price of Fanapt® is not fixed or determinable upon delivery of Fanapt® to Probiomed. We defer revenue recognition until the revenue sharing provision is calculated. As of December 31, 2014, we recorded $0.2 million of deferred revenue related to Fanapt® sales.

Product Sales Discounts and Allowances

HETLIOZ® product sales revenue is recorded net of applicable discounts, chargebacks, rebates, co-pay assistance, service fees and product returns that are applicable for various government and commercial payors. Reserves established for discounts and returns are classified as reductions of accounts receivable if the amount is payable to direct customers, with the exception of service fees. Service fees are classified as a liability. Reserves established for chargebacks, rebates or co-pay assistance are classified as a liability if the amount is payable to a party other than customers. We currently record sales allowances for the following:

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory discount rates and expected utilization. Estimates for the expected utilization of rebates are based in part on actual and pending prescriptions for which we have validated the insurance benefits. Rebates are generally invoiced and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarter's unpaid rebates.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from specialty pharmacies. Contracted customers, which currently consist primarily of Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy, in turn, charges back the difference between the price initially paid by the specialty pharmacy and the discounted price paid to the specialty pharmacy by the contracted customer. The allowance for chargebacks is based on actual and pending prescriptions for which we have validated the insurance benefits.

Medicare Part D Coverage Gap: Medicare Part D prescription drug benefit mandates manufacturers to fund approximately 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Estimates for expected Medicare Part D coverage gap are based in part on historical invoices received and on actual and pending prescriptions for which we have validated the insurance benefits. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarter activity. If actual future funding varies from estimates, we may need to adjust accruals, which would affect net sales in the period of adjustment.

Service Fees: We also incur specialty pharmacy fees for services and their data. These fees are based on contracted terms and are known amounts. We accrue service fees at the time of revenue recognition, resulting in a reduction of product sales revenue and the recognition of an accrued liability, unless it receives an identifiable and separate benefit for the consideration and it can reasonably estimate the fair value of the benefit received. In which case, service fees are recorded as selling, general and administrative expense.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. Co-pay assistance utilization is based on information provided by our third-party administrator. The allowance for co-pay assistance is based on actual and pending sales for which we have validated the insurance benefits.

Prompt-pay: Specialty pharmacies are offered discounts for prompt payment. We expect that the specialty pharmacy will earn prompt payment discounts and, therefore, deducts the full amount of these discounts from total product sales when revenues are recognized.

Product Returns: Consistent with industry practice, we generally offer direct customers a limited right to return as defined within our returns policy. We consider several factors in the estimation process, including expiration dates of product shipped to specialty pharmacies, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors.

There were no discounts or rebates associated with Fanapt® product sales recognized in the period ended December 31, 2014. Our partners have a limited right to return Fanapt®. Once Fanapt® has been delivered to our partners it generally may not be returned for any reason other than product recall.

The following table summarizes sales discounts and allowance activity as of December 31, 2014.

(in thousands)	Rebates & Chargebacks	Discounts, Returns & Other	Total
Balance as of December 31, 2013	$ —	$ —	$ —
Provision related to current period sales	419	720	1,139
Adjustments for prior period sales	—	—	—
Credits/payments made	(51)	(452)	(503)
Balance as of December 31, 2014	$ 368	$ 268	$ 636

License revenue. Our license revenues were derived from the amended and restated sublicense agreement with Novartis and include an upfront payment and future milestone and royalty payments. Pursuant to the amended and restated sublicense agreement, Novartis had 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. Revenue related to the upfront payment was recognized ratably from the date the amended and restated sublicense agreement became effective (November 2009) through the expected duration of the Novartis commercialization of Fanapt® in the U.S. which was estimated to be through the expiry of the Fanapt® composition of patent, including a granted Hatch-Waxman extension (November 2016). In connection with the Settlement Agreement with Novartis, we recognized the remaining deferred revenue as of December 31, 2014 as part of the gain on arbitration settlement. See *Settlement Agreement with Novartis* footnote to the consolidated financial statements included in Part II of this annual report on Form 10-K for information.

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. Beginning in 2014, we started using a mid-point scenario to calculate the weighted average expected term of stock options granted, which combines our historical exercise data with hypothetical exercise data for unexercised stock options. Prior to 2014, the expected term assumption was determined using the simplified method.

The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have not paid dividends to our stockholders since our inception (other than a dividend of preferred share purchase rights which was declared 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.

In January 2014, we elected to change our method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions to the straight-line method. Previously, attribution was based on the accelerated attribution method, which treated each vesting tranche as an individual award and amortized them concurrently. See *Change in Method of Accounting for Stock-based Compensation* footnote to the consolidated financial statements included in Part II of this annual report on Form 10-K for further information.

Employee stock-based compensation expense related to stock-based awards for the years ended December 31, 2014, 2013 and 2012, was comprised of the following:

	Year Ended December 31,		
(in thousands)	2014	2013	2012
Research and development	$1,810	$2,098	$1,673
Selling, general and administrative	3,945	3,238	3,353
	$5,755	$5,336	$5,026

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, 2014.

Recent Accounting Pronouncements

See *Summary of Significant Accounting Policies* footnote 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 $288.0 million as of December 31, 2014. Our total stockholders' equity was $160.8 million as of December 31, 2014, and reflects net proceeds of $62.3 million from the public offering of common stock completed in October 2014 and $25.0 million from the issuance of common stock to Novartis.

Year ended December 31, 2014 compared to year ended December 31, 2013

Revenues. Total revenues increased by $16.3 million, or 48%, to $50.2 million for the year ended December 31, 2014 compared to $33.9 million for the year ended December 31, 2013. During the years ended December 31, 2014 and 2013, revenues consisted of the following:

(in thousands)	December 31, 2014	2013	$ Change	% Change
HETLIOZ® product sales, net	$12,802	$ —	$12,802	100%
Fanapt® product sales, net	107	—	107	100%
Fanapt® royalty revenue	6,502	7,090	(588)	-8%
Fanapt® licensing agreement	30,746	26,789	3,957	15%
	$50,157	$33,879	$16,278	

HETLIOZ® was commercially launched in the U.S. in April 2014. Fanapt® product sales consists of shipments to our distribution partner for the sale of Fanapt® in Israel. Royalty revenues for the years ended December 31, 2014 and 2013 represent amounts due from Novartis based on U.S. sales of Fanapt® by Novartis. License revenues for the years ended December 31, 2014 and 2013 represent amortization of deferred revenue from the $200.0 million up-front license fee received from Novartis. Pursuant to the Settlement Agreement with Novartis, we recognized the remaining deferred revenue as of December 31, 2014 related to the up-front license fee as part of gain on arbitration settlement in the consolidated statement of operations for the year ended December 31, 2014. Beginning in 2015, we started selling Fanapt® commercially in the U.S. See *Settlement Agreement with Novartis* footnote to the consolidated financial statements included in Part II of this annual report on Form 10-K for information.

Cost of goods sold. Cost of goods sold for the year ended December 31, 2014 were $1.6 million compared to zero for the year ended December 31, 2013. Cost of goods sold includes third party manufacturing costs of product sold, third party royalty costs and distribution and other costs. During the year ended December 31, 2014, we made royalty payments to BMS equal to 10% of net sales of HETLIOZ®.

HETLIOZ® inventory manufactured prior to FDA approval consisted of raw materials and work-in-process inventory, which was expensed as research and development costs as incurred and was combined with other research and development expenses. While we tracked the quantities of individual product lots, we did not track pre-FDA approval manufacturing costs and therefore the manufacturing cost of HETLIOZ® raw materials and work-in-process inventory produced prior to FDA approval is not reasonably determinable. However, based on our expectations for future manufacturing costs to produce HETLIOZ® inventory, we estimate that approximately $1.2 million of commercial HETLIOZ® inventory was expensed prior to FDA approval.

We began capitalizing HETLIOZ® manufacturing costs as inventory following the receipt of marketing approval from the FDA on January 31, 2014. As of December 31, 2014, we had approximately $0.6 million, $0.9 million and $0.1 million of reduced-cost finished goods, work-in-process inventory and raw materials inventory, respectively, on hand.

The aggregate selling price of reduced-cost finished goods inventory on hand may be affected by a number of factors including, but not limited to, market demand, future pricing of the product, competition and reimbursement by government and other payers. At this time we cannot reasonably estimate the timing and rate of consumption of reduced-cost raw materials and work-in-progress inventory, or the timing of sales of finished goods manufactured with this inventory. We expect our cost of goods sold to increase in the future as this inventory is sold, which will have a negative impact on gross margin. The time period over which reduced-cost finished goods inventory is consumed will depend on a number of factors, including the amount of future HETLIOZ® sales, the ultimate use of this inventory in either commercial sales, clinical development or other research activities, and the ability to utilize inventory prior to its expiration date.

Cost of goods sold as a percentage of revenue for the expected sales of inventory capitalized after FDA approval will depend upon our cost to manufacture inventory at normalized production levels with our third party manufacturers. However, we expect that, in the future, total HETLIOZ® manufacturing cost included in cost of goods sold will be less than 2% of our net HETLIOZ® product sales.

Research and development expenses. Research and development expenses decreased by $9.3 million, or 33%, to $19.2 million for year ended December 31, 2014 compared to $28.5 million for the year ended December 31, 2013. Lower research and development expenses were primarily due to 2013 costs incurred for the HETLIOZ® NDA submission to the FDA and completion of Non-24 and Major Depressive Disorder efficacy studies in 2013. The following table summarizes the costs of our product development initiatives for the years ended December 31, 2014 and 2013. Included in this table are the research and development expenses recognized in connection with the clinical development of HETLIOZ®, tradipitant, Trichostatin A and Fanapt®.

(in thousands)	December 31, 2014	2013
Direct project costs (1)		
HETLIOZ®	$12,478	$22,307
Tradipitant	2,303	2,343
Trichostatin A	335	—
Fanapt®	160	493
	15,276	25,143
Indirect project costs (1)		
Employee stock-based compensation	1,810	2,098
Other indirect overhead	2,144	1,261
	3,954	3,359
Total research & development expense	$19,230	$28,502

(1) We record direct costs, including personnel costs and related benefits, on a project-by-project basis. Many of our research and development costs are not attributable to any individual project because we share resources across several development projects. We record indirect costs that support a number of our research and development activities in the aggregate, including employee stock-based compensation.

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

Selling, general and administrative expenses. Selling, general and administrative expenses increased by $59.5 million, or 237%, to $84.6 million for the year ended December 31, 2014 compared to $25.1 million for the year ended December 31, 2013. The increase is primarily due to the commercial launch of HETLIOZ® in the U.S. for the treatment of Non-24. Our sales and marketing effort included the addition of marketing programs, field-based sales and national account teams. We incurred cost associated with a HETLIOZ® branded advertising campaign and our Non-24 Disease Awareness campaign, which included radio and television advertisements broadcast nationwide. In addition, we added a medical affairs team, which were deployed in 2014 to support HETLIOZ® and Non-24 medical education.

Gain on arbitration settlement. Pursuant to the Settlement Agreement with Novartis, we recorded a gain of $77.6 million for the year ended December 31, 2014.

Intangible asset amortization. Intangible asset amortization was $2.3 million for year ended December 31, 2014 compared to $1.5 million for the year ended December 31, 2013. The increase is primarily due to amortization related to the $8.0 million milestone payment made to BMS as a result of receiving FDA approval for HETLIOZ® that was capitalized in the first quarter of 2014.

Tax benefit. The tax benefit for the years ended December 31, 2014 and 2013 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, 2013 compared to year ended December 31, 2012

Revenues. Total revenues increased by $1.2 million, or 4%, to $33.9 million for the year ended December 31, 2013 compared to $32.7 million for the year ended December 31, 2012. During the years ended December 31, 2013 and 2012, revenues consisted of the following:

(in thousands)	December 31, 2013	2012	$ Change	% Change
Fanapt® royalty revenue	7,090	5,938	1,152	19%
Fanapt® licensing agreement	26,789	26,789	—	0%
	$33,879	$32,727	$ 1,152	

Royalty revenues for the years ended December 31, 2013 and 2012 represent amounts due from Novartis based on U.S. sales of Fanapt® by Novartis. License revenues for the years ended December 31, 2013 and 2012 represent amortization of deferred revenue from the $200.0 million up-front license fee received from Novartis.

Research and development expenses. Research and development expenses decreased by $17.3 million, or 38%, to $28.5 million for the year ended December 31, 2013 compared to $45.8 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 summarizes the costs of our product development initiatives for the years ended December 31, 2013 and 2012. Included in this table are the research and development expenses recognized in connection with the clinical development of HETLIOZ®, tradipitant and Fanapt®.

(in thousands)	December 31, 2013	2012
Direct project costs (1)		
HETLIOZ®	$22,307	$39,716
Tradipitant	2,343	1,144
Fanapt®	493	1,362
Other direct project costs	—	—
	25,143	42,222
Indirect project costs (1)		
Employee stock-based compensation	2,098	1,673
Other indirect overhead	1,261	1,869
	3,359	3,542
Total research & development expense	$28,502	$45,764

(1) We record direct costs, including personnel costs and related benefits, on a project-by-project basis. Many of our research and development costs are not attributable to any individual project because we share resources across several development projects. We record indirect costs that support a number of our research and development activities in the aggregate, including employee stock-based compensation.

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

Selling, general and administrative expenses. Selling, general and administrative expenses increased by $10.6 million, or 73%, to $25.1 million for the year ended December 31, 2013 compared to $14.5 million for the year ended December 31, 2012 primarily due to an increase in costs as we built our marketing and sales organization for the U.S. commercial launch of HETLIOZ®, for the treatment of Non-24.

Other income. Other income decreased $0.5 million, or 83%, 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.

Intangible Assets

The following is a summary of our intangible assets as of December 31, 2014:

		December 31, 2014		
(in thousands)	Estimated Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	January 2033	$ 8,000	$ 539	$ 7,461
Fanapt®	November 2016	$27,941	$ 8,678	$ 19,263

In January 2014, we announced that the FDA had approved the NDA for HETLIOZ®. As a result of this approval, we met a milestone under our license agreement with BMS that required us to make a license payment of $8.0 million to BMS. The $8.0 million is being amortized on a straight-line basis over the remaining life of the U.S. patent for HETLIOZ®, which prior to June 2014, we expected to last until December 2022. In June 2014, we received a notice of allowance from the U.S. Patent and Trademark Office for a patent covering the method of use of HETLIOZ®. The patent expires in January 2033, thereby potentially extending the exclusivity protection in the U.S. beyond the composition of matter patent. As a result of the patent allowance, we extended the estimated useful life of the U.S. patent for HETLIOZ® from December 2022 to January 2033.

In 2009, we announced that the FDA had approved the NDA for Fanapt®. As a result of this approval, we met a milestone under our original sublicense agreement with Novartis that required us 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 we expected to last until May 2017. In February 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 resulted in a six-month reduction to the estimated patent life from May 2017 to November 2016.

Pursuant to the Settlement Agreement, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us. As a result, we recognized an intangible asset of $15.9 million on December 31, 2014 related to the reacquired right to Fanapt®, which is being amortized on a straight-line basis through November 2016. The useful life estimation for the Fanapt® intangible asset is based on the market participant methodology prescribed by ASC Subtopic 805, *Business Combinations* (ASC 805), and therefore does not reflect the impact of the Fanapt® patent number 8,586,610, which is solely owned by us and expires in 2027. See *Settlement Agreement with Novartis* footnote to the consolidated financial statements included in Part II of this annual report on Form 10-K for information.

In January 2015, we announced that Fanapt® patent number 8,586,610 was listed in the FDA Orange Book. This patent covers a method of treating schizophrenia by administering Fanapt® to a patient by reducing the dose in patients who are poor metabolizers of CYP2D6. The patent expires in November 2027, thereby potentially extending the exclusivity protection in the U.S. beyond the composition of matter patent.

The following table summarizes our future intangible asset amortization schedule as of December 31, 2014:

(in thousands)	Total	2015	2016	2017	2018	2019	Thereafter
HETLIOZ®	$ 7,461	$ 411	$ 411	$411	$411	$411	$ 5,406
Fanapt®	19,263	10,050	9,213	—	—	—	—
	$26,724	$10,461	$9,624	$411	$411	$411	$ 5,406

Deferred Revenue

The following is a summary of changes in total deferred revenue for the years ended December 31, 2014 and 2013:

	Year Ended December 31,	
(in thousands)	2014	2013
Balance beginning of period	$ 90,275	$ 117,064
Deferred Fanapt® product sales	174	—
Licensing revenue recognized	30,746	26,789
Recognized as part of gain on arbitration settlement	59,529	—
Balance end of period	$ 174	$ 90,275

We entered into an amended and restated sublicense agreement with Novartis in 2009, pursuant to which Novartis had 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. Vanda and Novartis established a Joint Steering Committee (JSC) following the effective date of the amended and restated sublicense agreement. We concluded that the JSC constituted 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 of Fanapt®. Revenue related to the upfront payment was 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® (November 2016). During the years ended December 31, 2014, 2013 and 2012, we recognized revenue of $30.7 million, $26.8 million and $26.8 million, respectively, related to the license agreement.

In connection with the Settlement Agreement with Novartis, we recognized the remaining deferred revenue balance of $59.5 million as part of the gain on arbitration settlement. See *Settlement Agreement with Novartis* footnote to the consolidated financial statements included in Part II of this annual report on Form 10-K for information.

Liquidity and Capital Resources

Pursuant to the Settlement Agreement with Novartis, we issued them an aggregate of 1,808,973 shares of our common stock at $13.82 per share, which per share represented a 10% premium to the average closing prices of our common stock for the ten trading days prior to December 22, 2014. Net cash proceeds from the issuance were $25.0 million. In October 2014, we completed a public offering of 5,750,000 shares of common stock at a price to the public of $11.60 per share. Net cash proceeds from the public offering were $62.3 million, after deducting the underwriting discounts and commissions and offering expenses.

As of December 31, 2014, our total cash and cash equivalents and marketable securities were $129.8 million, compared to $130.4 million at December 31, 2013. 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, 2014 and 2013, our liquidity resources are summarized as follows:

(in thousands)	As of December 31, 2014	2013
Cash and cash equivalents	$ 60,901	$ 64,764
Marketable securities:		
U.S. Treasury and government agencies	30,618	31,566
Corporate debt	38,303	34,020
Total marketable securities	68,921	65,586
Total cash and cash equivalents	$129,822	$130,350

As of December 31, 2014, 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 in connection with the continued U.S. commercial launch of HETLIOZ® and commercialization of Fanapt® in the U.S. In the first quarter of 2014, we made milestone payments of $8.0 million under the license agreement with BMS and $2.0 million under a regulatory consulting agreement as a result of HETLIOZ® being approved by the FDA.

Because of the uncertainties discussed above, the costs to advance our research and development projects and the commercial launch of HETLIOZ® and commercialization of Fanapt® in the U.S., 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 our ability to generate revenue, 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.

Cash flow

The following table summarizes our cash flows for the years ended December 31, 2014, 2013 and 2012.

	Year Ended December 31, 2014	2013	2012
Net cash provided by (used in):			
Operating activities	$(81,554)	$(39,592)	$(44,917)
Investing activities	(12,037)	(34,275)	45,754
Financing activities	89,728	49,859	12
Net increase (decrease) in cash and cash equivalents	$ (3,863)	$(24,008)	$ 849

In assessing cash used in operating activities, we consider several principal factors: (i) net income (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, 2014 compared to year ended December 31, 2013

Net cash used in operating activities was $81.6 million for the year ended December 31, 2014, an increase of $42.0 million from net cash used in operating activities of $39.6 million for the year ended December 31, 2013. The increase in net cash used for operating activities resulted from a decrease of $76.3 million in non-cash charges, driven by a $77.6 million gain on arbitration settlement recognized in 2014 and a $6.9 million net use of working capital. These increases were partially offset by a change in net income (loss) of $41.2 million.

Net cash used in investing activities of $12.0 million for the year ended December 31, 2014, a decrease of $22.3 million, from net cash used in investing activities of $34.3 million for the year ended December 31, 2013. The decrease primarily resulted from $30.6 million in higher net proceeds from sales, maturities and purchases of marketable securities, which was partially offset by an $8.0 million milestone payment to BMS as a result of the FDA approval of HETLIOZ® in January 2014.

Net cash provided by financing activities of $89.7 million for the year ended December 31, 2014, an increase of $39.8 million from net cash provided by financing activities of $49.9 million for the year ended December 31, 2013. The increase primarily reflects the proceeds related to the issuance of stock to Novartis of $25.0 million, $13.8 million in higher net proceeds received from the public offering of common stock in 2014 versus 2013 and $1.3 million higher proceeds received from the exercise of employee stock options.

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 $7.6 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, $0.3 million increase in non-cash charges and $0.2 million lower net use of working capital.

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.

Off-balance sheet arrangements

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

Contractual obligations and commitments

The following is a summary of our non-cancellable long-term contractual cash obligations as of December 31, 2014:

	Cash payments due by period (1)(2)(3)						
(in thousands)	Total	2015	2016	2017	2018	2019	Thereafter
Operating leases	$14,710	$1,395	$1,500	$1,538	$1,576	$1,616	$ 7,085

(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 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 cumulative worldwide sales of HETLIOZ® reach $250.0 million.

(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 tradipitant 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 (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 were 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.

In March 2014, we entered into a lease amendment (Lease Amendment) with the Landlord to occupy an additional 8,860 square feet in our headquarters building located in Washington, D.C. The Lease Amendment has a 12 year and one month term beginning on September 1, 2014, but may be terminated early by either the Landlord or us upon certain conditions. We will pay approximately $0.4 million in additional annual rent over the term of the Lease Amendment, however rent will be abated for the first nine months. The Landlord will provide us with an allowance of approximately $0.8 million for construction on the premises to our specifications, subject to certain conditions. Subject to the prior rights of other tenants in the building, we will have the right to renew the Lease Amendment for five years following the expiration of its original term. We will also have the right to sublease or assign all or a portion of the premises, subject to standard conditions.

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, 2014. 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, 2014, the end of the period covered by this annual report, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Management's Report on Internal Control over Financial Reporting

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 2013 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, 2014, our internal control over financial reporting was effective.

Management has excluded the U.S. and Canadian commercial rights to the Fanapt® franchise acquired pursuant to the Settlement Agreement with Novartis from its assessment of internal control over financial reporting as of December 31, 2014 because they were acquired in a business combination effective December 31, 2014. The fair value of assets acquired represent 11% of our total assets as of December 31, 2014. We did not recognize any revenue related to U.S. sales of Fanapt® during the year ended December 31, 2014.

The effectiveness of our internal control over financial reporting as of December 31, 2014 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

We have expanded our internal control under Section 404 of the Sarbanes-Oxley Act of 2002 and applicable rules and regulations to include controls with respect to our net product sales, accounts receivable and our capitalization of inventory. Except for the expansion of our controls related to our accounting for net product sales, accounts receivable and capitalization of inventory, no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the period covered by this report. These changes have not materially affected, and are not reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required under this item will be contained in 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, 2014, 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, 2014, 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

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, 2014, under the captions “Equity Compensation Plan Information” and “Security Ownership of Certain Beneficial Owners and Management” and is incorporated herein by reference pursuant to General Instruction G(3) to Form 10-K.

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

Information required under this item will be contained in 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, 2014, 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, 2014, 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.

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.

March 13, 2015 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)	March 13, 2015
/s/ James P. Kelly James P. Kelly	Senior Vice President, Chief Financial Officer, Secretary and Treasurer (principal financial officer and principal accounting officer)	March 13, 2015
/s/ H. Thomas Watkins H. Thomas Watkins	Chairman of the Board and Director	March 13, 2015
/s/ Michael Cola Michael Cola	Director	March 13, 2015
/s/ Richard W. Dugan Richard W. Dugan	Director	March 13, 2015
/s/ Steven K. Galson, M.D. Steven K. Galson, M.D.	Director	March 13, 2015
/s/ Vincent J. Milano Vincent J. Milano	Director	March 13, 2015
/s/ Howard Pien Howard Pien	Director	March 13, 2015

Vanda Pharmaceuticals Inc.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of comprehensive income (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 at December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 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, 2014, based on criteria established in *Internal Control—Integrated Framework* (2013) 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.

As discussed in Note 4 to the consolidated financial statements, the Company changed the manner in which it accounts for share based compensation expense from the accelerated attribution method to the straight line method.

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.

As described in the Report of Management on Internal Control over Financial Reporting appearing under Item 9A, management has excluded the U.S. and Canadian commercial rights to the Fanapt franchise ("the Franchise") acquired during 2014 from its assessment of internal control over financial reporting as of December 31, 2014 because the Franchise was acquired by the Company in a purchase business combination during 2014. We have also excluded the Franchise from our audit of internal control over financial reporting. The Franchise is included in the consolidated results of the Company and its total assets and total revenues represent 11% and 0%, respectively of the related consolidated financial statement amounts as of and for the year ended December 31, 2014.

/s/ PricewaterhouseCoopers LLP

McLean, Virginia
March 13, 2015

Vanda Pharmaceuticals Inc.
Consolidated Balance Sheets

(in thousands, except for share and per share amounts)	December 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 60,901	$ 64,764
Marketable securities	68,921	65,586
Accounts receivable, net	3,654	2,031
Inventory	5,170	—
Prepaid expenses and other current assets	3,084	2,703
Restricted cash	—	530
Total current assets	141,730	135,614
Property and equipment, net	2,437	2,198
Intangible assets, net	26,724	5,037
Restricted cash, non-current	785	500
Other assets, non-current	28	—
Total assets	$ 171,704	$ 143,349
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 835	$ 661
Accrued liabilities	6,502	5,180
Deferred rent	247	221
Deferred revenues	174	26,789
Other liabilities	28	—
Total current liabilities	7,786	32,851
Deferred rent, non-current	3,101	2,888
Deferred revenues, non-current	—	63,486
Total liabilities	10,887	99,225
Commitments and contingencies (Note 14 and 21)		
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; 41,486,361 and 33,338,543 shares issued and outstanding at December 31, 2014 and 2013, respectively	41	33
Additional paid-in capital	448,744	352,240
Accumulated other comprehensive income	16	21
Accumulated deficit	(287,984)	(308,170)
Total stockholders' equity	160,817	44,124
Total liabilities and stockholders' equity	$ 171,704	$ 143,349

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

Vanda Pharmaceuticals Inc.
Consolidated Statements of Operations

(in thousands, except for share and per share amounts)	Year Ended December 31, 2014	2013	2012
Revenues:			
Net product sales	$ 12,909	$ —	$ —
Royalty revenue	6,502	7,090	5,938
Licensing agreement	30,746	26,789	26,789
Total revenues	50,157	33,879	32,727
Operating expenses:			
Cost of goods sold	1,583	—	129
Research and development	19,230	28,502	45,764
Selling, general and administrative	84,644	25,082	14,517
Intangible asset amortization	2,254	1,495	1,495
Gain on arbitration settlement	(77,616)	—	—
Total operating expenses	30,095	55,079	61,905
Income (loss) from operations	20,062	(21,200)	(29,178)
Other income	124	145	561
Net income (loss)	$ 20,186	$ (21,055)	$ (28,617)
Net income (loss) per share:			
Basic	$ 0.58	$ (0.69)	$ (1.01)
Diluted	$ 0.55	$ (0.69)	$ (1.01)
Weighted average shares outstanding:			
Basic	34,774,163	30,351,353	28,228,409
Diluted	36,686,723	30,351,353	28,228,409

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

Vanda Pharmaceuticals Inc.
Consolidated Statements of Comprehensive Income (Loss)

(in thousands)	Year Ended December 31, 2014	2013	2012
Net income (loss)	$20,186	$(21,055)	$(28,617)
Other comprehensive income (loss):			
Change in net unrealized gain (loss) on marketable securities	(5)	11	(11)
Tax provision on other comprehensive income (loss)	—	—	—
Other comprehensive income (loss), net of tax:	(5)	11	(11)
Comprehensive income (loss)	$20,181	$(21,044)	$(28,628)

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

Vanda Pharmaceuticals Inc.
Statements of Changes in Stockholders' Equity

(in thousands, except for share amounts)	Common Stock		Additional Paid-In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Par Value				
Balances at December 31, 2011	28,117,026	28	296,868	21	(263,443)	33,474
Adjustment for change in accounting method	—	—	(4,945)	—	4,945	—
Adjusted balances at December 31, 2011	28,117,026	28	291,923	21	(258,498)	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 expense	—	—	5,047	—	—	5,047
Net loss	—	—	—	—	(28,617)	(28,617)
Other comprehensive loss, net of tax	—	—	—	(11)	—	(11)
Balances at December 31, 2012	28,241,743	28	296,982	10	(287,115)	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 expense	—	—	5,404	—	—	5,404
Net loss	—	—	—	—	(21,055)	(21,055)
Other comprehensive income, net of tax	—	—	—	11	—	11
Balances at December 31, 2013	33,338,543	33	352,240	21	(308,170)	44,124
Net proceeds from public offering of common stock	5,750,000	5	62,308	—	—	62,313
Issuance of common stock to Novartis Pharma AG	1,808,973	2	25,903	—	—	25,905
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	621,231	1	2,851	—	—	2,852
Shares withheld upon settlement of restricted stock units	(32,386)	—	(436)	—	—	(436)
Employee and non-employee stock based compensation expense	—	—	5,878	—	—	5,878
Net income	—	—	—	—	20,186	20,186
Other comprehensive loss, net of tax	—	—	—	(5)	—	(5)
Balances at December 31, 2014	41,486,361	41	448,744	16	(287,984)	160,817

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

Vanda Pharmaceuticals Inc.
Consolidated Statements of Cash Flows

(in thousands)	Year Ended December 31, 2014	2013	2012
Cash flows from operating activities			
Net income (loss)	$ 20,186	$(21,055)	$ (28,617)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property and equipment	530	432	633
Employee and non-employee stock-based compensation	5,878	5,404	5,047
Amortization of discounts and premiums on marketable securities	174	155	560
Intangible asset amortization	2,254	1,495	1,495
Gain on arbitration settlement with Novartis Pharma AG	(77,616)	—	—
Landlord contributions for tenant improvements	—	—	1,826
Changes in assets and liabilities:			
Accounts receivable	(1,623)	(863)	450
Prepaid expenses and other current assets	(290)	1,264	(884)
Inventory	(2,210)	—	—
Other assets	(28)	—	—
Accounts payable	174	374	(709)
Accrued liabilities	1,322	(113)	1,806
Other liabilities	267	104	265
Deferred revenue	(30,572)	(26,789)	(26,789)
Net cash used in operating activities	(81,554)	(39,592)	(44,917)
Cash flows from investing activities			
Acquisition of intangible assets	(8,000)	—	—
Purchases of property and equipment	(769)	(176)	(2,017)
Purchases of marketable securities	(93,343)	(65,598)	(60,866)
Proceeds from sale of marketable securities	8,948	—	2,497
Maturities of marketable securities	80,882	31,499	106,140
Change in restricted cash	245	—	—
Net cash (used in) provided by investing activities	(12,037)	(34,275)	45,754
Cash flows from financing activities			
Net proceeds from public offering of common stock	62,313	48,505	—
Net proceeds from offering common stock to Novartis Pharma AG	25,000	—	—
Tax obligations paid in connection with settlement of restricted stock units	(436)	(196)	—
Proceeds from exercise of employee stock options	2,851	1,550	12
Net cash provided by financing activities	89,728	49,859	12
Net increase (decrease) in cash and cash equivalents	(3,863)	(24,008)	849
Cash and cash equivalents			
Beginning of period	64,764	88,772	87,923
End of period	$ 60,901	$ 64,764	$ 88,772
Non-cash investing and financing activities			
Intangible asset related to re-acquired right to Fanapt ®	$(15,940)	$ —	$ —
Inventories	$ 2,960	$ —	$ —
Prepaid services	$ 91	$ —	$ —
Purchase of property and equipment in accrued liabilities	$ —	$ 106	$ —

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 and the Company's portfolio includes the following products.

- HETLIOZ® (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) for which a New Drug Application (NDA) was approved by the U.S. Food and Drug Administration (FDA) in January 2014 and launched commercially in the U.S. in April 2014.
- Fanapt® (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which was being marketed and sold in the U.S. by Novartis Pharma AG (Novartis) until December 31, 2014. On December 31, 2014, Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt® franchise to the Company. See Note 3, *Settlement Agreement with Novartis,* for further information. Additionally, the Company's distribution partners launched Fanapt® in Israel and Mexico in 2014.
- Tradipitant (VLY-686), a small molecule neurokinin-1 receptor (NK-1R) antagonist, which is presently in clinical development for the treatment of chronic pruritus in atopic dermatitis. Results from a Phase II study for the treatment of chronic pruritus in atopic dermatitis were announced in March 2015. Clinical evaluation is ongoing to assess potential future development activities.
- Trichostatin A, a small molecule histone deacetylase (HDAC) inhibitor.
- AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

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.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

Inventory

Inventory, which is recorded at the lower of cost or market, includes the cost of third-party manufacturing and other direct and indirect costs and is valued using the first-in, first-out method. The Company capitalizes inventory costs associated with its products upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. Inventory is evaluated for impairment by consideration of factors such as lower of cost or market, net realizable value, obsolescence or expiry.

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 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.

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.

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.

Net Product Sales

The Company's 2014 net product sales consist of U.S. sales of HETLIOZ® for the treatment of Non-24 and sales of Fanapt® in Israel. The Company applies the revenue recognition guidance in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Subtopic 605-15, *Revenue*

Recognition—Products. The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collectability is reasonably assured and the Company has no further performance obligations.

In the U.S., HETLIOZ® is only available for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. The Company invoices and records revenue when the specialty pharmacies receive HETLIOZ® from the third-party logistics warehouse.

The Company has entered into distribution agreements with Probiomed S.A. de C.V. (Probiomed) for the commercialization of Fanapt® in Mexico and Megapharm Ltd. for the commercialization of Fanapt® in Israel. With the exception of sales to Probiomed, the Company invoices and records revenue upon delivery of Fanapt® to the distribution partner. The Probiomed distribution agreement contains a contracted delivery price plus a revenue sharing provision based on Probiomed's sales of Fanapt®. As a result, the selling price of Fanapt® is not fixed or determinable upon delivery of Fanapt® to Probiomed. The Company defers revenue recognition until the revenue sharing provision is calculated. As of December 31, 2014, the Company recorded $0.2 million of deferred revenue related to Fanapt® sales.

Product Sales Discounts and Allowances

HETLIOZ® product sales revenue is recorded net of applicable discounts, chargebacks, rebates, co-pay assistance, service fees and product returns that are applicable for various government and commercial payors. Reserves established for discounts and returns are classified as reductions of accounts receivable if the amount is payable to direct customers, with the exception of service fees. Service fees are classified as a liability. Reserves established for chargebacks, rebates or co-pay assistance are classified as a liability if the amount is payable to a party other than customers. The Company currently records sales allowances for the following:

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory discount rates and expected utilization. Estimates for the expected utilization of rebates are based in part on actual and pending prescriptions for which the Company has validated the insurance benefits. Rebates are generally invoiced and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarter's unpaid rebates.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from specialty pharmacies. Contracted customers, which currently consist primarily of Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy, in turn, charges back the difference between the price initially paid by the specialty pharmacy and the discounted price paid to the specialty pharmacy by the contracted customer. The allowance for chargebacks is based on actual and pending prescriptions for which the Company has validated the insurance benefits.

Medicare Part D Coverage Gap: Medicare Part D prescription drug benefit mandates manufacturers to fund approximately 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Estimates for expected Medicare Part D coverage gap are based in part on historical invoices received and on actual and pending prescriptions for which the Company has validated the insurance benefits. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarter activity. If actual future funding varies from estimates, the Company may need to adjust accruals, which would affect net revenue in the period of adjustment.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

Service Fees: The Company also incurs specialty pharmacy fees for services and their data. These fees are based on contracted terms and are known amounts. The Company accrues service fees at the time of revenue recognition, resulting in a reduction of product sales revenue and the recognition of an accrued liability, unless it receives an identifiable and separate benefit for the consideration and it can reasonably estimate the fair value of the benefit received. In which case, service fees are recorded as selling, general and administrative expense.

Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. Co-pay assistance utilization is based on information provided by the Company's third-party administrator. The allowance for co-pay assistance is based on actual and pending sales for which the Company has validated the insurance benefits.

Prompt-pay: Specialty pharmacies are offered discounts for prompt payment. The Company expects that the specialty pharmacy will earn prompt payment discounts and, therefore, deducts the full amount of these discounts from total product sales when revenues are recognized.

Product Returns: Consistent with industry practice, the Company generally offers direct customers a limited right to return as defined within the Company's returns policy. The Company considers several factors in the estimation process, including expiration dates of product shipped to specialty pharmacies, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors.

There were no discounts or rebates associated with Fanapt® product sales recognized in the period. The Company's partners have a limited right to return Fanapt®. Once Fanapt® has been delivered to the partners it generally may not be returned for any reason other than product recall.

License Revenue

The Company's license revenues were derived from the amended and restated sublicense agreement with Novartis and include an upfront payment and future milestone and royalty payments. Pursuant to the amended and restated sublicense agreement, Novartis had 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. Revenue related to the upfront payment was recognized ratably from the date the amended and restated sublicense agreement became effective (November 2009) through the expected duration of the Novartis commercialization of Fanapt® in the U.S. which was estimated to be through the expiry of the Fanapt® composition of patent, including a granted Hatch-Waxman extension (November 2016). In connection with the Settlement Agreement with Novartis, the Company recognized the remaining deferred revenue as of December 31, 2014 as part of the gain on arbitration settlement. See Note 3, *Settlement Agreement with Novartis*, for further discussion.

Cost of goods sold

Cost of goods sold includes royalties payable, the cost of inventory sold, manufacturing and supply chain costs and product shipping and handling costs related to U.S. sales of HETLIOZ® and sales of Fanapt® to the Company's distribution partners.

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.

Selling, general and administrative expenses

Selling, general and administrative expenses consist of salaries, including employee stock-based compensation, facilities and third party expenses. Selling, general and administrative expenses are associated with the activities of the executive, finance, accounting, information technology, business development, commercial support, trade and distribution, sales, 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.

In January 2014, the Company elected to change its method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions to the straight-line method. Previously, attribution was based on the accelerated attribution method, which treated each vesting tranche as an individual award and amortized them concurrently. See Note 4, *Change in Method of Accounting for Stock-based Compensation,* for further information. The fair value of restricted stock units (RSUs) awarded is also amortized using the straight line method. Stock-based compensation expense recognized in the consolidated statements of operations is based on awards ultimately expected to vest. Therefore, 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, 2014, 2013 and 2012 was comprised of the following:

	Year Ended December 31,		
(in thousands)	2014	2013	2012
Research and development	$1,810	$2,098	$1,673
Selling, general and administrative	3,945	3,238	3,353
	$5,755	$5,336	$5,026

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. Beginning in 2014, the Company started using a mid-point scenario to calculate the weighted average expected term of stock options granted, which combines the Company's historical exercise data with hypothetical exercise data for unexercised stock options. Prior to 2014, the expected term assumption was determined using the simplified method. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception (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.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

Assumptions used in the Black-Scholes-Merton option pricing model for employee and director stock options granted during the years ended December 31, 2014, 2013 and 2012 were as follows:

	Year Ended December 31,		
	2014	2013	2012
Expected dividend yield	0%	0%	0%
Weighted average expected volatility	62%	65%	68%
Weighted average expected term (years)	5.90	6.03	6.03
Weighted average risk-free rate	1.73%	1.59%	0.94%
Weighted average fair value per share	$6.99	$6.10	$2.08

Advertising Expense

The Company expenses the costs of advertising, including branded promotional expenses, as incurred. Branded advertising expenses, recorded in selling, general and administrative expenses, were $5.0 million for the year ended December 31, 2014. The Company did not incur any advertising expense during the years ended December 31, 2013 and 2012.

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 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, 2014 and 2013, 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.

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.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

Concentrations of credit risk

Financial instruments, which potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company places its cash, cash equivalents and marketable securities with highly-rated financial institutions. At December 31, 2014, 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.

Segment information

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

Recent accounting pronouncements

In January 2015, the FASB issued Accounting Standards Update (ASU) 2015-01, *Income Statement-Extraordinary and Unusual Items*, to simplify income statement classification by removing the concept of extraordinary items from U.S. GAAP. As a result, items that are both unusual and infrequent will no longer be separately reported net of tax after continuing operations. The new standard is effective for both public and private companies for periods beginning after December 15, 2015. Adoption of this new standard is not expected to have a material impact on the Company's condensed consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements—Going Concern*. The new standard requires management of public and private companies to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern and, if so, disclose that fact. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. The new standard is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Adoption of this new standard is not expected to have a material impact on the Company's condensed consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. This new standards requires companies to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which a company expects to be entitled in exchange for those goods or services. Under the new standard, revenue is recognized when a customer obtains control of a good or service. The standard allows for two transition methods—entities can either apply the new standard (i) retrospectively to each prior reporting period presented, or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial adoption. The new standard is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption of the standard is prohibited. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's condensed consolidated financial statements.

In July 2013, the FASB issued 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. Adoption of this new standard did not have a material impact on the Company's condensed consolidated financial statements.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

3. Settlement Agreement with Novartis

In May 2014, the Company commenced arbitration proceedings with Novartis relating to the license of Fanapt® (the Fanapt® Arbitration). In December 2014, the Company entered into a settlement agreement with Novartis and certain of its affiliates (the Settlement Agreement). Pursuant to the terms of the Settlement Agreement, the Company and Novartis dismissed the Fanapt® Arbitration and released each other from any related claims. In addition, in connection with the Settlement Agreement, Novartis (i) transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company, (ii) purchased $25.0 million of the Company's common stock at a price per share equal to $13.82, and (iii) granted to the Company an exclusive worldwide license to AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

Pursuant to the stock purchase agreement entered into as part of the Settlement Agreement, Novartis purchased $25.0 million of the Company's common stock. The Company issued to Novartis an aggregate of 1,808,973 shares at $13.82 per share, which per share represented a 10% premium to the average closing prices of the Company's common stock for the ten trading days prior to December 22, 2014. The Company recorded a loss of $0.9 million as part of gain on arbitration settlement in the consolidated statement of operations for the period ending December 31, 2014 related to the issuance of stock, which was valued using the Company's closing stock price on December 31, 2014, the effective date of the transaction.

In connection with the Settlement Agreement, the Company received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize AQW051. Under the AQW051 license agreement, the Company is obligated to use its commercially reasonable efforts to develop and commercialize AQW051 and is responsible for all development costs under the AQW051 license agreement. Novartis is eligible to receive tiered-royalties on net sales at percentage rates up to the mid-teens. The Company evaluated AQW051 and determined that the asset is both incomplete and has substance. However, given the early stage of AQW051 and the future costs of development, no transaction value was allocated to this asset.

The Company accounted for the Settlement Agreement in accordance with the provisions of ASC Subtopic 805, *Business Combinations* (ASC 805). Under the provisions of ASC 805, the acquisition date for a business is the date on which the company obtains control of the acquiree. The Company obtained control on December 31, 2014, the effective date of the Settlement Agreement. The following summarizes the fair value of consideration exchanged as part of the Settlement Agreement:

(in thousands)	
Equity issued	$ 25,904
Cash received	(25,000)
Settlement of pre-existing non-contractual relationship	18,087
	$ 18,991

Assets acquired and recorded at fair value as of December 31, 2014 were as follows:

(in thousands)	
Inventory	$ 2,960
Intangible—Re-acquired right	15,940
Prepaid services	91
	$18,991

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

The Company recorded the reacquired right as an intangible asset as of December 31, 2014. The Company is amortizing the reacquired right on a straight-line basis through November 2016. See Note 11, *Intangible Assets*, for further discussion.

Due to the effective date of the Settlement Agreement being December 31, 2014, the Company did not recognize any revenue or operating expenses related to U.S. or Canadian commercial sales of Fanapt® in the consolidated statement of operations for the period ending December 31, 2014. Non-recurring transaction costs of $0.6 million related to the acquisition are recorded in selling, general and administrative expenses in the consolidated statement of operations for the period ending December 31, 2014.

In connection with the Settlement Agreement, the Company and Novartis terminated the 2009 Amended Sublicense Agreement (the 2009 Agreement). Given the termination of this pre-existing contractual relationship and that there is no further obligations under the 2009 Agreement, the Company recognized a gain of $59.5 million, representing the remaining deferred revenue related to the $200.0 million upfront payment received from Novartis under the 2009 Agreement. This amount is included in gain on arbitration settlement in the consolidated statement of operations for the period ending December 31, 2014.

The Settlement Agreement provided for mutual release of claims and dismissed the Fanapt® Arbitration, which effectively settled a pre-existing non-contractual relationship. As a result, the Company recorded an $18.1 million gain on the settlement of arbitration, which represented the value of a potential future arbitration outcome. This amount was valued based on a probability weighted scenario analysis that took into consideration the probability of each potential future alternative outcomes of the arbitration between the parties. This amount is included in gain on arbitration settlement in the consolidated statement of operations for the period ending December 31, 2014.

Unaudited Pro forma Information

The following supplemental pro forma information summarizes the combined results of operations of the Company and the Fanapt® business as though the acquisition occurred on January 1, 2013. These supplemental pro forma results of operations are provided for illustrative purposes only and do not purport to be indicative of the actual results that would have been achieved by the combined company for the periods presented or that may be achieved by the combined company in the future. The pro forma results do not include any cost savings or other synergies that may result from the Fanapt® acquisition or any estimated costs that will be incurred to integrate Fanapt® into the Company. Future results may vary significantly from the results in this pro forma information because of future unknown events.

(in thousands, except per share amounts)	Year Ended December 31, 2014	2013
Revenue	$ 79,335	$ 75,270
Net income (loss)	$(100,742)	$ 41,048
Basic income (loss) per share	$ (2.90)	$ 1.35
Diluted income (loss) per share	$ (2.90)	$ 1.29

The Company's historical financial information was adjusted to give effect to the pro forma events that were directly attributable to the Fanapt® business. The pro forma consolidated results include historical revenues and expenses for the both the Company and the Fanapt® business with the following adjustments:

- The timing of the gain on arbitration settlement as of January 1, 2013.
- The increase to the gain on arbitration settlement due to the larger deferred revenue balance associated with the license agreement as of January 1, 2013.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

- The removal of licensing revenue from the Company's revenue associated with the up-front license fee received from Novartis.
- The inclusion of intangible asset amortization expense associated with the intangible asset recorded as part of the acquisition.
- The removal of the royalty associated with U.S. sales of Fanapt® from both the Company's revenue and the expenses of the Fanapt® business.
- The difference between the cost of inventory that Novartis incurred and the Company's recorded fair value of inventory.

4. Change in Method of Accounting for Stock-based Compensation

In January 2014, the Company elected to change its method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions to the straight-line method. Previously, attribution was based on the accelerated attribution method, which treated each vesting tranche as an individual award and amortized them concurrently. The straight-line method of accounting was adopted to better align the Company's recognition of stock option compensation cost with its peers and to expense stock options and RSUs in a consistent manner. Comparative financial statements for prior periods have been adjusted to apply the straight-line method retrospectively. As a result of the change in method of accounting for stock-based compensation, the expense for stock-based compensation related to option awards was $2.2 million lower than it would have been under the accelerated attribution method for the year ended December 31, 2014. This resulted in an increase to net income of $2.2 million, or $0.06 per basic and diluted share for the year ended December 31, 2014.

There was no adjustment as a result of the change in method of accounting for stock-based compensation to amounts previously reported as assets, liabilities and total stockholders' equity in the consolidated balance sheets for prior periods. However, amounts previously reported as additional paid-in capital and accumulated deficit for prior periods have been adjusted to reflect the change in method of accounting for stock-based compensation. The cumulative effect of the change on accumulated deficit as of January 1, 2012, the beginning of the earliest period presented in the financial statements was a reduction of $4.9 million. The adjustments as of December 31, 2011 were as follows:

Balance Sheet

	December 31, 2011		
(in thousands, except for share and per share amounts)	As Previously Reported	Retrospective Adjustment	As Adjusted
Stockholders' equity:			
Preferred stock, $0.001 par value; 20,000,000 shares authorized, and no shares issued or outstanding	—		—
Common stock, $0.001 par value; 150,000,000 shares authorized; 28,117,026 shares issued and outstanding at December 31, 2011	$ 28	$ —	$ 28
Additional paid-in capital	296,868	(4,945)	291,923
Accumulated other comprehensive income	21	—	21
Accumulated deficit	(263,443)	4,945	(258,498)
Total stockholders' equity	$ 33,474	$ —	$ 33,474

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

The amounts previously reported in the consolidated statement of operations for research and development expense, selling, general and administrative expense and net loss for prior periods have been adjusted as a result of the change in method of accounting for stock-based compensation. The adjustments for the years ended December 31, 2013 and 2012 were as follows:

Statement of Operations

(in thousands, except for share and per share amounts)	Year Ended December 31, 2013			Year Ended December 31, 2012		
	As previously Reported	Retrospective Adjustment	As Adjusted	As previously Reported	Retrospective Adjustment	As Adjusted
Revenues:						
Licensing agreement	$ 26,789	$ —	$ 26,789	$ 26,789	$ —	$ 26,789
Royalty revenue	7,090	—	7,090	5,938	—	5,938
Total revenues	33,879	—	33,879	32,727	—	32,727
Operating expenses:						
Cost of goods sold	—	—	—	129	—	129
Research and development	28,190	312	28,502	45,446	318	45,764
Selling, general and administrative	24,594	488	25,082	13,882	635	14,517
Intangible asset amortization	1,495	—	1,495	1,495	—	1,495
Total operating expenses	54,279	800	55,079	60,952	953	61,905
Loss from operations	(20,400)	(800)	(21,200)	(28,225)	(953)	(29,178)
Other income	145	—	145	561	—	561
Loss before tax benefit	(20,255)	(800)	(21,055)	(27,664)	(953)	(28,617)
Tax benefit	—	—	—	—	—	—
Net loss	$ (20,255)	$ (800)	$ (21,055)	$ (27,664)	$ (953)	$ (28,617)
Basic and diluted net loss per share	$ (0.67)	$ (0.02)	$ (0.69)	$ (0.98)	$ (0.03)	$ (1.01)
Weighted average shares outstanding, basic and diluted	30,351,353	—	30,351,353	28,228,409	—	28,228,409

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

The amounts previously reported for net loss in the consolidated statement of comprehensive loss for prior periods have been adjusted as a result of the change in method of accounting for stock-based compensation. The adjustments for the years ended December 31, 2013 and 2012 were as follows:

Statement of Comprehensive Loss

	Year Ended December 31, 2013			Year Ended December 31, 2012		
(in thousands)	As Previously Reported	Retrospective Adjustment	As Adjusted	As Previously Reported	Retrospective Adjustment	As Adjusted
Net loss	$ (20,255)	$ (800)	$(21,055)	$ (27,664)	$ (953)	$(28,617)
Other comprehensive income (loss):						
Change in net unrealized loss on marketable securities	11	—	11	(11)	—	(11)
Tax provision on other comprehensive income (loss)	—	—	—	—	—	—
Other comprehensive income (loss), net of tax:	11	—	11	(11)	—	(11)
Comprehensive loss	$ (20,244)	$ (800)	$(21,044)	$ (27,675)	$ (953)	$(28,628)

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

There was no adjustment to the amounts previously reported for net cash used in operating activities in the consolidated statements of cash flows for prior periods as a result of the change in method of accounting for stock-based compensation. However, the amounts previously reported as net loss and employee and non-employee stock-based compensation expense in cash flows from operating activities have been adjusted to reflect the change in method of accounting for stock-based compensation. The adjustments for the years ended December 31, 2013 and 2012 were as follows:

Statement of Cash Flows

	Year Ended December 31, 2013			Year Ended December 31, 2012		
(in thousands)	As Previously Reported	Retrospective Adjustment	As Adjusted	As Previously Reported	Retrospective Adjustment	As Adjusted
Cash flows from operating activities						
Net loss	$ (20,255)	$ (800)	$(21,055)	$ (27,664)	$ (953)	$(28,617)
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization of property and equipment	432	—	432	633	—	633
Employee and non-employee stock-based compensation	4,604	800	5,404	4,094	953	5,047
Amortization of discounts and premiums on marketable securities	155	—	155	560	—	560
Intangible asset amortization	1,495	—	1,495	1,495	—	1,495
Landlord contributions for tenant improvements	—	—	—	1,826	—	1,826
Changes in assets and liabilities, net	(26,023)	—	(26,023)	(25,861)	—	(25,861)
Net cash used in operating activities	$ (39,592)	$ —	$(39,592)	$ (44,917)	$ —	$(44,917)

5. 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.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

The following table presents the calculation of basic and diluted net income (loss) per share of common stock for the years ended December 31, 2014, 2013, and 2012:

(in thousands, except for share and per share amounts)	Year Ended December 31, 2014	2013	2012
Numerator:			
Net income (loss)	$ 20,186	$ (21,055)	$ (28,617)
Denominator:			
Weighted average shares outstanding: Basic	34,774,163	30,351,353	28,228,409
Effect of dilutive securities	1,912,560	—	—
Weighted average shares outstanding: Diluted	36,686,723	30,351,353	28,228,409
Net income (loss) per share, basic and diluted:			
Basic	$ 0.58	$ (0.69)	$ (1.01)
Diluted	$ 0.55	$ (0.69)	$ (1.01)
Antidilutive securities excluded from calculations of diluted net income (loss) per share	3,524,656	4,409,811	5,462,476

The Company incurred a net loss for each of the years ended December 31, 2013 and 2012 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.

6. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2014, which all have contract maturities of less than one year:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 30,618	$ 4	$ (4)	$30,618
Corporate debt	$ 38,287	$ 25	$ (9)	$38,303
	$ 68,905	$ 29	$ (13)	$68,921

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
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

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

7. Accounts Receivable

Accounts receivable are recorded for product sales and royalty income and do not bear interest. As of December 31, 2014 and 2013, the Company recorded a royalty receivable from Novartis of $1.6 million and $2.0 million, respectively. The Company determines an allowance for doubtful accounts based on assessed customers' ability to pay and economic trends. Such allowance is the Company's best estimate of the amount of probable credit losses in the Company's existing accounts receivable. The Company did not record any bad debt expense for the years ended December 31, 2014 2013 and 2012. At December 31, 2014 and 2013 the allowance for doubtful accounts was zero.

8. Inventory

The Company evaluates expiry risk by evaluating current and future product demand relative to product shelf life. The Company builds demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage. Inventory consisted of the following as of December 31, 2014 and December 31, 2013:

(in thousands)	December 31, 2014	2013
Raw materials	$ 198	$—
Work-in-process	1,326	—
Finished goods	3,394	—
Deferred cost of goods sold	252	—
Total	$5,170	$—

9. 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, 2014 and 2013:

(in thousands)	December 31, 2014	2013
Prepaid insurance	$ 270	$ 167
Prepaid manufacturing cost	358	—
Other prepaid expenses and vendor advances	2,302	2,408
Other current assets	154	128
Total prepaid expenses and other current assets	$3,084	$2,703

10. Property and Equipment

The following is a summary of the Company's property and equipment-at cost, as of December 31, 2014 and 2013:

(in thousands)	Estimated Useful Life (Years)	December 31, 2014	2013
Computer equipment	3	$ 1,316	$ 983
Furniture and fixtures	7	765	580
Leasehold improvements	11	2,089	1,884
		$ 4,170	$ 3,447
Accumulated depreciation and amortization		$(1,733)	$(1,249)
		$ 2,437	$ 2,198

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

Depreciation and amortization expense for the years ended December 31, 2014, 2013 and 2012 was $0.5 million, $0.4 million and $0.6 million, respectively.

11. Intangible Assets

The following is a summary of the Company's intangible assets as of December 31, 2014 and 2013:

		December 31, 2014		
(in thousands)	Estimated Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	January 2033	$ 8,000	$ 539	$ 7,461
Fanapt®	November 2016	$ 27,941	$ 8,678	$ 19,263

		December 31, 2013		
(in thousands)	Estimated Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	November 2016	$ 12,000	$ 6,963	$ 5,037

In January 2014, the Company announced that the FDA had approved the NDA for HETLIOZ®. As a result of this approval, the Company met a milestone under its license agreement with Bristol-Myers Squibb (BMS) that required the Company to make a license payment of $8.0 million to BMS. The $8.0 million is being amortized on a straight-line basis over the remaining life of the U.S. patent for HETLIOZ®, which prior to June 2014, the Company expected to last until December 2022. In June 2014, the Company received a notice of allowance from the U.S. Patent and Trademark Office for a patent covering the method of use of HETLIOZ®. The patent expires in January 2033, thereby potentially extending the exclusivity protection in the U.S. beyond the composition of matter patent. As a result of the patent allowance, the Company extended the estimated useful life of the U.S. patent for HETLIOZ® from December 2022 to January 2033.

In 2009, the Company announced that the FDA had approved the NDA for Fanapt®. As a result of this approval, the Company met a milestone under its original sublicense agreement with Novartis that 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 reflected the expected duration of the Novartis commercialization of Fanapt® in the U.S. which was estimated to be through the expiry of the Fanapt® composition of matter patent, including a granted Hatch-Waxman extension and an assumed additional six month pediatric extension. In February 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 resulted in a six-month reduction to the estimated patent life from May 2017 to November 2016.

Pursuant to the Settlement Agreement, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company. As a result, the Company recognized an intangible asset of $15.9 million on December 31, 2014 related to the reacquired right to Fanapt®, which is being amortized on a straight-line basis through November 2016. The useful life estimation for the Fanapt® intangible asset is based on the market participant methodology prescribed by ASC 805, and therefore does not reflect the impact of the Fanapt® patent number 8,586,610, which is solely owned by the Company and expires in 2027. See Note 3, *Settlement Agreement with Novartis*, for further discussion.

The intangible assets are being amortized over their estimated useful economic life using the straight line method. Amortization expense was $2.3 million, $1.5 million and $1.5 million for the years ended December 31, 2014, 2013 and 2012, respectively.

The following is a summary of the future intangible asset amortization schedule as of December 31, 2014:

(in thousands)	Total	2015	2016	2017	2018	2019	Thereafter
HETLIOZ®	$ 7,461	$ 411	$ 411	$411	$411	$411	$ 5,406
Fanapt®	19,263	10,050	9,213	—	—	—	—
	$26,724	$10,461	$9,624	$411	$411	$411	$ 5,406

12. Accrued Liabilities

The following is a summary of the Company's accrued liabilities as of December 31, 2014 and 2013:

	December 31,	
(in thousands)	2014	2013
Accrued research and development expenses	$1,759	$2,324
Accrued consulting and other professional fees	2,522	2,015
Compensation and employee benefits	388	176
Other accrued liabilities	1,833	665
	$6,502	$5,180

13. Deferred Revenue

The following is a summary of changes in total deferred revenue for the years ended December 31, 2014 and 2013:

	Year Ended December 31,	
(in thousands)	2014	2013
Balance beginning of period	$ 90,275	$ 117,064
Deferred Fanapt® product sales	174	—
Licensing revenue recognized	30,746	26,789
Recognized as part of gain on arbitration settlement	59,529	—
Balance end of period	$ 174	$ 90,275

The Company entered into an amended and restated sublicense agreement with Novartis in 2009, pursuant to which Novartis had 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. 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 had no term as the exact length of the JSC is undefined. As a result, the Company deemed the performance period of the JSC to be the life of the U.S. patent of Fanapt®. Revenue related to the upfront payment was recognized ratably from the date the amended and restated sublicense agreement became effective (November 2009) through the expected duration of the Novartis commercialization of Fanapt® in the U.S. which was estimated to be through the expiry of the Fanapt® composition of patent, including a granted Hatch-Waxman extension (November 2016). During the years ended December 31, 2014, 2013 and 2012, the Company recognized revenue of $30.7 million, $26.8 million and $26.8 million, respectively, related to the license agreement.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

In connection with the Settlement Agreement with Novartis, the Company recognized the remaining deferred revenue balance of $59.5 million as part of the gain on arbitration settlement. See Note 3, *Settlement Agreement with Novartis*, for further discussion.

14. Commitments and Contingencies

Operating leases

The following is a summary of the minimum annual future payments under operating leases as of December 31, 2014:

(in thousands)	Total	2015	2016	2017	2018	2019	Thereafter
Operating leases	$14,710	$1,395	$1,500	$1,538	$1,576	$1,616	$ 7,085

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.

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 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.

In March 2014, the Company and the Landlord entered into a lease amendment (the Lease Amendment). Under the Lease Amendment, the Company has the right to occupy an additional 8,860 square feet in the building. The Lease Amendment has a 12 year and one month term beginning on September 1, 2014, but may be terminated early by either the Landlord or the Company upon certain conditions. The Company will pay approximately $0.4 million in additional annual rent over the term of the Lease Amendment, however, rent will be abated for the first nine months. The Landlord will provide the Company with an allowance of approximately $0.8 million for construction on the premises to the Company's specifications, subject to certain conditions. Subject to the prior rights of other tenants in the building, the Company will have the right to renew the Lease Amendment for five years following the expiration of its original term. The Company will also have the right to sublease or assign all or a portion of the premises, subject to standard conditions.

Rent expense under operating leases, was $1.7 million, $1.1 million and $2.0 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Consulting fees

The Company 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 approval of the NDA for HETLIOZ®, the Company made a milestone payment of $2.0 million in 2014. In 2013, 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. These payments are included as research and development expense in the consolidated statements of operations for the years ended December 31, 2014 and 2013, respectively. In March 2014, the Company terminated the engagement.

Guarantees and indemnifications

The Company has entered into a number of standard intellectual property indemnification agreements in the ordinary course of its business. Pursuant to these agreements, the Company indemnifies, holds harmless, and

agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company's products. The term of these indemnification agreements is generally perpetual from the date of execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain 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 Company (BMS) under which it 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. 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. As a result of the FDA's approval of the HETLIOZ® NDA in January 2014, the Company incurred an $8.0 million milestone obligation in the first quarter of 2014 under the same license agreement that was capitalized as an intangible asset and is being amortized over the expected HETLIOZ® patent life in the U.S. The Company is obligated to make a future milestone payment to BMS of $25.0 million in the event that cumulative worldwide sales of HETLIOZ® reach $250.0 million. Additionally, the Company is obligated to make royalty payments on HETLIOZ® net sales to BMS in any territory where it commercializes HETLIOZ® for a period equal to the greater of 10 years post the first commercial sale in the territory or the expiry of the new chemical entity patent in that territory. During the period prior to the expiry of the new chemical entity patent in a territory, the Company is obligated to pay a 10% royalty on net sales in that territory. The royalty rate is decreased by half for countries in which no new chemical entity patent existed or for the remainder of the 10 years after the expiry of the new chemical entity patent. 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 it 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 our license agreement for HETLIOZ® to use our commercially reasonable efforts to develop and commercialize HETLIOZ®.

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.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

Fanapt®. Pursuant to the terms of the Settlement Agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company on December 31, 2014.

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 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 a milestone under the sublicense agreement, which required it to make a payment of $12.0 million to Novartis.

In October 2009, the Company 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 was responsible for the further clinical development activities in the U.S. and Canada. Pursuant to the amended and restated sublicense agreement, the Company received an upfront payment of $200.0 million and was 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. The Company also received royalties, which, as a percentage of net sales, were in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. The Company retained exclusive rights to Fanapt® outside the U.S. and Canada and is obligated to make royalty payments to Sanofi S.A. on Fanapt® sales outside the U.S. and Canada.

The Company has entered into agreements with the following partners for the commercialization of Fanapt® in the countries set forth below:

Country	Partner	Market Approval Date
Mexico	Probiomed S.A. de C.V.	October 2013
Israel	Megapharm Ltd.	August 2012

Pursuant to the terms of the Settlement Agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company on December 31, 2014. The Company is obligated to make royalty payments to Sanofi, S.A. and Titan, at a percentage rate equal to 23% on annual U.S. net sales of Fanapt® up to $200 million, and at a percentage in the mid-twenties on sales over $200 million through November 2016. After the expiration of the new chemical entity patent in major markets (US, United Kingdom, Germany, France, Italy, Spain and Japan) and some non-major markets, the Company will have a fixed royalty obligation to Sanofi on Fanapt® net sales of up to 9%. See Note 3, *Settlement Agreement with Novartis,* for further information.

Tradipitant. 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, tradipitant, for all human indications. The patent describing tradipitant 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 tradipitant.

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 tradipitant.

AQW051. In connection with the Settlement Agreement, the Company received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

Pursuant to the license agreement, the Company is obligated to use its commercially reasonable efforts to develop and commercialize AQW051 and is responsible for all development costs under the AQW051 license agreement. The Company has no milestone obligations; however, Novartis is eligible to receive tiered-royalties on net sales at percentage rates up to the mid-teens.

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, 2014 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.

15. Income Taxes

As of December 31, 2014 and 2013, 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.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

The following is a summary of the Company's current and deferred income tax provision (benefit) for years ended December 31, 2014, 2013 and 2012:

(in thousands)	Year Ended December 31, 2014	2013	2012
Current income tax expense (benefit):			
Federal	$ —	$ —	$ —
State	—	—	—
Deferred income tax expense (benefit):			
Federal	—	—	—
State	—	—	—
Total income tax expense (benefit)	$ —	$ —	$ —

The following is a reconciliation between the Company's statutory tax rate and effective tax rate for the years ended December 31, 2014, 2013 and 2012:

	Year Ended December 31, 2014	2013	2012
Federal tax at statutory rate	34.0%	-34.0%	-34.0%
State taxes	7.2%	-4.0%	-3.3%
Change in valuation allowance	-59.7%	43.9%	70.3%
Research and development credit	1.3%	-1.1%	0.8%
Orphan drug credit	8.5%	-22.7%	-30.3%
Stock options	0.0%	0.0%	1.4%
Section 162(m) limitation	1.1%	1.2%	0.0%
Stock issuance cost	1.6%	0.0%	0.0%
Tax rate change	4.8%	-0.3%	-7.0%
Change in Maryland NOL	0.0%	18.5%	0.0%
Other non-deductible items	1.2%	-1.5%	2.1%
Effective tax rate	0.0%	0.0%	0.0%

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

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, 2014 and 2013:

(in thousands)	December 31, 2014	December 31, 2013
Deferred tax assets:		
Net operating loss carry forwards	$ 73,626	$ 48,206
Stock-based compensation	17,160	17,626
Deferred revenue	—	36,670
Accrued and deferred expenses	532	566
Research and development and orphan drug credit carryforwards	36,772	38,597
Depreciation and amortization, net	118	110
Contributions carryforward	420	—
Reacquired rights	182	—
Licensing agreements	86	—
Total deferred tax assets	128,896	141,775
Deferred tax liabilities:		
Licensing agreements	—	(616)
Unrealized gain on available for sale securities	(6)	(9)
Total deferred tax liabilities	(6)	(625)
Deferred tax assets	128,890	141,150
Valuation allowance	(128,890)	(141,150)
Net deferred tax assets	$ —	$ —

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, 2014 and 2013. The net decrease in the tax valuation allowance was $12.3 million for the year ended December 31, 2014. The net increase in the tax valuation allowance was $7.9 million and $19.4 million for the years ended December 31, 2013 and 2012, respectively.

As of December 31, 2014, the Company had federal NOL carryforwards of $197.4 million, state NOL carryforwards of $201.3 million, which include $4.2 million of excess windfall benefits generated from stock options. The Company also has research and development credits of $6.2 million and orphan drug carryforward credits of $30.6 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, 2014, all income tax returns filed by the Company are open to examination by tax jurisdictions. As of December 31, 2014, 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 (tax attributes). Ownership changes did occur as of December 31, 2014 and December 31, 2008. However, the Company believes that it had sufficient Built-In-Gain to offset the IRC Section 382 limitation generated by the ownership changes. Any future ownership changes may cause the Company's existing tax attributes to have additional limitations. Additionally, the Company maintains a valuation allowance on its tax attributes, therefore, any IRC Section 382 limitation would not have a material impact on the Company's provision for income taxes as of December 31, 2014.

As of December 31, 2014 and 2013, the Company had no uncertain tax positions.

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

(in thousands)	Balance At Beginning Of Period	Additions Charged To Income Tax Expense	Reductions Credited To Income Tax Expense	Balance At End Of Period
Calendar year ended:				
December 31, 2012	$113,823	$ 28,102	$ 8,654	$ 133,271
December 31, 2013	$133,271	$ 22,998	$ 15,119	$ 141,150
December 31, 2014	$141,150	$ 27,893	$ 40,153	$ 128,890

16. 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, 2014 and 2013 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, 2014, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

		Fair Value Measurement as of December 31, 2014 Using		
(in thousands)	December 31, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale securities	$ 68,921	$ 30,618	$ 38,303	$ —

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 Measurement as of December 31, 2013 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)
Available-for-sale securities	$ 65,586	$ 31,566	$ 34,020	$ —

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, 2014 and 2013, there were no transfers between Level 1 and Level 2 of the fair value hierarchy.

17. Restricted Cash

The following is a summary of the Company's restricted cash used to collateralize various letters of credit as of December 31, 2014 and 2013:

	December 31,	
(in thousands)	2014	2013
Current:		
Rockville, Maryland office lease	$—	$430
Maryland Board of Pharmacy license	—	100
Total current	$—	$530
Non-current:		
Washington, D.C. office lease	$785	$500
Maryland Board of Pharmacy license	—	—
Total non-current	$785	$500

18. Public Offering of Common Stock

In October 2014, the Company completed a public offering of 5,750,000 shares of common stock at a price to the public of $11.60 per share. Net cash proceeds from the public offering were $62.3 million, after deducting the underwriting discounts and commissions and offering expenses. 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 2013 public offering were $48.5 million, after deducting the underwriting discounts and commissions and offering expenses.

19. Equity Incentive Plans

As of December 31, 2014, 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 652,810 shares were subject to outstanding options granted under the 2004 Plan as of December 31, 2014, and no additional options will be granted under this plan. As of December 31, 2014, there were 10,329,472 shares of the Company's common stock reserved for issuance under the 2006 Plan, of which 7,253,073 shares were subject to outstanding options and RSUs granted to employees and non-employees and 956,265 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 the lesser of 4% of the total number of shares of common stock that are outstanding at that time or 1,500,000 shares (or such lesser number as may be approved by the Company's board of directors). As of January 1, 2015, the number of shares of common stock that may be issued under the 2006 Plan was automatically increased by 1,500,000 shares, increasing the number of shares of common stock available for issuance under the Plan to 11,829,472 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, 2014, $14.0 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.7 years. No option awards are classified as a liability as of December 31, 2014.

The following is a summary of option activity for the 2004 Plan for the years ended December 31, 2014, 2013, and 2012:

(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, 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
Exercised	(115)	4.73		
Expired	(1,286)	3.67		
Outstanding at December 31, 2013	670,744	1.79	1.78	7,124
Exercised	(17,934)	3.57		
Outstanding at December 31, 2014	652,810	1.74	0.78	8,212
Exercisable at December 31, 2014	652,810	1.74	0.78	8,212

There are no options expected to vest as of December 31, 2014 under the 2004 Plan, given that the Company stopped issuing options from this plan in 2006.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

The following is a summary of option activity for the 2006 Plan for the years ended December 31, 2014, 2013, and 2012:

(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, 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
Granted	1,324,337	12.17		
Forfeited	(237,108)	8.35		
Exercised	(393,735)	7.08		2,923
Outstanding at December 31, 2014	6,227,112	11.58	6.71	28,523
Exercisable at December 31, 2014	3,822,302	12.31	5.18	19,110
Expected to vest at December 31, 2014	2,263,369	10.34	9.12	9,034

Proceeds from the exercise of stock options amounted to $2.9 million, $1.6 million and $0.01 million for the years ended December 31, 2014, 2013 and 2012, 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, 2014, $8.3 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, 2014.

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, 2014, 2013, and 2012:

	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
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
Granted	436,115	12.28
Forfeited	(84,282)	6.75
Vested	(209,562)	6.67
Unvested at December 31, 2014	1,025,961	9.94

The grant date fair value for the 209,562 shares underlying RSUs that vested during the year ended December 31, 2014 was $1.4 million. In order for certain employees to satisfy the minimum statutory employee tax withholding requirements related to the issuance of common stock underlying certain of the RSUs that vested and settled during the year ended December 31, 2014, the Company withheld 32,386 shares of common stock and paid employee payroll withholding taxes of $0.4 million relating to the vesting and settlement of the RSUs.

20. Employee Benefit Plan

The Company has a defined contribution plan under the Internal Revenue Code Section 401(k). This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Currently, the Company matches 50 percent up to the first six percent of employee contributions. All matching contributions have been paid by the Company. The Company match vests over a four year period. The total Company match was $0.2 million, $0.2 million and $0.1 million for the years ended December 31, 2014, 2013 and 2012, respectively.

21. Legal Matters

In June 2014, the Company filed suit against Roxane Laboratories, Inc. (Roxane) in the U.S. District Court for the District of Delaware. The suit seeks an adjudication that Roxane has infringed one or more claims of the Company's U.S. Patent No. 8,586,610 (the Patent) by submitting to the FDA an Abbreviated New Drug Application for generic versions of Fanapt® oral tablets in 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg strengths. The relief requested by the Company includes a request for a permanent injunction preventing Roxane from infringing the asserted claims of the Patent by engaging in the manufacture, use, offer to sell, sale, importation or distribution of generic versions of Fanapt® before the expiration of the Patent in 2027.

Pursuant to the Settlement Agreement with Novartis, the Company assumed Novartis' patent infringement action against Roxane in the U.S. District Court for the District of Delaware. The suit alleges that Roxane's filing of an ANDA for generic iloperidone with a paragraph IV certification infringes Sanofi's new chemical entity patent.

Vanda Pharmaceuticals Inc.

Notes to the Consolidated Financial Statements — (Continued)

Roxane is defending on the grounds that the patent claims are invalid or unenforceable or that certain patent claims are not infringed. Roxane also filed a motion to dismiss on the grounds that the court lacks jurisdiction.

22. Quarterly Financial Data (unaudited)

(in thousands, except for per share amounts)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2014				
Revenue	$ 9,143	$ 10,862	$14,782	$15,370
Income (loss) from operations	(26,578)	(21,606)	(1,448)	69,693
Net income (loss)	(26,533)	(21,575)	(1,426)	69,719
Net income (loss) per share:				
Basic	$ (0.79)	$ (0.64)	$ (0.04)	$ 1.85
Diluted	$ (0.79)	$ (0.64)	$ (0.04)	$ 1.77
2013 (1)				
Revenue	$ 8,068	$ 8,319	$ 8,709	$ 8,783
Loss from operations	(4,565)	(3,413)	(5,431)	(7,791)
Net loss	(4,519)	(3,383)	(5,406)	(7,747)
Net loss per share, basic and diluted	$ (0.16)	$ (0.12)	$ (0.17)	$ (0.23)

The Company's results for the fourth quarter of 2014 include a gain on arbitration settlement of $77.6 million, or $2.06 and $1.97 per basic and diluted share, respectively. See Note 3, *Settlement Agreement with Novartis*, for further discussion.

(1) In the first quarter of 2014, the Company elected to change its method of accounting for stock-based compensation from the accelerated attribution method to the straight-line method. The consolidated financial data above for the year ended 2013 has been adjusted to reflect this change. See Note 4, *Change in Method of Accounting for Stock-based Compensation*, for further discussion.

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).

Exhibit Number	Description
10.10	Summary Plan Description provided for the registrant's 401(k) Profit Sharing Plan & Trust (filed as Exhibit 10.10 to the registrant's Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference).
10.11	Form of Indemnification Agreement entered into by directors (filed as Exhibit 10.11 to the registrant's Registration Statement on Form S-1 (File No. 333-130759), as originally filed on December 29, 2005, and incorporated herein by reference).
10.17	2006 Equity Incentive Plan (filed as Exhibit 10.17 to Amendment No. 2 to the registrant's Registration Statement on Form S-1 (File No. 333-130759), as filed on March 17, 2006, and incorporated herein by reference).
10.19	Amendment to Lease Agreement between the registrant and MCC3 LLC (by Spaulding and Slye LLC) dated November 15, 2006 (filed as Exhibit 10.19 to the registrant's annual report on Form 10-K (File No. 000-51863) for the year ending December 31, 2006 and incorporated herein by reference).
10.20	Form of Tax Indemnity Agreement (filed as Exhibit 10.20 to the registrant's quarterly report on Form 10-Q (File No. 000-51863) for the period ending September 30, 2007 and incorporated herein by reference).
10.34	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).
10.37#	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).
10.41	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).

Exhibit Number	Description
10.46	Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of April 15, 2010 (filed as Exhibit 10.38 to the registrant's current report on Form 8-K filed on April 19, 2010 and incorporated herein by reference).
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).
10.50	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.
10.53#	Manufacturing Agreement between the Registrant and Patheon Pharmaceuticals Inc. dated January 24, 2014 (relating to HETLIOZ®).
10.54	Amendment to Lease agreement dated July 25, 2011 by and between Registrant and Square 54 Office Owner LLC, dated March 18, 2014, by and between the Registrant and Square 54 Office Owner LLC.
10.55*	Settlement Agreement and Mutual General Release by and among the Registrant and Novartis Pharma AG dated December 22, 2014.
10.56*†	Asset Transfer Agreement by and among the Registrant, Novartis Pharma AG and Novartis AG dated December 22, 2014 (relating to Fanapt®).
10.57#	Sublicense Agreement by and between Titan Pharmaceuticals, Inc. and Novartis Pharma AG dated November 20, 1997 (filed as Exhibit 10.30 to Titan Pharmaceutical Inc.'s Registration Statement on Form S-3 (File No. 333-42367), as filed on December 16, 1997, and incorporated herein by reference).
10.58*†	Amendment No. 1 to Sublicense Agreement by and between Titan Pharmaceuticals, Inc. and Novartis Pharma AG dated November 30, 1998.
10.59*†	Amendment No. 2 to Sublicense Agreement by and between Titan Pharmaceuticals, Inc. and Novartis Pharma AG dated April 10, 2001.
10.60*†	Amendment No. 3 to Sublicense Agreement by and between Titan Pharmaceuticals, Inc. and Novartis Pharma AG dated June 4, 2004.
10.61*	Stock Purchase Agreement between the Registrant and Novartis AG dated December 22, 2014.
10.62*†	License Agreement by and between the Registration and Novartis Pharma AG dated December 22, 2014 (relating to AQW051).
18.1	Preferability Letter of Independent Public Accounting Firm dated May 7, 2014.

Exhibit Number	Description
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, 2014 and December 31, 2013; (ii) Consolidated Statements of Operations for the years ended December 31, 2014, 2013 and 2012; (iii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2014, 2013 and 2012; (iv) Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2014, 2013 and 2012; (v) Consolidated Statements of Cash Flows for the years ended December 31, 2014, 2013 and 2012; and (vi) Notes to the Consolidated Financial Statements.

Confidential treatment has been granted with respect to certain provisions of this exhibit.
* Filed herewith.
† Confidential treatment has been requested with respect to certain provisions of this exhibit.

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

Exhibit Number	Description
10.55	Settlement Agreement and Mutual General Release by and among the Registrant and Novartis Pharma AG dated December 22, 2014.
10.56†	Asset Transfer Agreement by and among the Registrant, Novartis Pharma AG and Novartis AG dated December 22, 2014 (relating to Fanapt®).
10.57#	Sublicense Agreement by and between Titan Pharmaceuticals, Inc. and Novartis Pharma AG dated November 20, 1997 (filed as Exhibit 10.30 to Titan Pharmaceutical Inc.'s Registration Statement on Form S-3 (File No. 333-42367), as filed on December 16, 1997, and incorporated herein by reference).
10.58†	Amendment No. 1 to Sublicense Agreement by and between Titan Pharmaceuticals, Inc. and Novartis Pharma AG dated November 30, 1998.
10.59†	Amendment No. 2 to Sublicense Agreement by and between Titan Pharmaceuticals, Inc. and Novartis Pharma AG dated April 10, 2001.
10.60†	Amendment No. 3 to Sublicense Agreement by and between Titan Pharmaceuticals, Inc. and Novartis Pharma AG dated June 4, 2004.
10.61	Stock Purchase Agreement between the Registrant and Novartis AG dated December 22, 2014.
10.62†	License Agreement by and between the Registration and Novartis Pharma AG dated December 22, 2014 (relating to AQW051).
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, 2014 and December 31, 2013; (ii) Consolidated Statements of Operations for the years ended December 31, 2014, 2013 and 2012; (iii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2014, 2013 and 2012; (iv) Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2014, 2013 and 2012; (v) Consolidated Statements of Cash Flows for the years ended December 31, 2014, 2013 and 2012; and (vi) Notes to the Consolidated Financial Statements

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

Exhibit 10.55

Confidential

FINAL VERSION

SETTLEMENT AGREEMENT AND MUTUAL GENERAL RELEASE

THIS SETTLEMENT AGREEMENT AND MUTUAL RELEASE (this "**Agreement**"), dated as of December 22, 2014 (the "**Signing Date**"), is entered into by and between Novartis Pharma AG, a corporation organized under the laws of Switzerland, having its principal office at Lichtstrasse 35, CH-4056 Basel, Switzerland ("**Novartis**"), and Vanda Pharmaceuticals Inc., a corporation organized and existing under the laws of the State of Delaware, having its principal office at 2200 Pennsylvania Avenue, N.W., Suite 300E, Washington, D.C. 20037 ("**Vanda**"). All parties identified above shall be collectively referred to as the "**Parties**" and individually as "**Party**".

RECITALS

WHEREAS, Vanda and Novartis entered into a certain Amended and Restated Sublicense Agreement on October 12, 2009 (the "**Sublicense Agreement**") and a certain Supply Agreement on May 2, 2012 (the "**Supply Agreement**");

WHEREAS, Vanda has initiated an arbitration against Novartis, before the American Arbitration Association, Case No. 01-14-0000-5126 (the "**Arbitration**"), asserting claims as to Novartis' performance of its obligations under the Sublicense Agreement and the Supply Agreement;

WHEREAS, Novartis has raised counterclaims in the Arbitration, asserting claims as to Vanda's performance of its obligations under the Sublicense Agreement;

WHEREAS, each Party disputes the merits of the other Party's claims and counterclaims, as the case may be, asserted in the Arbitration;

WHEREAS, the Parties wish to fully and finally resolve all differences, disputes, claims, and disagreements between them with respect to the Arbitration, the Sublicense Agreement, the Supply Agreement, and any related claims on the terms set forth herein, and to terminate any further litigation or arbitration with respect thereto, with no Party admitting fault or wrongdoing, on the terms and subject to the conditions set forth herein;

WHEREAS, the Parties are contemporaneously negotiating and executing documents to effect the transfer of certain assets from Novartis to Vanda, licensing of certain assets from Novartis and an equity investment by Novartis in Vanda as consideration for the dismissal of the Arbitration.

NOW, THEREFORE, with the intent to be legally bound hereby and in consideration of mutual covenants contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

AGREEMENT

ARTICLE I. DEFINITIONS

Section 1.1 The following terms shall have the following meaning when used in this Agreement:

"**Affiliate**" shall mean, as to any person, entity or Party, any other person, entity or Party that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such first person, entity or Party. As used in this definition, "**control**" (including, with its correlative meanings, "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of management or policies of a person, entity or Party, whether through the ownership of voting interests, by Contract or otherwise. With respect to natural persons controlled by or Affiliates of entities, "Affiliate" shall include employees, officers, directors, administrators, and agents. All references hereto to either Vanda or Novartis shall include any affiliate of either Vanda or Novartis.

"Effective Date" shall mean the Closing Date as that term is defined in the Asset Transfer Agreement.

"**Product**" shall have the same meaning as set forth in the Sublicense Agreement.

"Settlement Agreements" shall mean the Asset Transfer Agreement, the Fanapt License Agreement, the Stock Purchase Agreement, Commercial Agreement, Transition Services Agreement, Inventory Supply Agreement, AQW License Agreement, and any ancillary agreements or related agreements required to be entered into between the Parties and their respective Affiliates under such agreements.

ARTICLE II. COVENANT NOT TO SUE

Section 2.1 Subject to Section 4.4 hereof, Novartis and Vanda mutually agree that they will not bring or cause to be brought any arbitration, proceeding, or action in any Court or with any government agency against each other concerning the Product, the Sublicense Agreement or the Supply Agreement.

Section 2.2 This Agreement attaches to and shall run with the Product. In the event of an assignment of any of the rights in and to the Product, the assignor shall notify the assignee in writing of the covenants described in Section 2.1 above, and shall refuse to consummate such assignment unless the assignee agrees in writing to be bound by such covenants.

Section 2.3 It is the intention of the Parties that, following the execution of this Agreement, all arbitration, litigation, and disputes between the Parties relating to the Product, the Sublicense Agreement, the Supply Agreement and any other related claims be terminated.

ARTICLE III. CONSIDERATION

Section 3.1 Dismissal of Arbitration. As soon as practicable after the Effective Date, the Parties shall file with the American Arbitration Association executed requests to terminate the Arbitration. Pursuant to Rule 48 of the Arbitration Rules and Mediation

Procedures, the Parties shall seek a consent award. Such consent award will include an allocation of arbitration costs, including administrative fees and expenses as well as arbitrator fees and expenses, for which each Party shall be responsible for its pro-rata 50% share. Such consent award will also include a provision declaring that neither Party is to be deemed a "losing party" under Section 16 of the Sublicense Agreement, and that neither Party is responsible, in whole or in part, for the other Party's attorneys' fees or costs.

Section 3.2 Transfer of FANAPT® Franchise to Vanda. On the Signing Date, Vanda and Novartis shall enter into the Asset Transfer Agreement, attached as Exhibit A to this Agreement ("**Asset Transfer Agreement**"), the Fanapt License Agreement, attached as Exhibit B to this Agreement ("**Fanapt License Agreement**"), the Commercial Agreement, attached as Exhibit C to this Agreement ("**Commercial Agreement**"), the Transition Services Agreement, attached as Exhibit D to this Agreement ("**Transition Services Agreement**"), Supply Agreement, attached as Exhibit E to this Agreement ("**Inventory Supply Agreement**"), and other ancillary agreements, as specified in the Asset Transfer Agreement, and at the Closing (as defined) in the Asset Transfer Agreement shall execute and deliver such other documents and certificates as are required pursuant to the Asset Transfer Agreement.

Section 3.3 Equity Investment by Novartis in Vanda.

(a) On the Signing Date, Vanda and Novartis shall enter into the Stock Purchase Agreement attached as Exhibit F to this Agreement (the "**Stock Purchase Agreement**"). Pursuant to the Stock Purchase Agreement, on the Effective Date, Novartis shall purchase 1,808,973 shares of Vanda's Common Stock, par value $0.001 per share (the "Shares") at a purchase price per share equal to $13.82 for an aggregate purchase price of US$25,000,000.

(b) Restrictions on Transfer. The sale or transfer of the Shares shall be subject to the restrictions set forth in the Stock Purchase Agreement.

Section 3.4 License of AQW Phase II Asset by Novartis to Vanda. On the Signing Date, Vanda and Novartis shall enter into the License Agreement in respect of Novartis' compound known as AQW051, attached as Exhibit G to this Agreement (the "**AQW License Agreement**").

Section 3.5 Effectiveness. It is understood and agreed by the Parties that if the Closing, as that term is defined in the Asset Transfer Agreement, does not occur, then the dismissal of the arbitration provided for in Section 3.1 will not occur hereunder, and the releases provided for in Article IV will not come into effect and each of the Settlement Agreements and other agreements, documents and certificates contemplated thereby shall become null and void.

Section 3.6 No Admission of Liability. It is understood and agreed that this is a compromise settlement of disputed claims and that the furnishing of consideration under this Agreement shall not be deemed or construed at any time or for any purpose as an admission of liability or otherwise by any Party hereto.

ARTICLE IV. MUTUAL RELEASE

Section 4.1 Effective upon the Effective Date, Novartis and Vanda and each of their Affiliates each release and forever discharge the other, and each of their respective parents, subsidiaries, Affiliates, successors, assigns, directors, officers and employees from all manner of claims, demands, actions, suits, causes of action, damages, fines, penalties, and liabilities, of any nature whatsoever (collectively "**Claims**") (whether such Claims arise or are incurred before, during or after the Effective Date), including costs, expenses, penalties, and attorney's fees, known or unknown, suspected or unsuspected, in law, equity, tort, or contract that any Party ever had, now has, or hereafter can, shall or may have, directly, indirectly, as assignee, representatively, derivatively, in a proprietary capacity, or in any other capacity, to the extent that such Claims (i) could have been, should have been, or were asserted in the Arbitration; (ii) arise out of any conduct alleged in the Arbitration; or (iii) relate to the Sublicense Agreement, Supply Agreement or Product (collectively "**Released Claims**").

Section 4.2 In the event that any Party asserts a claim that is a Released Claim, this Agreement shall operate as a complete bar to such claim.

Section 4.3 The Parties expressly acknowledge that this Agreement is intended to include in its effect, without limitation, all claims, known and unknown, within the scope of the Release in Section 4.1. Each Party represents and warrants that it does not know or suspect to exist any other Claims against the other Party in their favor at the time of the Effective Date.

Section 4.4 Nothing in Article II or this Article IV shall act to bar, prevent, or release claims for the breach or enforcement of the terms or conditions of any of this Agreement or the Settlement Agreements.

ARTICLE V. MISCELLANEOUS

Section 5.1 Subject to the exceptions contained in Section 5.2, neither Party shall disclose to any third party nor use for any purpose outside of the scope of this Agreement any information which is not in the public domain and which was disclosed solely in connection with this Agreement: (a) by the disclosing Party or any of its Affiliates; or (b) any unaffiliated third party at the request of the disclosing Party ("**Confidential Information**"). The receiving Party may provide the disclosing Party's Confidential Information only to its and its Affiliates' directors, officers, employees, advisors, and consultants ("**Representatives**") who are informed of the confidential nature of the Confidential Information and who are bound by obligations of confidentiality and non-use no less restrictive than those contained herein and provided that the receiving Party shall be responsible for any breach of this Agreement by its Representatives, which shall be considered a breach by the receiving Party. The obligations of confidentiality and non-use shall expire for Confidential Information which (i) is or becomes part of the public domain without a violation of this Agreement; (ii) was already in the receiving Party's possession at the time of receipt from the disclosing Party, as shown by documentary evidence; or (iii) after the date of this Agreement is received from a Third Party whose direct or indirect source is not the disclosing Party. Upon termination or expiration of this Agreement for any reason, each Party will promptly return to the other Party all Confidential Information received from such other Party in connection with this Agreement, except to the extent and for the period of time that retaining such Confidential Information is reasonably necessary in order for the receiving Party to continue to enjoy or enforce the rights received, or to satisfy its obligations,

under any of the Settlement Agreements or any other agreement between the Parties that survives following such expiration or termination, in which case, all such Confidential Information shall remain subject to restrictions and obligations set forth herein. The obligations of confidentiality and non-use contained in this Section 5.1 shall survive the termination of this Agreement for a period of ten (10) years.

Section 5.2 Disclosure of Confidential Information.

(a) Subject to the limitations set forth below, the Parties may disclose Confidential Information to the extent (i) required to be disclosed to regulatory authorities or governmental agencies for registration purposes, (ii) requested pursuant to an order of a competent court or administrative agency, or (iii) required by applicable law. In furtherance of the foregoing, the Parties acknowledge that, Vanda will be permitted pursuant to the rules and regulations promulgated under the Securities Exchange Act of 1934, as amended, to file a Current Report on Form 8-K disclosing, to the extent required thereby, the entry into this Agreement by Vanda and a description of the terms and conditions hereof, and of any of the Settlement Agreements that are material to Vanda, provided, however, that Vanda shall provide drafts of such Current Report on Form 8-K sufficiently in advance of filing to permit Novartis to review and comment on such Current Report on Form 8-K and the Parties shall, to the extent reasonably practicable, coordinate and work in good faith to create a mutually acceptable Current Report on Form 8-K and Vanda shall take into consideration and comply with any reasonable comments or requests of Novartis.

(b) To the extent that either Party is required to make a filing or any other public disclosure (other than as set forth in the preceding sentence) with respect to this Agreement, any Settlement Agreement or the terms or existence hereof or thereof to comply with the requirements, rules, laws or regulations of any applicable stock exchange, The NASDAQ Global Market or any governmental or regulatory authority or body, including without limitation the U.S. Securities and Exchange Commission (the "**SEC**") (collectively, the "**Disclosure Obligations**"), such Party shall promptly inform the other Party thereof and shall use reasonable efforts to maintain the confidentiality of the other Party's confidential information in any such filing or disclosure. To the extent that either Party is required to file a copy of this Agreement or any Settlement Agreement to comply with the Disclosure Obligations, such Party shall promptly inform the other Party thereof. Prior to making any such filing of a copy of this Agreement or any such Settlement Agreement, the Parties shall mutually agree on the provisions of this Agreement and/or Settlement Agreement, as applicable, for which the Parties shall seek confidential treatment, it being understood that if one Party determines to seek confidential treatment for a provision for which the other Party does not, then the Parties will use reasonable efforts in connection with such filing to seek the confidential treatment of any such provision. The Parties shall cooperate, each at its own expense, in such filing, including without limitation such confidential treatment request, and shall execute all documents reasonably required in connection therewith. The Parties shall agree with each other as to the form, timing and substance of any such filing. Each Party shall have the right to review in advance, and shall consult with the other Party on, all information relating to this Agreement or any Settlement Agreement, that appear in any such filing. In furtherance of the foregoing, the Parties will agree as promptly as practicable after the date of this Agreement on the confidential treatment request to be filed with the SEC and the redacted form or forms of this Agreement and/or Settlement

Agreements, as applicable, related thereto. In furtherance thereof, any redaction reasonably requested by either Party shall be included in such filing. The Parties will reasonably cooperate in responding promptly to any comments received from the SEC with respect to such filing in an effort to achieve confidential treatment of such redacted form; provided, however, that a Party shall be relieved of such obligation to seek confidential treatment for a provision requested by the other Party if such treatment is not achieved after the second round of responses to comments from the SEC.

Section 5.3 Each Party and its undersigned representative represent and warrant that they have the right to enter into this Agreement and the Settlement Agreements and to grant the rights and assume the obligations hereunder and thereunder, and further warrant that they are under no restriction with respect to a grant of such rights or an assumption of such obligations.

Section 5.4 Nothing contained in this Agreement is intended or should be construed as to constitute the Parties as partners or joint venturers or as the agent of the other Party. Neither Party shall have any power or express or implied right or authority to assume or create any obligation on behalf of or in the name of the other Party or to bind the other Party in any manner whatsoever, including to any other contract, agreement or undertaking with any third party.

Section 5.5 The prevailing Party in any controversy or claim arising out of or related to this Agreement or the breach thereof shall be entitled to recover its reasonable attorneys' fees and costs in addition to any other relief that may be granted.

Section 5.6 The Parties acknowledge that they have read this Agreement and that they have reviewed this Agreement with legal counsel of their own choosing. The Parties further acknowledge that they have been provided a full and ample opportunity to study this Agreement, and that it fully and accurately reflects the content of any and all understandings and agreements between the Parties concerning the matters referenced herein and that they are not relying on any other representations whatsoever as an inducement to execute this Agreement.

Section 5.7 Both Parties have participated substantially in the negotiation and drafting of this Agreement and each Party hereby disclaims any defense or assertion in any litigation that any ambiguity herein should be construed against either Party hereto.

Section 5.8 This Agreement and the Settlement Agreements (together with the Schedules and Exhibits attached thereto and any ancillary agreements, or other documents or requirements contemplated thereby) together constitute the entire agreement among, and supersede all prior agreements and understandings, both written and oral, between or among, the Parties with respect to the subject matter hereof. Except as specifically provided herein, no provision of this Agreement or any of the Settlement Agreements (together with the Schedules and Exhibits attached thereto and any ancillary agreements, or other documents or requirements contemplated thereby) is intended to confer upon any Person other than the Parties any rights or remedies hereunder or thereunder.

Section 5.9 To the extent not inconsistent with the express provisions of this Agreement, each of the provisions contained in Article XIV (General Provisions) of the Asset Transfer Agreement is hereby incorporated into this Agreement by this reference as if each is a part hereof. Without limitation and without negation of any other inconsistency, the Parties acknowledge and agree that nothing in the Non-Recourse provision of the Asset Transfer Agreement (Section 14.1 thereof) shall limit the effectiveness of the releases given by and on behalf of Affiliates of the Parties hereunder or the enforceability of those releases against those Affiliates.

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be signed by their respective representatives thereunto duly authorized, all as of the date first written above.

NOVARTIS PHARMA AG

By: /s/ Matt Owens
Name: Matt Owens
Title: Head Legal GBS & Strategy

By: /s/ Marc Ceulemans
Name: Marc Ceulemans
Title: Head Strategic Venture Capital Fund & Pharma Entities

VANDA PHARMACEUTICALS INC.

By: /s/ Mihael H. Polymeropoulos, M.D.
Name: Mihael H. Polymeropoulos, M.D.
Title: CEO, Vanda

EXHIBIT 10.56

CONFIDENTIAL TREATMENT REQUESTED

Confidential
FINAL VERSION

ASSET TRANSFER AGREEMENT

by and among

VANDA PHARMACEUTICALS INC.

NOVARTIS PHARMA AG

and

NOVARTIS AG

Dated as of December 22, 2014

CONFIDENTIAL TREATMENT REQUESTED

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CONFIDENTIAL TREATMENT REQUESTED

ASSET TRANSFER AGREEMENT

THIS ASSET TRANSFER AGREEMENT, dated as of December 22, 2014 (this "**Agreement**"), is made by and among Vanda Pharmaceuticals Inc., a Delaware corporation ("**Buyer**"), Novartis Pharma AG, a company organized under the laws of Switzerland ("**NPhAG**") and Novartis AG, a company organized under the laws of Switzerland ("**NAG**" and, together with NPhAG, "**Sellers**"). Sellers and Buyer may hereinafter be referred to individually as a "**Party**" and, collectively, as the "**Parties**".

WHEREAS, Sellers (a) sell Fanapt (as defined below) commercially in the United States of America, (b) have certain contractual rights to sell Fanapt in the United States and Canada and their respective territories and possessions and (c) own certain Intellectual Property Rights (as defined below) in respect of the Fanapt Drug Substance (as defined below);

WHEREAS, Sellers desire to transfer to Buyer, and Buyer desires to accept the transfer from Sellers, the Transferred Assets (as defined below) related to Fanapt (as defined below), the Fanapt Development Stage Products (as defined below), the Fanapt Drug Substance (as defined below), and the finished Fanapt product, all upon the terms and subject to the conditions hereinafter set forth; and

WHEREAS, concurrently with execution and delivery of this Agreement, the Parties will execute and deliver a Settlement Agreement and Mutual General Release to be effective upon the Closing (the "**Settlement Agreement**").

NOW, THEREFORE, in consideration of the mutual covenants herein contained and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE I
DEFINITIONS

Section 1.1 Definitions. As used in this Agreement, the following terms have the meanings set forth below:

"**Act**" means the U.S. Federal Food, Drug and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.

"**Adolescent Efficacy Study**" means the safety and efficacy study in adolescent patients referred to as Study CILO522D2302 ("2302") which shall be conducted following the Adolescent PK Study.

"**Adolescent PK Study**" means the Adolescent Pharmacokinetic and safety study referred to as Study CILO522D2402 ("**2402**") and its extensions.

"**Affiliate**" means, as to any Person, any other Person that, directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such first Person. As used in this definition, "**control**" (including, with its correlative meanings, "controlled by" and "under common control with") means the possession, directly or indirectly,

of the power to direct or cause the direction of management or policies of a Person, whether through the ownership of voting interests, by Contract or otherwise.

"**Ancillary Agreements**" means, collectively, the Assumption Agreement, the Bill of Sale, the Commercial Agreement, the Fanapt Domain Name Assignment Agreement, the Fanapt License Agreement, the Fanapt Supply Agreement, the Fanapt-Patheon Assignment Agreement, the Fanapt-Titan Assignment Agreement, and the Transition Services Agreement.

"**Assumed IP Litigation Matter**" has the meaning set forth in Section 2.2(a)(iii).

"**Assumed Liabilities**" has the meaning set forth in Section 2.3.

"**Assumption Agreement**" means the Assumption Agreement to be executed and delivered by Buyer and Sellers at Closing, substantially in the form of Exhibit A.

"**Bill of Sale**" means the Bill of Sale and Assignment to be executed and delivered by Buyer and Sellers at Closing, substantially in the form of Exhibit B.

"**Business Day**" means a day (other than a Saturday, Sunday or a public holiday) on which the banks are open for business in Basel, Switzerland, and New York, NY, USA.

"**Buyer**" has the meaning set forth in the recitals.

"**Buyer Claims**" has the meaning set forth in Section 13.2(a)(iii).

"**Buyer Indemnified Parties**" has the meaning set forth in Section 13.2(a).

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"**Buyer's Fundamental Representations**" has the meaning set forth in Section 13.1.

"**Closing**" and "**Closing Date**" have the respective meanings given such terms in Section 4.1.

"**Commercial Agreement**" means the Commercial Agreement, dated as of the date hereof , between NPhAG or an Affiliate and Buyer.

"**Confidential Information**" has the meaning set forth in Section 9.3(a).

"**Contemplated Transactions**" means the transactions contemplated by this Agreement and the Ancillary Agreements.

"**Contracts**" means any binding written, oral, express, implied or other contracts, subcontracts, leases, licenses, covenants, understandings, instruments, notes, indentures, agreements, purchase orders and all other legally binding arrangements, including all amendments thereto.

****

"**Disclosure Letter**" means the letter being delivered to Buyer by Sellers on the date hereof and identified as the Disclosure Letter with respect to this Agreement.

"**Disclosure Obligations**" has the meaning set forth in Section 9.3(c).

"**Domain Names**" means those domain names listed in Section 1.1 of the Disclosure Letter.

"**Encumbrance**" means any mortgage, charge, lien, security interest, pledge, claim, easement, defect in title, restrictive covenant or other restriction or encumbrance of any nature whatsoever.

"**Excluded Assets**" has the meaning set forth in Section 2.2(b).

"**Excluded Liabilities**" has the meaning set forth in Section 2.4.

"**Exhibits**" means, collectively, the Exhibits referred to throughout this Agreement.

"**Fanapt**" means the pharmaceutical product currently approved, marketed, distributed and sold as Fanapt® (iloperidone) Tablets under the Fanapt NDA.

"**Fanapt Commercial Information**" means any and all marketing, advertising and promotional materials and sales information, product literature, training materials, market research, customer surveys, and any similar information to the extent related to Fanapt, that, as of the Closing Date, are existing and owned by Sellers and/or their respective Affiliates or which Sellers and/or their respective Affiliates have a right to provide to Buyer, but excluding the Novartis Names and Marks.

"**Fanapt Development Stage Products**" means any and all pharmaceutical products (other than Fanapt) containing the Fanapt Drug Substance, researched, formulated, licensed, or developed, under or in connection with the Fanapt-Vanda Sublicense, Fanapt-Titan Sublicense, and/or otherwise by Sellers or their Affiliates prior to the Closing, in each case such product to which Sellers or their Affiliates have a right to assign or otherwise provide to Buyer.

"**Fanapt Domain Name Assignment Agreement**" means the Domain Name Assignment Agreement, dated as of the Closing Date hereof, by and among NAG, Novartis Services Inc., a Delaware corporation, and Buyer, effective at Closing.

"**Fanapt Drug Substance**" means the chemical compound known as iloperidone, whose specific chemical name is 1-[4-[3-[4-(6-fluoro-1,2-benzisoxazol-3-y1)-1-piperidinyl] propoxy]-3-methoxyphenyl]ethanone, including any salts, hydrates, solvates, and/or stereoisomers thereof and only the metabolites listed in Appendix B of the Fanapt-Titan Sublicense, including salts, hydrates, solvates and stereoisomers of such metabolites.

"**Fanapt IP**" means any and all Intellectual Property Rights to the extent exclusively related to any Fanapt Drug Substance, Fanapt or any Fanapt Development Stage Products or the

manufacture, use, development, research or exploitation thereof, or genotyping in connection therewith, that, as of the Closing Date, are in existence and owned by Sellers and/or their respective Affiliates or which Sellers and/or their respective Affiliates have a right to provide to Buyer, but excluding the Novartis Names and Marks.

"**Fanapt License Agreement**" means the License Agreement relating to Fanapt and the Fanapt Development Stage Products, dated the date hereof, between the applicable Sellers and Buyer, and effective at Closing.

"**Fanapt Medical Information**" means any and all medical or clinical information, including clinical and technical matters, such as therapeutic uses for the licensed indications, drug-disease information, patient registry information, and other product characteristics, in each case to the extent related to the Fanapt Drug Substance, Fanapt or any Fanapt Development Stage Products, that, as of the Closing Date, are in existence and owned by Sellers and/or their respective Affiliates or which Sellers and/or their respective Affiliates have a right to provide to Buyer.

"**Fanapt NDA**" means NDA No. 22-192.

"**Fanapt-Patheon Assignment Agreement**" means the Assignment Agreement – Patheon Agreements, dated the date hereof, between NPhAG and Buyer, necessary to transfer to Buyer, NPhAG's rights and obligations, solely relating to the supply of Fanapt, under the Fanapt-Patheon Supply Agreement.

"**Fanapt-Patheon Supply Agreement**" means, the Toll Manufacturing and Supply Agreement, dated May 1, 2006, between NPhAG and Patheon Inc., along with all of its exhibits and amendments, including but not limited to the Side Letter and Amendment-Toll Manufacturing and Supply Agreement dated September 4, 2013, between NPhAG and Patheon Inc. and the Quality Agreement(s), by and between Patheon Inc. and NPhAG.

"**Fanapt Pharmacovigilance Agreement**" means that certain Pharmacovigilance Agreement, dated June 7, 2010, by and between Buyer and NPhAG.

"**Fanapt Registration Data**" means the existing and available dossiers used by Sellers and/or their respective Affiliates at the Closing Date to obtain and maintain the Fanapt Registrations, in each case that, as of the Closing Date, are owned by Sellers and/or their respective Affiliates or which Sellers and/or their respective Affiliates have a right to provide to Buyer.

"**Fanapt Registrations**" means the Fanapt NDA and INDs relating to Fanapt or any Fanapt Development Stage Products as set forth in Section 1.1 of the Disclosure Letter.

"**Fanapt Supply Agreement**" means the Supply Agreement, along with all of its exhibits, dated as of the date hereof , between NPhAG and Buyer (or Buyer's Affiliate), relating to (i) the supply and transfer of inventories of Fanapt and the Fanapt Drug Substance and (ii) purchase and sale of inventories of Fanapt and Fanapt Drug Substance that were ordered by Buyer prior to the Closing Date for the supply of Fanapt outside of the United States and Canada.

"**Fanapt Technical Information**" means any and all technical information, know-how and data, including specifications, inventions (whether patentable or not), instructions and descriptions of manufacturing processes, formulae, materials and drawings and formulation information, reports and other technology and techniques and biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, clinical safety, safety data, validation, formation, packaging, release testing, stability and shelf life, manufacturing and quality control (and all records and operating procedures related thereto), supplier lists, preclinical and clinical data, in each case to the extent exclusively related to the Fanapt Drug Substance, Fanapt or any Fanapt Development Stage Products or the manufacture, use, development, research or exploitation thereof, or genotyping in connection therewith, that, as of the Closing Date, are existing and owned by Sellers and/or their respective Affiliates or which Sellers and/or their respective Affiliates have a right to provide to Buyer, but, excluding Fanapt Registration Data, Fanapt Commercial Information and Fanapt Medical Information.

"**Fanapt-Titan Assignment Agreement**" means the Titan – Assignment Agreement, dated as of the date hereof, among Titan, NPhAG and Buyer, which agreement shall provide for the assignment by NPhAG of all of NPhAG's right, title and interest under the Fanapt-Titan Sublicense, and the assumption by Buyer of all of NPhAG's obligations and liabilities under the Fanapt-Titan Sublicense.

"**Fanapt-Titan Sublicense**" means that certain Sublicense Agreement, dated as of November 20, 1997, between Titan and NPhAG, as amended by Amendment No. 1 to Sublicense Agreement, dated as of November 30, 1998, Amendment No. 2 to Sublicense Agreement dated as of April 10, 2001 and Amendment No. 3 to Sublicense Agreement, dated as of June 4, 2004.

"**Fanapt-Vanda Agreements**" means, collectively, the Fanapt Pharmacovigilance Agreement, the Fanapt-Vanda Quality Agreement, the Fanapt-Vanda Sublicense and the Fanapt-Vanda Supply Agreement.

"**Fanapt-Vanda Quality Agreement**" means that certain Quality Agreement on Supply of Fanapt, effective as of May 2, 2012, by and between Buyer and NPhAG.

"**Fanapt-Vanda Sublicense**" means that certain Amended and Restated Sublicense Agreement, dated as of October 12, 2009, between Buyer and NPhAG.

"**Fanapt-Vanda Supply Agreement**" means that certain Supply Agreement, effective as of May 2, 2012, by and between Buyer and NPhAG, including all schedules attached thereto.

"**FDA**" means the United States Food and Drug Administration.

"**Governmental Entity**" means any court, tribunal, agency, authority, department, commission, legislative, taxing, or regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member or quasi-governmental authority or self-regulatory organization of competent authority.

"**Governmental Order**" means any Law, judgment, order, decree, statute, ordinance, rule or regulation issued or promulgated by any Governmental Entity.

"**IND**" means (i) an Investigational New Drug Application with the FDA, as defined in the Act, (ii) any equivalent of an Investigational New Drug Application in any jurisdiction outside the United States and (iii) all supplements and amendments that may be filed with respect to the foregoing, in each case, for Fanapt or any Fanapt Development Stage Product as in effect as of the Closing Date.

"**Indemnified Party**" has the meaning set forth in Section 13.7(a).

"**Indemnifying Party**" has the meaning set forth in Section 13.7(a).

"**Intellectual Property Rights**" shall mean any and all: (i) patents and patent applications (and any patents that issue as a result of those patent applications), renewals, reissues, reexaminations, extensions, continuations, continuations-in-part, divisions, certificate of invention, substitutions, supplementary protection certificates and other administrative protection of any kind relating to any of the patents and patent applications, and any other governmental grant for the protection of inventions or industrial designs (collectively, "**Patents**"), (ii) trademarks, service marks, trade dress, logos, slogans, brand names, trade names and corporate names, whether registered or unregistered, and the goodwill associated therewith, together with any registrations and applications for registration thereof (collectively, "**Trademarks**"), (iii) copyrights and rights under copyrights, whether registered or unregistered, including moral rights, and any registrations and applications for registration thereof (collectively, "**Copyrights**"), (iv) trade secrets and know-how meeting the definition of a trade secret under the Uniform Trade Secrets Act (collectively, "**Trade Secrets**"), and (v) URL and domain name registrations.

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"**Knowledge**" of Sellers means the actual knowledge after reasonable inquiry of the employees of Sellers set forth in Section 1.1 of the Disclosure Letter.

"**Law**" means any statute, law, ordinance, requirement, decree, regulatory rule, code or order of a Governmental Entity.

"**Liabilities**" means any and all debts, liabilities, expenses and obligations, of any nature or kind whether accrued or fixed, absolute or contingent, matured or unmatured, or determined or determinable, asserted or unasserted, known or unknown, due including product liability, and, more generally, any liability arising under any law, action or governmental order and any liability arising under any contract or undertaking.

"**Licensed IP**" means those Intellectual Property Rights that are licensed to Buyer pursuant to the Fanapt License Agreement

"**Licensor Consents**" means the consents from the parties specified in Section 1.1 of the Disclosure Letter.

"**Losses**" means, collectively, any and all damages, losses, Liabilities, charges, claims (including Third Party Claims), fees, judgments, penalties, costs and expenses (including settlement costs and reasonable fees and expenses of attorneys, experts and other professionals); provided, however, Losses shall not include opportunity costs, punitive, consequential, indirect, incidental, exemplary or special damages (unless any of the foregoing Losses is actually incurred as part of a Third Party Claim in which case they shall constitute Losses hereunder), and shall not be calculated by using or taking into account any multiple of earnings, cash flow, revenue or other similar measure.

"**Material Adverse Effect**" means an effect which is materially adverse to Fanapt and the Transferred Assets, taken as a whole, but will not include (i) any adverse effect to the extent due to changes in conditions generally affecting (A) the pharmaceutical industry or (B) the economy, financial or securities markets or political, legislative or regulatory conditions, taken as a whole, except in the case of effects referenced in clauses (A) or (B), to the extent such effects disproportionately impact Fanapt and the Transferred Assets, taken as a whole, as compared to other companies in the pharmaceutical industry or other products designed for the treatment of schizophrenia, (ii) any adverse effect caused by the announcement of this Agreement and the pendency of the transactions contemplated hereby, (iii) any adverse effect due to legal or regulatory changes or other binding directives issued by a Governmental Entity except for any such effects that disproportionately impact Fanapt or the Transferred Assets, taken as a whole, as compared to other companies in the pharmaceutical industry or other products designed for the treatment of schizophrenia, (iv) any adverse effect due to acts of natural disaster, war, armed hostility or acts of terrorism, or (v) any adverse effect due to any product liability claims or actions or government or other investigations pending as of the date hereof and disclosed in Section 1.1 of the Disclosure Letter or otherwise constituting Excluded Liabilities.

"**NAG**" has the meaning set forth in the recitals.

"**NDA**" means (i) a New Drug Application, as defined in the Act, (ii) any equivalent of a New Drug Application in any jurisdiction outside the United States and (iii) all supplements and amendments that may be filed with respect to the foregoing.

"**Novartis Names and Marks**" has the meaning set forth in Section 8.2.

"**NPhAG**" has the meaning set forth in the recitals.

"**Party**" and "**Parties**" have the meanings set forth in the Preamble.

"**Permitted Encumbrance**" means (i) any Encumbrance for Taxes, assessments and other governmental charges that are not yet due and payable or that are being contested in good faith by appropriate proceedings, (ii) with respect to licenses, permits or Contracts, any restrictions, obligations, limitations or other Encumbrances contained in such license, permit or Contract or existing at Law or under the regulatory regime pursuant to which such permit or license is granted that do not materially impair the current use of Fanapt or the Transferred Assets, individually or in the aggregate, (iii) with respect to an NDA, any restrictions,

obligations, limitations or other Encumbrances contained in such NDA or existing at Law or under the regulatory regime pursuant to which such NDA is granted that do not materially impair the current use of Fanapt or the Transferred Assets, individually or in the aggregate, or (iv) any imperfection of title or other Encumbrance that, individually or in the aggregate with other such imperfections and Encumbrances, do not materially impair the current use of Fanapt or the Transferred Assets.

"**Permits**" has the meaning set forth in Section 5.7.

"**Person**" means any individual, corporation, partnership, limited liability company, joint venture, trust, business association, organization, Governmental Entity or other entity.

"**Registered IP**" shall mean Intellectual Property Rights that are registered, filed or issued under the authority of, with or by any Governmental Entity, including all Patents, registered Trademarks, registered Copyrights, Domain Names, and all currently outstanding applications for any of the foregoing.

"**Regulatory Approval**" means any and all approvals (including NDAs and supplements and attachments thereto), licenses, registrations (except manufacturing establishment registrations) or authorizations of any Governmental Entity necessary to commercially distribute, sell or market Fanapt, including, where applicable, (i) pricing or reimbursement approvals, (ii) pre- and post-approval marketing authorizations and (iii) labeling approvals.

"**Regulatory Authority**" means the FDA and all equivalent Governmental Entities and any successor entities thereto in the United States.

"**Relapse Prevention Study**" means Study CILO522D2301 ("2301") the relapse prevention in adults with Schizophrenia (REPRIEVE) study and the respective extensions (Part B and C).

"**Related Agreement**" has the meaning set forth in Section 2.5.

"**SEC**" has the meaning in Section 9.3(c).

"**Sellers**" and "**Seller**" have the meaning set forth in the recitals.

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"**Sellers' Fundamental Representations**" has the meaning set forth in Section 13.1.

"**Sellers Indemnified Parties**" has the meaning set forth in Section 13.3(a).

"**Settlement Agreement**" has the meaning set forth in the recitals.

"**Survival Period**" has the meaning set forth in Section 13.1.

"**Tax**" means all Federal, state, local and foreign taxes and assessments, including all interest, penalties and additions with respect thereto.

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

"**Tax Return**" means any report, return, election, notice, estimate, declaration, information statement and other forms and documents (including all schedules, exhibits and other attachments thereto) relating to and filed or required to be filed with a taxing authority in connection with any Taxes (including estimated Taxes).

"**Third Party**" means any Person other than Sellers or Buyer or their respective Affiliates.

"**Third Party Agreements**" means those contracts, licenses and other agreements between Sellers or any of their respective Affiliates, on the one hand, and Third Parties, on the other hand, that are listed on Section 1.1 of the Disclosure Letter.

"**Third Party Claim**" has the meaning set forth in Section 13.7(b).

"**Titan**" means Titan Pharmaceuticals, Inc., a Delaware corporation.

"**Transfer Taxes**" has the meaning set forth in Section 7.3.

"**Transferred Assets**" has the meaning set forth in Section 2.2(a).

"**Transferred IP**" means any Domain Names, Fanapt Technical Information, Fanapt Commercial Information, Fanapt Medical Information, Fanapt IP and Fanapt Registration Data.

"**Transferred Registered IP**" has the meaning set forth in Section 5.10(a).

"**Transition Services Agreement**" means the Transition Services Agreement, dated the date hereof, among Sellers and Buyer, effective as of Closing.

Section 1.2 Interpretation. In this Agreement unless otherwise specified:

(a) "**includes**" and "**including**" means respectively includes and including without limitation;

(b) a Party includes its permitted assignees and/or the respective successors in title to substantially the whole of its undertaking;

(c) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;

(d) references to Sections are to Sections of this Agreement unless otherwise specified;

(e) the headings in this Agreement are for information only and shall not be considered in the interpretation of this Agreement;

(f) the words "**hereof**", "**herein**" and "**hereunder**" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement;

(g) references to any agreement or contract are to that agreement or contract as amended, modified or supplemented from time to time in accordance with the terms hereof and thereof; provided that with respect to any agreement or contract listed in the Disclosure Letter, all such amendments, modifications or supplements in existence on the date hereof must also be listed in the appropriate section of the Disclosure Letter; and

(h) the Parties agree that the terms and conditions of this Agreement are the result of negotiations between the Parties and that this Agreement shall not be construed in favor of or against any Party by reason of the extent to which any Party participated in its preparation.

Section 1.3 Currency. All currency amounts referred to in this Agreement are in U.S. Dollars unless otherwise specified.

ARTICLE II
TRANSFER OF TRANSFERRED ASSETS; THIRD PARTY AGREEMENTS

Section 2.1 Transfer. Upon the terms and subject to the conditions of this Agreement, on the Closing Date, each Seller will, or will cause its Affiliates to, severally assign, transfer, convey and deliver to Buyer, and Buyer will acquire and accept, all right, title and interest of such Seller or its Affiliates in, to and under the Transferred Assets held by such Seller or its Affiliates free and clear of all Encumbrances (other than Permitted Encumbrances).

Section 2.2 Transferred Assets.

(a) The term "**Transferred Assets**" means solely all of Sellers' right, title and interest in and to all the following properties, assets and rights, other than the Excluded Assets, existing on the Closing Date:

(i) the Fanapt Registrations;

(ii) the Transferred IP; and

(iii) the intellectual property litigation matter set forth on Section 2.2(a)(iii) of the Disclosure Letter (the "**Assumed IP Litigation Matter**") and any other intellectual property claim or litigation arising prior to or after the Closing Date related to Fanapt, notice of which is provided pursuant to 21 U.S.C.§355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) and/or that is specifically set forth on Section 2.2(a)(iii) of the Disclosure Letter;

(b) Notwithstanding any other provision contained in this Agreement or in the Ancillary Agreements, Sellers and Buyer expressly agree and acknowledge that Buyer is not acquiring any right, title or interest in or to any of the assets of Sellers or any of their respective Affiliates, which are not specifically identified in Section 2.2(a) (the "**Excluded Assets**"). For the avoidance of doubt, such Excluded Assets include the following:

(i) the Novartis Names and Marks;

(ii) accounts receivable, pre-paid expenses and any cash or cash equivalents of Sellers or any of their respective Affiliates;

(iii) any real property or leaseholds (together with all fixtures and fittings related to any property), physical plant, machinery, equipment, supplies, motor vehicles or laboratory or office equipment of Sellers or any of their respective Affiliates;

(iv) any rights under Sellers', or their respective Affiliates', insurance policies or self-insurance which are related to Fanapt; and

(v) any books and records of Sellers or any of their respective Affiliates.

(c) Buyer acknowledges and agrees that Sellers may retain one copy of all or any part of the documentation that is delivered to Buyer hereunder.

Section 2.3 Assumption of Certain Liabilities and Obligations. As of the Closing Date, Buyer will assume, be responsible for and pay, perform and discharge when due, any and all Liabilities arising from the ownership or use of the Transferred Assets by Buyer from and after the Closing Date, including the following (collectively, the "**Assumed Liabilities**"):

(i) any Liabilities arising from any product liability claim or action, intellectual property infringement or misappropriation claim or action or any other claim or action brought by any Third Party, the FDA or any other Governmental Entity relating to Fanapt sold by Buyer, its Affiliates or its Third Party collaborators after the Closing Date, to the extent not retained by Sellers pursuant to Section 2.4;

(ii) any Liabilities arising from the Assumed IP Litigation Matter;

(iii) any Liabilities arising from any FDA or any other Governmental Entity action or notification first filed on or after the Closing Date relating to Fanapt that is sold by Buyer following the Closing, to the extent not retained by Sellers pursuant to Section 2.4;

(iv) any Liabilities that Buyer expressly assumes or agrees to assume under this Agreement or the Ancillary Agreements; and

(v) any Liabilities arising from Buyer's conduct of the Adolescent Efficacy Study, the Adolescent PK Study and Relapse Prevention Study, including, but not limited to the obligations to conduct each of those studies and any other Fanapt clinical studies.

Section 2.4 Excluded Liabilities. Subject to the provisions of this Agreement, Sellers shall retain and remain responsible for and pay, perform and discharge any and all Liabilities other than the Assumed Liabilities, including, without limitation, any and all Liabilities arising from (a) any product liability claim or action, intellectual property infringement or misappropriation claim or action or any other claim or action brought by any Third Party to the extent arising from Fanapt or Fanapt Development Stage Products, sold or distributed by Sellers or any of their respective Affiliates (or Third Party collaborators) prior to the Closing Date; (b) any activities to the extent arising from Fanapt or Fanapt Development Stage Products

distributed, used or sold by or on behalf of Sellers or their respective Affiliates (or Third Party collaborators) prior to the Closing Date; (c) any Liabilities that Sellers expressly assume or agree to assume under this Agreement or the Ancillary Agreements; and (d) all Liabilities for Taxes arising out of or relating to the ownership of the Transferred Assets in any taxable period, or portion thereof, prior to the Closing Date as well as any Transfer Taxes (collectively, the "**Excluded Liabilities**").

Section 2.5 Assignment of Third Party Agreements. Each Third Party Agreement that can be assigned to Buyer without the consent of the respective Third Parties thereto, or for which consent has been obtained prior to the Closing Date, shall, if requested by Buyer, be so assigned, solely as they relate to the Fanapt Drug Substance, Fanapt, Fanapt Development Stage Products or other Transferred Assets, pursuant to the terms of this Agreement on the Closing Date. After the Closing, Sellers shall assign their respective rights and obligations, if requested by Buyer, under (i) any other Third Party Agreements and (ii) any agreements with Third Parties that are not Third Party Agreements, but that are necessary or desirable to effectively transfer the Transferred Assets as contemplated by this Agreement (each a "**Related Agreement**"), in case of both (i) and (ii), as mutually agreed to by the Parties, such mutual agreement not to be unreasonably withheld, conditioned or delayed, such assignment to be effective on a date to be agreed after the Closing Date and subject to consent, if required, by the respective Third Parties thereto. The Parties shall use reasonable efforts in obtaining such consent, however, Sellers cannot guarantee that such consent will be received. In the event that such consent is not obtained or the Parties do not mutually agree to assign such Third Party Agreement or Related Agreement, the applicable Seller shall terminate, subject to the terms and conditions set forth therein, such Third Party Agreement or Related Agreement as it relates to Fanapt as soon as practicable but shall remain as the contracting party under the relevant Third Party Agreement or Related Agreement for its duration and Buyer shall, as Sellers' agent, perform and discharge all outstanding obligations and liabilities of Sellers (or as applicable, Sellers' respective Affiliates) under the Third Party Agreement or Related Agreement with respect to Fanapt, and shall indemnify Sellers against any Losses Sellers may incur arising out of Buyer's failure to do so.

Section 2.6 Assignment of Assumed IP Litigation Matter.

(a) Subject to the provisions ****, the Assumed IP Litigation Matter shall be assigned by Sellers to Buyer on the Closing Date and, following the Closing Date, Buyer shall be responsible for (i) conducting and/or defending such Assumed IP Litigation Matter and (ii) taking all such actions it determines, in its sole discretion, to take in connection therewith. In furtherance of the foregoing, the Parties shall use reasonable efforts to effectuate such assignment and the transfer of all rights, interests and Liabilities in respect of such Assumed IP Litigation Matter from Sellers to Buyer, including through cooperation with each other in making any applicable filings as may be required to be made with any courts or Governmental Entities to effect such assignment and transfer.

(b) For the avoidance of doubt, subject to the provisions of ****, all costs and expenses incurred on or after the Closing Date by or on behalf of Buyer in connection with conducting and/or defending the Assumed IP Litigation Matter shall be borne by Buyer, and Buyer shall be entitled to receive all settlements, awards, judgments and any other

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amounts payable by Third Parties to the Assumed IP Litigation Matter in connection with the same.

ARTICLE III
CONSIDERATION

Section 3.1 Consideration. No purchase price shall be paid for the Transferred Assets. The consideration for such Transferred Assets consists of the mutual obligations, releases and promises exchanged between the Parties contained herein and in the Ancillary Agreements and the Settlement Agreement, the sufficiency of which the Parties hereby acknowledge.

ARTICLE IV
THE CLOSING

Section 4.1 Closing Date. The closing of the transactions contemplated by this Agreement (the "**Closing**") will take place at the offices of Kaye Scholer LLP, 250 West 55th Street, New York, New York 10019 at 10:00 a.m. (local time) on December 31, 2014, or at such other time and place as Sellers and Buyer may mutually agree after the satisfaction or waiver of the conditions set forth in Article XI (the "**Closing Date**").

Section 4.2 Deliveries.

(a) On or prior to the date hereof, Sellers, as applicable, shall deliver to Buyer the following:

(i) the Fanapt License Agreement, duly executed by the applicable Sellers;

(ii) the Settlement Agreement, duly executed by the applicable Sellers;

(iii) the Fanapt-Titan Assignment Agreement, duly executed by the applicable Sellers and Titan;

(iv) the Transition Services Agreement, duly executed by the applicable Sellers;

(v) the Licensor Consents, duly executed by the applicable licensors;

(vi) the Stock Purchase Agreement, duly executed by the applicable Sellers or an Affiliate thereof;

(vii) the Fanapt Supply Agreement, duly executed by the applicable Sellers; and

(viii) the Commercial Agreement, duly executed by the applicable Sellers or Affiliates of Sellers.

(b) On or prior to the Closing Date, Sellers, as applicable, shall deliver to Buyer the following:

(i) the Fanapt Domain Name Assignment Agreement, duly executed by the applicable Sellers;

(ii) the Fanapt-Patheon Assignment Agreement, duly executed by the applicable Sellers;

(iii) the Assumption Agreement, duly executed by the applicable Sellers; and

(iv) the Bill of Sale, duly executed by the applicable Sellers.

(c) On or prior to the date hereof, Buyer shall deliver to Sellers, as applicable, the following:

(i) the Fanapt License Agreement, duly executed by Buyer;

(ii) the Settlement Agreement, duly executed by Buyer;

(iii) the Fanapt-Titan Assignment Agreement, duly executed by Buyer;

(iv) the Transition Services Agreement, duly executed by Buyer; and

(v) the Stock Purchase Agreement, duly executed by Buyer;

(vi) the Fanapt Supply Agreement, duly executed by Buyer; and

(vii) the Commercial Agreement, duly executed by Buyer.

(d) On or prior to the Closing Date, Buyer shall deliver to Sellers, as applicable, the following:

(i) the Fanapt Domain Name Assignment Agreement, duly executed by Buyer;

(ii) the Fanapt-Patheon Assignment Agreement, duly executed by Buyer;

(iii) the Assumption Agreement, duly executed by Buyer; and

(iv) the Bill of Sale, duly executed by Buyer.

Buyer shall be responsible for the recording and registration of all assignments and instruments referred to in this Section 4.2.

Section 4.3 Transfer of Title; Insurance. Title and risk of loss or damage to the Transferred Assets shall pass to Buyer on the Closing Date. As of the Closing Date, the Transferred Assets shall cease to be insured by the applicable Sellers' insurance policies or by the applicable Sellers' self-insurance, as the case may be, and Buyer shall have no right or obligation with respect to any such policy. From and after the Closing, to the extent any future inventions, discoveries or improvements arise from Buyer's, its Affiliates' or sublicensees' work relating to the Transferred Assets, such future inventions, discoveries or improvements shall be exclusively owned by Buyer.

Section 4.4 Termination of Fanapt-Vanda Agreements. Each of Buyer and Sellers acknowledge and agree that, effective as of the Closing, and without any need for any Party to take any further action, each of the Fanapt-Vanda Agreements shall terminate, with no further obligations of any of the parties thereto, including without limitation (a) any obligation to pay any further payments under such Fanapt-Vanda Agreements, except for accrued amounts due under the Fanapt-Vanda Supply Agreement as of the Closing Date and (b) any indemnification provisions of the Fanapt-Vanda Agreements and other provisions notwithstanding the fact that by their terms such provisions stated that they would survive termination of the Fanapt-Vanda Agreements, except that the confidentiality provisions thereof shall survive.

ARTICLE V
REPRESENTATIONS AND WARRANTIES OF SELLERS

Each Seller hereby jointly and severally represents and warrants to Buyer as follows:

Section 5.1 Sellers Organization; Good Standing. Such Seller is a company duly organized, validly existing and in good standing under the laws of its jurisdiction of organization or formation. Such Seller has the requisite power and authority to (i) own the Transferred Assets owned by such Seller and to carry on its business as currently conducted and (ii) consummate the Contemplated Transactions. Such Seller is duly qualified to conduct business as a foreign corporation and is in good standing in each jurisdiction where the nature of the business conducted by it makes such qualification necessary, except where the failure to so qualify or be in good standing would not or would not reasonably be expected to have a Material Adverse Effect.

Section 5.2 Authority; Execution and Delivery. Such Seller has the requisite corporate power and authority to enter into this Agreement and the Ancillary Agreements, to consummate the Contemplated Transactions and to take all other actions required to be taken by it pursuant to the provisions hereof and thereof. The execution and delivery of this Agreement by such Seller and the consummation of the Contemplated Transactions have been duly and validly authorized. This Agreement has been duly executed and delivered by such Seller and, assuming the due authorization, execution and delivery of this Agreement by Buyer, will constitute the legal, valid and binding obligation of such Seller, enforceable against it in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar laws affecting creditors' rights generally from time to time in effect and to general principles of equity regardless of whether considered in a proceeding in equity or at Law.

Section 5.3 Consents; No Violation, Etc. Except for any filings with Governmental Entities or other authorizations necessary to transfer the Fanapt Registrations and Transferred IP and except as set forth in Section 5.3 of the Disclosure Letter, no consent of any Governmental Entity is required by or with respect to Sellers in connection with the execution or delivery of this Agreement or the Ancillary Agreements or the consummation of the Contemplated Transactions, and the execution and delivery of this Agreement and the Ancillary Agreements do not, and the consummation of the Contemplated Transactions and the compliance with the terms hereof will not (i) violate any Governmental Order applicable to such Seller or its assets, (ii) violate, breach or conflict with any provision of the certificate of incorporation or by-laws (or similar organizational document) of such Seller, (iii) give rise to any approval, authorization, consent, license, filing or registration with any court, arbitrator or Governmental Entity, (iv) conflict with or result in any breach of, constitute a default or result in the right to exercise any remedy under, cause the acceleration, cancellation or modification of any obligation or right under, result in a violation of, or result in the creation of any lien or Encumbrance (other than any Permitted Encumbrances) upon any assets of such Seller under any indenture, mortgage, agreement or instrument that is currently binding upon such Seller or (v) other than pursuant to the Fanapt-Vanda Agreement, cause any Intellectual Property Rights in or to Fanapt, the Fanapt Development Stage Products or the Fanapt Drug Substance, whether owned by or licensed to the Parties, be subject to reversion, option, termination, license or any other Encumbrance; provided, however, that no representation or warranty is made in the foregoing clauses (i), (iii) or (iv) with respect to matters that, individually or in the aggregate, would not or would not reasonably be expected to result in a Material Adverse Effect.

Section 5.4 Title to Transferred Assets. Except as set forth in Section 5.4 of the Disclosure Letter, Sellers are the legal and beneficial owners of, and have good, valid and marketable title to, all of the Transferred Assets that are owned by a Seller, free and clear of all Encumbrances, other than Encumbrances that constitute Permitted Encumbrances under clauses (ii) or (iii) of the definition of Permitted Encumbrances. None of the Transferred Assets is subject to any outstanding option or similar right of any other Person to acquire the same. None of the Transferred Assets is subject to any restriction on transfer thereof (other than any Permitted Encumbrances), and Sellers have the right to sell the Transferred Assets. Upon consummation of the transactions contemplated hereby in accordance with the terms hereof, Buyer will hold good and marketable title to all of the Transferred Assets, free and clear of any Encumbrances other than any Permitted Encumbrances. The Transferred Assets and Buyer's rights under this Agreement and the Ancillary Agreements will include all of the Fanapt IP (other than Novartis Names and Marks and any other Excluded Assets) and NDAs approved by a Governmental Entity that Sellers used to develop, sell or have manufactured Fanapt, Fanapt Development Stage Products or the Fanapt Drug Substance.

Section 5.5 Litigation. Except as set forth in Section 5.5 of the Disclosure Letter, as of the date hereof, there is no suit, claim, action, investigation or proceeding pending or, to the Knowledge of Sellers, threatened against such Seller or its Affiliates, that (i) relates to Fanapt, any Fanapt Development Stage Products, the Fanapt Drug Substance or otherwise relates to the Transferred Assets or (ii) alleges that Sellers' or their respective Affiliates' activities with respect to Fanapt, Fanapt Development Stage Products, the Fanapt Drug Substance, the Transferred Assets or any of their other Intellectual Property Rights relating to Fanapt, any Fanapt Development Stage Products or the Fanapt Drug Substance have infringed or misappropriated

any of the Intellectual Property Rights of any Third Party. There is no suit, claim, action, investigation or proceeding pending or, to the Knowledge of Sellers, threatened against such Seller, which challenges or seeks to prevent, delay or enjoin the Contemplated Transaction.

Section 5.6 Regulatory Issues. Except as set forth in Section 5.6 of the Disclosure Letter:

(a) Since ****, with respect to Fanapt, such Seller or its Affiliates has not received or been subject to: (i) any FDA 483's or (ii) any warning letters or other written correspondence from the FDA in which the FDA asserted that the operations of such Seller or its Affiliates were not in compliance with applicable Governmental Orders or guidelines. Since ****, (i) there has not been any occurrence of any product recall, market withdrawal or replacement, suspension, discontinuation or post-sale warning conducted by or on behalf of such Seller or its Affiliates (or any licensee, distributor or marketer) concerning Fanapt held by such Seller or any product recall, market withdrawal or replacement conducted by or on behalf of any entity as a result of any alleged defect in Fanapt and (ii) no Seller or its Affiliates has received any notice that any Governmental Entity has commenced, or to the Knowledge of Sellers, threatened to initiate, any action to withdraw or refuse approval, place sales or marketing restrictions on or request the recall of Fanapt, or has received any notice that any Governmental Entity has commenced, or, to the Knowledge of Sellers, threatened to initiate, any action to enjoin or place restrictions on the production of Fanapt.

(b) Sellers have in their possession copies of all material documentation filed in connection with the Fanapt Registrations. The Fanapt Registrations are the only NDAs, INDs or foreign equivalents thereof that Sellers have obtained or for which Sellers have submitted applications in the United States or Canada.

(c) Sellers have made or filed all material declarations, notices, filings, reports, documents, claims, permits and notices with the FDA and any other Governmental Entity that are necessary for the lawful sale or distribution, as applicable, of Fanapt.

(d) In connection with Fanapt, the Fanapt Development Stage Products, the Fanapt Drug Substance and the Transferred Assets, no Seller or any of its Affiliates has, and to the Knowledge of the Sellers, no officer, employee or agent of any Seller or any of its Affiliates, has made any untrue statement of a material fact or a fraudulent statement, or failed to disclose a material fact required to be disclosed, to the FDA or any other Governmental Entity.

(e) Since **** (i) Fanapt has, in all material respects, been manufactured, tested, packaged, labeled, held, distributed, marketed, imported, exported, sold and provided in compliance with applicable Law and applicable Regulatory Approvals and (ii) the Fanapt Development Stage Products, have in all material respects, been manufactured, tested, held, imported, exported and provided in compliance with applicable Law and applicable Regulatory Approvals.

(f) Sellers possess or have the benefit of all material Regulatory Approvals necessary to manufacture (or have manufactured), sell or distribute Fanapt in those jurisdictions where Sellers or their Affiliates have manufactured, sold or distributed Fanapt, as the case may

be, and such Regulatory Approvals are in full force and effect. Sellers are in compliance in all materials respects with the terms of all such Regulatory Approvals. No proceeding is pending or, to the Knowledge of Sellers, threatened by a Governmental Entity since **** that is reasonably expected by Sellers to result in the revocation, cancellation, non-renewal, adverse modification or suspension of any such Regulatory Approval.

(g) Since ****, (i) none of Sellers nor their Affiliates, nor, to the Knowledge of Sellers, any employee, agent or subcontractor of any Seller, materially involved in the development and/or commercialization of Fanapt has been debarred under Subsection (a) or (b) of Section 306 of the Act; (ii) none of Sellers nor their Affiliates, nor, to the Knowledge of Sellers, any employee, agent or subcontractor of any Seller, materially involved in the development of any Fanapt Development Stage Product has been debarred under Subsection (a) or (b) of Section 306 of the Act; and (iii) no Person who is known by Sellers to have been debarred under Subsection (a) or (b) of Section 306 of the Act has been employed by Sellers in the performance of any activities hereunder.

(h) Since ****, to the Knowledge of Sellers, the development, manufacture, labeling and storage, as applicable, of Fanapt have been and are being conducted in compliance in all material respects with all applicable Laws including the FDA's current Good Laboratory Practices, Good Manufacturing Practices and Good Clinical Practices. Since ****, to the Knowledge of Sellers, the development of the Fanapt Development Stage Products has been and are being conducted in compliance in all material respects with all applicable Laws including the FDA's current Good Laboratory Practices and Good Clinical Practices. In addition, Sellers and their Affiliates (i) have, at all times since ****, been and are in compliance in all material respects with all other applicable FDA requirements, including registration and listing requirements set forth in 21 U.S.C. Section 360 and 21 C.F.R. Part 207 and (ii) have, at all times since ****, been and are in compliance in all material respects with all other applicable FDA requirements, including registration and listing requirements set forth in 21 U.S.C. Section 360 and 21 C.F.R. Part 207.

(i) Sellers and their Affiliates are and at all times since **** have been and, to the Knowledge of Sellers, all agents, representatives and contractors of Sellers are and at all times have been, in compliance in all material respects with the federal Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), Stark Law (42 U.S.C. Section 1395nn), False Claims Act (31 U.S.C. Section 3729 et seq.), Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191), in each case as amended from time to time.

(j) Since ****, no Seller or its Affiliates has engaged in (i) any unlawful or unauthorized practice of medicine or (ii) other professionally licensed activities through any websites sponsored or operated, or formerly sponsored or operated, by any Seller or its Affiliates, in each case, with respect to Fanapt and the Fanapt Development Stage Products.

(k) Since ****, Sellers and their Affiliates have operated the business in material compliance with import control Laws, including those administered by the United States Department of Commerce and the United States Department of State, or asset control laws, including those administered by the United States Department of Treasury, in each case that are applicable to Sellers with respect to the importation of Fanapt.

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(l) Since ****, no Seller nor its Affiliates nor, to the Knowledge of Sellers, any of the officers, employees, agents or clinical investigators of any Seller or its Affiliates has committed any act, made any statement or failed to make any statement that would reasonably be expected to provide a basis for the FDA to invoke its policy with respect to "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto, in each case with respect to Fanapt and the Fanapt Development Stage Products. Since ****, no Seller nor its Affiliates nor, to the Knowledge of Sellers, any of the officers, employees or agents of any Seller or its Affiliates has been convicted of any crime or engaged in any conduct that has resulted in or would reasonably be expected to result in (i) debarment under 21 U.S.C. Section 335a or any similar Law, or (ii) exclusion under 42 U.S.C. Section 1320a-7 or any similar Law, in each case with respect to Fanapt and the Fanapt Development Stage Products.

Section 5.7 Compliance with Laws. Except as set forth in Section 5.7 of the Disclosure Letter, such Seller and its Affiliates are in compliance in all material respects with all Governmental Orders applicable to it, and the Fanapt Development Stage Products are being developed and Fanapt is being labeled, stored, tested and distributed in compliance in all material respects with all applicable requirements under all Governmental Orders, and all applicable state and foreign regulatory requirements of any Governmental Entity, including those relating to investigational use, premarket clearance and applications or abbreviated applications. Each Seller and its Affiliates and, to the Knowledge of Sellers, each of their respective members, managers, directors, officers, key employees and Persons performing management functions similar to officers, hold all material permits, registrations, findings of suitability, licenses, variances, exemptions, certificates of occupancy, orders and approvals of all Governmental Entities ("**Permits**") that are required by applicable law and which are necessary for the development of the Fanapt Development Stage Products and the manufacture and commercialization of Fanapt, each of which is in full force and effect. To the Knowledge of Sellers, no event has occurred which permits, or upon the giving of notice or passage of time or both, would permit, revocation, non-renewal, modification, suspension, limitation or termination of any Permit that currently is in effect. To the Knowledge of Sellers, each of Seller's and its Affiliates' respective members, managers, directors, officers, key employees and Persons performing management functions similar to officers, in each case whose position is related to Fanapt, are in compliance in all material respects with the terms of the Permits. There are no actions, suits or proceedings by any Governmental Entity with respect to any Seller or its Affiliates that are pending, or to the Knowledge of Sellers, threatened, which may result in the revocation, cancellation, termination or suspension, or any adverse modification of any Permits. Except as set forth in Section 5.7 of the Disclosure Letter, neither such Seller nor its Affiliates have received any written notice within the past year of any asserted violation of any Governmental Orders.

Section 5.8 Right to Sell Fanapt. Sellers have the right to develop, have developed, sell, have sold, market, have marketed, distribute, have distributed, commercialize, have commercialized, manufacture and have manufactured Fanapt in those jurisdictions where Sellers and their Affiliates conduct such activities. Sellers have the right to develop and have developed the Fanapt Development Stage Products in those jurisdictions where Sellers and their Affiliates conduct such activities. Except for any Permitted Encumbrances, no Seller nor its Affiliates has, directly or indirectly, sold, transferred, assigned, conveyed, mortgaged, encumbered,

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hypothecated or otherwise disposed of, or granted any interests in or to, such rights, except as provided herein and in the Ancillary Agreements.

Section 5.9 Conduct of the Business. Since ****, no Seller nor any of its respective Affiliates has sold, transferred or otherwise disposed of Fanapt, except in the ordinary course of business consistent with industry standards.

Section 5.10 Intellectual Property.

(a) Section 5.10(a) of the Disclosure Letter accurately identifies all of the Transferred IP and Licensed IP that is Registered IP and that is owned or purported to be owned by or exclusively licensed to Seller ("**Transferred Registered IP**"), and lists: (i) the name of the current owner; (ii) the jurisdiction in which such item of Transferred Registered IP has been registered or filed; (iii) the applicable registration or serial number; and (iv) the filing date, and issuance/registration/grant date.

(b) Sellers own, or have a valid right to use, free and clear of Encumbrances (other than Permitted Encumbrances), the Transferred IP and Licensed IP and, to the Knowledge of Sellers, no Person is infringing, misappropriating or otherwise violating the Transferred IP or Licensed IP.

(c) The Transferred Assets, together with the Licensed IP will constitute, as of the Closing Date, all of the rights, interests and other intangible assets currently used by Sellers and its Affiliates to use, research, develop, have manufactured, market, promote, sell, distribute, and otherwise exploit and commercialize (as applicable) Fanapt, the Fanapt Development Stage Products and the Fanapt Drug Substance.

(d) Each current and former employee and officer of each Seller and its Affiliates who materially delivered, developed, contributed to, modified or improved any of the Transferred IP or Licensed IP that is material to the commercialization of Fanapt has executed a proprietary information and inventions agreement, or was otherwise bound by policies or conditions of employment, assigning rights in such Transferred IP or Licensed IP to such Seller or an Affiliate of such Seller.

(e) All fees (including legal fees) required to be paid by Sellers in order to maintain the Transferred IP that is material to the use, research, development, manufacturing, marketing, promotion, sale, distribution, exploitation and commercialization of Fanapt have been timely paid such that there shall be no material claims upon the Transferred IP or Licensed IP.

(f) Since ****, Sellers and their Affiliates have not received any written notice (i) of a claim alleging that any of the Transferred IP or Licensed IP infringes, misappropriates or otherwise violates any intellectual property or other proprietary right of any Third Party, (ii) of a claim alleging that the manufacture, development and commercialization of Fanapt, any Transferred IP or Licensed IP by Sellers or their Affiliates infringes, misappropriates or violates the intellectual property rights of Third Parties, (iii) of a claim alleging that the development of the Fanapt Development Stage Products by Sellers or their Affiliates infringes, misappropriates or violates the intellectual property rights of Third Parties, (iv) of a claim alleging that the development of the Fanapt Drug Substance by Sellers or their Affiliates

infringes, misappropriates or violates the intellectual property rights of Third Parties, (v) that any Person is infringing on rights of the Transferred IP, Licensed IP, Fanapt, the Fanapt Development Stage Products or the Fanapt Drug Substance, or (vi) from a Third Party, provided pursuant to 21 U.S.C.§355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV), other than in respect of the Assumed IP Litigation Matter.

(g) The Fanapt Registration Data has been maintained in accordance with reasonable industry standards.

(h) Sellers and their Affiliates are in compliance in all material respects with all applicable Laws relating to registration and listing requirements for Fanapt, the Fanapt Development Stage Products, the Transferred IP and Licensed IP.

(i) Since ****, no material interference, derivation, opposition, reissue, reexamination (including ex parte reexamination, inter partes reexamination, inter partes review, post grant review, cancellation or other proceeding) is or has been pending, or to the Knowledge of Sellers, threatened, in which the scope, validity or enforceability of any of the Transferred Registered IP is being or has been contested or challenged.

(j) Subject to receipt of the Licensor Consents, neither the execution, delivery or performance of this Agreement or any of the Ancillary Agreements, nor the consummation of any of the Contemplated Transactions hereby will, with or without notice or lapse of time, result in, or give any other Person the right or option to cause or declare: (i) a loss of, or Encumbrance (other than Permitted Encumbrances) on, any Transferred IP or Licensed IP owned by, purported to be owned by or exclusively licensed to Sellers; or (ii) Sellers, Buyer or any of their Affiliates granting to any Person any ownership interest in, or any authorization, immunity, covenant not to sue, access to, or option, with respect to Transferred IP or Licensed IP.

(k) Seller has obtained all necessary consents required to transfer the Transferred Assets and Third Party Agreements to Buyer, and all such consents are valid and enforceable against Sellers and the Third Parties providing such consent.

Section 5.11 Taxes. Sellers have paid all material applicable Taxes related to the Transferred Assets, Fanapt and the Fanapt Development Stage Products that were required to have been paid and have filed with the appropriate tax authorities and all income, sales and other material Tax Returns required to be filed by them related to the Transferred Assets, Fanapt and the Fanapt Development Stage Products, and all such Tax Returns were true, correct and complete in all material respects as of the date such Tax Returns were filed. There are no Encumbrances for Taxes upon the Transferred Assets, except for Encumbrances relating to current taxes not yet due and payable.

Section 5.12 Third Party Agreements. True and complete copies of each Third Party Agreement have been made available to Buyer by Sellers. Each Third Party Agreement is a valid, binding and enforceable obligation of Seller(s) party thereto and, to the Knowledge of Sellers, of the other party or parties thereto, in accordance with its terms, except as may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other laws relating to or affecting creditors' rights generally or by general equity principles.

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Each Third Party Agreement is in full force and effect and, upon consummation of the Contemplated Transactions, shall continue to be in full force and effect without material penalty, acceleration, termination, repurchase right, amendment, payment, cancellation or loss of any benefit to which Sellers are entitled. Each Seller and its Affiliates are in compliance in all material respects with each Third Party Agreement to which such Seller or its Affiliates is a party and has not received any written notice that such Seller or its Affiliates has failed to perform any obligations required to be performed by it under such Third Party Agreement. Except as set forth in Section 5.12 of the Disclosure Letter, Sellers do not have Knowledge of, nor has any Seller or its Affiliates received notice of, any violation or default under any Third Party Agreement. Sellers and their Affiliates have not received any notice from any other party to any Third Party Agreement to the effect that, or otherwise has any Knowledge, that such party intends to terminate, or not renew, any such Third Party Agreement.

Section 5.13 Commercial Relationships. Since ****, with respect to Fanapt, no material customer or supplier has cancelled or terminated its relationship with any Seller or its Affiliates or otherwise materially reduced any contractually committed rate or amount of sales to or purchases from any Seller or its Affiliates, as the case may be, or materially increased the prices charged by such supplier to any Seller or its Affiliates or materially reduced any contractually committed prices paid by such customer to any Seller or its Affiliates, as the case may be, and no such customer or supplier has notified any Seller or its Affiliates in writing of any present intention to do any of the foregoing.

Section 5.14 No Brokers. Such Seller has not entered into any agreement, arrangement or understanding with any Person or firm which will result in the obligation to pay any finder's fee, brokerage commission or similar payment in connection with the Contemplated Transactions.

Section 5.15 Exclusive Representations and Warranties. Other than the representations and warranties set forth in this Article V, no Seller is making any other representations or warranties, express or implied, with respect to Fanapt or any of the Transferred Assets in this Agreement, and the Buyer expressly acknowledges same and agrees that it is not relying on any other representations. Each Seller hereby disclaims any other express or implied representations or warranties, including regarding any financial projections or other forward-looking statements provided by or on behalf of such Seller.

ARTICLE VI
REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer hereby represents and warrants to Sellers as follows:

Section 6.1 Buyer's Organization; Good Standing. Buyer is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Buyer has all requisite corporate power and authority to carry on its business as it is currently being conducted. Buyer is duly qualified to conduct business as a foreign corporation and is in good standing in every jurisdiction where the nature of the business conducted by it makes such qualification necessary, except where the failure to so qualify or be in good standing would not prevent or materially delay the consummation of the Contemplated Transactions.

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Section 6.2 Authority; Execution and Delivery. Buyer has the requisite power and authority to enter into this Agreement and to consummate the Contemplated Transactions. The execution and delivery of this Agreement by Buyer and the consummation of the Contemplated Transactions hereby have been duly and validly authorized. This Agreement has been duly executed and delivered by Buyer and, assuming the due authorization, execution and delivery of this Agreement by Sellers, constitutes the legal, valid and binding obligation of Buyer, enforceable against Buyer in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent transfer and other similar laws affecting creditors' rights generally from time to time in effect and to general principles of equity (including concepts of materiality, reasonableness, good faith and fair dealing) regardless of whether considered in a proceeding in equity or at Law.

Section 6.3 Consents; No Violations, Etc. The execution and delivery of this Agreement do not, and the consummation of the Contemplated Transactions and the compliance with the terms hereof will not (i) violate any Governmental Order applicable to Buyer, (ii) conflict with any provision of the certificate of incorporation or bylaws of Buyer or (iii) give rise to any approval, authorization, consent, license, filing or registration with any court, arbitrator or Governmental Entity; provided, however, that no representation or warranty is made in the foregoing clauses (i) or (iii) with respect to matters that, individually or in the aggregate, would not materially interfere with Buyer's performance of its obligations hereunder.

Section 6.4 Litigation. As of the date hereof, there is no suit, claim, action, investigation or proceeding pending or, to the knowledge of Buyer, threatened against Buyer or any of its Affiliates which if adversely determined would delay the ability of Buyer to perform its obligations hereunder.

Section 6.5 No Brokers. Buyer has not entered into any agreement, arrangement or understanding with any Person or firm which will result in the obligation to pay any finder's fee, brokerage commission or similar payment in connection with the Contemplated Transactions.

Section 6.6 Exclusive Representations and Warranties. Other than the representations and warranties set forth in this Article VI, Buyer is not making any other representations or warranties, express or implied, and each Seller expressly acknowledges the same and agrees that it is not relying on any other representations or warranties. Buyer hereby disclaims any other express or implied representations or warranties, including regarding any financial projections or other forward-looking statements provided by or on behalf of Buyer in connection with this Agreement.

ARTICLE VII
CERTAIN COVENANTS AND AGREEMENTS OF SELLERS

Section 7.1 Conduct of Business Until Closing. During the period from the date of this Agreement and continuing until the Closing, Sellers agree (except as otherwise provided in this Agreement or as otherwise consented to in writing by Buyer, which consent will not be unreasonably withheld, conditioned, or delayed) that they will conduct their respective businesses with respect to the Transferred Assets in all material respects in the ordinary course of business consistent with past practice. During the period from the date of this Agreement and

continuing until the Closing, each Seller covenants and agrees that, except as expressly contemplated by this Agreement, such Seller will not, and will cause its Affiliates to not, without Buyer's prior written consent: (i) enter into any transaction that would reasonably be expected to materially and adversely affect the Contemplated Transactions; (ii) grant or knowingly permit any Encumbrance (other than Permitted Encumbrances) on any of the Transferred Assets; (iii) sell, transfer, assign, convey, lease, license or otherwise dispose of any of the Transferred Assets (other than in the ordinary course of business); (iv) enter into any material contract for the purchase or sale of any of the Transferred Assets; (v) amend or terminate any of the Third Party Agreements; (vi) waive or release any material right or claim relating to the Transferred Assets; (vii) enter into or amend any contract pursuant to which any other party is granted exclusive rights or "most favored party" rights of any type or scope with respect to the Transferred Assets; or (viii) take or agree in writing or otherwise to take, any of the actions described in clauses (i) through (vii) in this Section 7.1.

Section 7.2 Assumed IP Litigation Matter. During the period from the date of this Agreement and continuing until the Closing, each Seller covenants and agrees that such Seller (i) will not settle, compromise, or offer to settle or compromise any claims in the Assumed IP Litigation Matter without providing reasonable notice to Buyer and without Buyer's written consent to said settlement, compromise, or offer to settle or compromise; and (ii) will provide Buyer or its counsel such information as Buyer or its counsel may reasonably request about the Assumed IP Litigation Matter to permit Buyer to conduct due diligence regarding the Assumed IP Litigation Matter and the claims and defenses asserted therein.

Section 7.3 Transfer Taxes. All transfer, documentary, sales, use, stamp, registration, value added and other such taxes and fees (including any penalties and interest) incurred in connection with this Agreement and the documents to be delivered hereunder ("**Transfer Taxes**") shall be borne and paid by Sellers when due. Sellers shall, at their own expense, timely file any Tax Return or other document with respect to such taxes or fees (and Buyer shall cooperate with respect thereto as necessary).

Section 7.4 Cooperation on Tax Matters. Buyer and Sellers shall furnish or cause to be furnished to each other, as promptly as practicable, such information and assistance relating to the Transferred Assets and the Assumed Liabilities as is reasonably necessary for the preparation and filing of any Tax Return, claim for refund or other filings relating to Tax matters, for the preparation for any Tax audit, for the preparation for any Tax protest, for the prosecution or defense of any suit or other proceeding relating to Tax matters.

ARTICLE VIII
CERTAIN COVENANTS AND AGREEMENTS OF BUYER

Section 8.1 Insurance. At all times from the Closing Date through that date which is the **** anniversary of the Closing Date, Buyer will maintain product liability insurance written on a claims-made basis in an amount of not less than **** per occurrence, **** annual aggregate. On the Closing Date, Buyer will provide Sellers with a certificate of insurance naming Sellers as additional insured parties solely with respect to claims relating to Fanapt sold by Buyer on or after the Closing Date as evidence of such insurance and thereafter upon the written request of Sellers. Buyer will promptly notify Sellers of any material change in

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the terms of such insurance from those set forth in the most recent certificate of insurance provided to Seller pursuant to this Section 8.1 (other than the identity of the insurer).

Section 8.2 Sellers' Names and Marks. Buyer hereby acknowledges that all right, title and interest in and to the names "Novartis", "Sandoz" and the Novartis logo, together with all variations thereof and all trademarks, service marks, domain names, trade names, trade dress, corporate names and other identifiers of source containing, incorporating or associated with any of the foregoing (the "**Novartis Names and Marks**") are owned exclusively by the applicable Seller and/or their respective Affiliates. Buyer further acknowledges that it has no rights, and is not acquiring any rights, to use the Novartis Names and Marks, except as expressly provided in the Fanapt Supply Agreement.

ARTICLE IX
MUTUAL COVENANTS AND AGREEMENTS

Section 9.1 Efforts to Closing. Subject to the terms and conditions of this Agreement, Sellers and Buyer will use their respective **** to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary or desirable under applicable Law to consummate the transactions contemplated by this Agreement. Sellers and Buyer agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be **** in order to consummate or implement expeditiously the transactions contemplated by this Agreement. In furtherance of the foregoing, Buyer agrees to provide such assurances as to financial capability, resources and creditworthiness as may be reasonably requested by any Governmental Entity or Third Party, whose consent or approval is sought hereunder.

Section 9.2 Notice of Certain Events. Each Party shall promptly notify the other of:

(a) any notice or other communication from any Person alleging that the consent of such Person is or may be required in connection with the transactions contemplated by this Agreement;

(b) any material notice or other material communication from any Regulatory Authority in connection with the transactions contemplated by this Agreement or with respect to Fanapt or any Fanapt Development Stage Product; and

(c) any inaccuracy of any representation or warranty or a failure to satisfy any covenant, agreement or condition contained in this Agreement.

Section 9.3 Confidentiality; Press Releases.

(a) Subject to the exceptions contained in Section 9.3(b) and Section 9.3(c) below, neither Party shall disclose to any Third Party nor use for any purpose outside of the scope of this Agreement any information which is not in the public domain and which was disclosed solely in connection with this Agreement: (i) by the disclosing Party or any of its Affiliates; or (ii) by any unaffiliated Third Party at the request of the disclosing Party ("**Confidential Information**"). The receiving Party may only provide the disclosing Party's Confidential Information to its and its Affiliates' directors, officers, employees, advisors, and

consultants ("**Representatives**") who are informed of the confidential nature of the Confidential Information and who are bound by obligations of confidentiality and non-use no less restrictive than those contained herein and provided that the receiving Party shall be responsible for any breach of this Agreement by its Representatives, which shall be considered a breach by the receiving Party. The obligations of confidentiality and non-use shall expire for Confidential Information which (1) is or becomes part of the public domain without a violation of this Agreement; (2) was already in the receiving Party's possession at the time of receipt from the disclosing Party, as shown by documentary evidence; or (3) after the date of this Agreement is received from a Third Party whose direct or indirect source is not the disclosing Party. Upon termination or expiration of this Agreement for any reason, each Party will promptly return to the other Party all Confidential Information received from such other Party in connection with this Agreement except to the extent that retaining such Confidential Information is **** in order for the receiving Party to continue to enjoy or enforce the rights received, or to satisfy its obligations, under any of the Ancillary Agreements or any other agreement between the Parties that survives following such expiration or termination. The obligations of confidentiality and non-use contained in this Section 9.3 shall survive the termination of this Agreement for a period of ****.

(b) Subject to the limitations set forth in Section 9.3(c) below, the Parties may disclose Confidential Information (i) which is required to be disclosed to Regulatory Authorities or governmental agencies for registration purposes, (ii) if requested pursuant to an order of a competent court or administrative agency; provided that in either case, the Party subject to such order has informed the other Party thereof in writing, and has used **** to limit the scope of the disclosure and to obtain confidential treatment by such Regulatory Authority of Confidential Information disclosed pursuant to such order or (iii) if required by applicable Law.

(c) Buyer's proposed press release for the Contemplated Transactions is attached as Exhibit C. Aside from Exhibit C, except as set forth below, neither Buyer nor Sellers shall issue a press release, trade announcement or any other public announcement with regard to the Contemplated Transactions without the other Party's prior consent, which shall not be unreasonably withheld or delayed. Where consent is forthcoming, the Parties agree to consult with each other regarding the content of any such press release or other announcement. This restriction shall not apply to announcements required by applicable Law or any Governmental Entity, however, in such event, the Parties shall**** **** coordinate and work in good faith to create mutually acceptable announcements and each Party shall take into consideration and comply with **** of the other Parties. Buyer acknowledges that Sellers shall have the right to disclose a brief summary of the transaction in its official financial reports, provided, however, that the Sellers shall provide drafts of such reports sufficiently in advance of disclosing or providing such reports to any Third Party to permit Buyer to review and comment on such reports and the Parties shall**** coordinate and work in good faith to create a mutually acceptable financial report and the Sellers shall take into consideration and comply with **** of Buyer. Sellers acknowledge that Buyer shall have the right to disclose a brief summary of the material terms of the Contemplated Transactions on a Current Report on Form 8-K no later than the fourth Business Day following the date of this Agreement, and file a copy of this Agreement and certain Ancillary Agreements with the United States Securities and Exchange Commission ("**SEC**"), provided, however, that Buyer shall provide drafts of such

Current Report on Form 8-K sufficiently in advance of filing to permit Sellers to review and comment on such Current Report on Form 8-K and the Parties shall**** coordinate and work in good faith to create a mutually acceptable Current Report on Form 8-K and Buyer shall take into consideration and comply with **** of the Sellers. To the extent that any Party is required to make a filing or any other public disclosure (other than as set forth in the preceding sentence) pursuant to applicable Law or any Governmental Entity with respect to this Agreement, any of the Ancillary Agreements or the terms or existence hereof or thereof to comply with the requirements, rules, laws or regulations of any applicable stock exchange, The NASDAQ Global Market or any Governmental Entity, including without limitation the SEC (collectively, the "**Disclosure Obligations**"), such Party shall promptly inform the other Parties thereof and shall use **** to maintain the confidentiality of the other Parties' confidential information in any such filing or disclosure. To the extent that any Party is required to file a copy of this Agreement or any Ancillary Agreement to comply with the Disclosure Obligations, such Party shall promptly inform the other Parties thereof. Prior to making any such filing of a copy of this Agreement or any such Ancillary Agreement, the Parties shall mutually agree on the provisions of this Agreement and/or Ancillary Agreement, as applicable, for which the Parties shall seek confidential treatment, it being understood that if one Party determines to seek confidential treatment for a provision for which the another Party does not, then the Parties will use **** in connection with such filing to seek the confidential treatment of any such provision. The Parties shall cooperate, each at its own expense, in such filing, including without limitation such confidential treatment request, and shall execute all documents **** in connection therewith. The Parties shall agree with each other as to the substance of any such filing. Each Party shall have the right to review in advance, and shall consult with the other Party on, all information relating to this Agreement or any Ancillary Agreement, that appear in any such filing. In furtherance of the foregoing, the Parties will agree as promptly as practicable after the date of this Agreement on the confidential treatment request to be filed with the SEC and the redacted form or forms of this Agreement and/or Ancillary Agreements, as applicable, related thereto. In furtherance thereof, **** requested by any Party shall be included in such filing. The Parties will reasonably cooperate in responding promptly to any comments received from the SEC with respect to such filing in an effort to achieve confidential treatment of such redacted form; provided, however, that a Party shall be relieved of such obligation to seek confidential treatment for a provision requested by the another Party if such treatment is not achieved after the second round of responses to comments from the SEC.

Section 9.4 Maintenance of Books and Records; Sellers' Access. For a period of **** after the Closing Date, (i) Buyer agrees to retain (and to cause it Affiliates to retain) and make available all data and books and records received from Sellers and their Affiliates for inspection and copying by Sellers or their respective agents ****, upon reasonable request and upon reasonable notice; provided that such data and books and records shall be made available only to the extent such availability is required for Sellers or one or more of their respective Affiliates to comply with a requirement of Law, this Agreement, the Ancillary Agreements, or to enable Sellers or one or more of their respective Affiliates to defend against, respond to, or otherwise participate in any litigation, investigation, audit process, subpoena, or other proceeding related to Fanapt, and (ii) no such data and other books and records shall be destroyed by Buyer without giving **** prior written notice to Sellers to permit Sellers, ****, to duplicate or take possession of any such data, books and records.

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Any such access by Sellers shall not unreasonably interfere with the conduct of the business of Buyer and its Affiliates. Sellers will hold, and will use **** to cause their respective officers, directors, employees, accountants, counsel, consultants, advisors and agents to hold, in confidence, unless compelled to disclose by judicial or administrative process or by other requirements of applicable Law, all confidential documents and information concerning Buyer provided to it pursuant to this Section 9.4. Sellers shall be permitted to keep a copy of all data, books and records provided to Buyer.

ARTICLE X
OTHER COVENANTS AND AGREEMENTS

Section 10.1 Transfer of Fanapt Registrations.

(a) Buyer and the applicable Sellers shall file, or shall cause to be filed, applications for the transfer of the Fanapt Registrations for the United States, as soon as practicable after, and in any event within **** after, the Closing Date. As soon as practicable after the Closing Date, and in any event within **** following the Closing Date, Sellers shall deliver to Buyer one copy of each NDA for Fanapt and all active INDs relating to the Fanapt Development Stage Products.

(b) In the event Sellers agree to continue conducting any clinical studies, Buyer agrees that such studies will be conducted **** under the existing IND that is being transferred to Buyer, and Buyer will inform the FDA that Sellers are agents of Buyer and will be conducting the trials for Buyer.

Section 10.2 Assumption of Regulatory Commitments. Subject to the terms and conditions of the Commercial Agreement, from and after the Closing Date, Buyer will assume control of, and responsibility for all costs, obligations and Liabilities arising from or related to any requirements, commitments or obligations to any Governmental Entity involving Fanapt and the Fanapt Development Stage Products.

Section 10.3 Response to Medical Inquiries and Fanapt Complaints. From and after the Closing, except as set forth in the Transition Services Agreement, Buyer will assume all responsibility for responding to any medical inquiries or complaints about Fanapt.

Section 10.4 Delivery of Assets. Until the **** anniversary of the Closing, in the event that after Closing, Sellers or Buyer discover that Transferred Assets or regulatory documents relating to the Fanapt Development Stage Products (to the extent that they exist and are reasonably available) have not been provided to Buyer, to the extent such Transferred Assets are in Sellers' or any of its Affiliates possession or control, Sellers shall use **** to provide such assets or documents to Buyer as promptly as possible; provided, that if Sellers are unable to provide such assets or documents, Sellers will, jointly and severally, promptly reimburse Buyer for the aggregate cost of replacing any and all such assets or documents and any indemnification obligations of Seller under Article XIII hereof shall be deemed satisfied in full; provided that the limitations on indemnification contained in Section 13.2(b) shall not apply to any such reimbursement under this Section 10.4.

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

Section 10.5 Representations to Customers. From and after the Closing, neither Party will make any knowing false or misleading representations to customers or others regarding the other Parties, their respective Affiliates, Fanapt or the Fanapt Development Stage Products and will not make any representations, warranties or guarantees with respect to the specifications, features or capabilities of Fanapt that are not consistent with the applicable current FDA approved labeling and package insert or other documentation accompanying or describing Fanapt. Neither Party will make any negative or disparaging statements about Fanapt, the Fanapt Development Stage Products, the Fanapt Drug Substance or any other Party or any of their respective Affiliates, except that Buyer may, in compliance with applicable Law, market, sell and promote Fanapt, the Fanapt Development Stage Products or other products which compete with products of Sellers and their respective Affiliates.

ARTICLE XI
CONDITIONS PRECEDENT

Section 11.1 Conditions to Each Party's Obligations. The respective obligations of each Party to effect the transactions contemplated hereby shall be subject to the satisfaction (or waiver, if permissible under applicable Law) on or prior to the Closing Date of the following condition:

(a) No Injunctions or Restraints. No Law or Governmental Order enacted, promulgated, issued, entered, amended or enforced by any Governmental Entity shall be in effect enjoining, restraining, preventing or prohibiting consummation of the transactions contemplated by this Agreement or making the consummation of such transactions illegal.

Section 11.2 Conditions to Obligations of Buyer. The obligations of Buyer to consummate the transactions contemplated by this Agreement are subject to the fulfillment at or prior to the Closing of each of the following conditions (any or all of which may be waived in whole or in part by Buyer):

(a) Representations and Warranties. The representations and warranties of Sellers set forth in this Agreement shall be true and correct as of the Closing (disregarding any qualifications of any such representations and warranties as to "materiality" or "Material Adverse Effect") except (i) for such representations and warranties that address matters as of a particular date which need be true only as of the particular date in question and (ii) where the failure of such representations and warranties of Sellers to be true and correct has not had, and would not reasonably be expected to result in, individually or in the aggregate, a Material Adverse Effect.

(b) Performance of Obligations of Seller. Each Seller shall have performed in all material respects all covenants and agreements required to be performed by it hereunder on or prior to the Closing and shall have tendered the required documents at the Closing as set forth in Section 4.2(a).

(c) Stock Purchase Agreement. The obligations of Buyer to consummate the transactions contemplated by the Stock Purchase Agreement have been satisfied or waived, other than those conditions which by their nature are satisfied concurrently with the consummation of

such transactions, including, without limitation, the Closing under this Agreement, in which case, such conditions shall be reasonably expected to be satisfied upon or immediately following Closing.

(d) Material Adverse Effect. No event shall have occurred that would or would reasonably be expected to result in a Material Adverse Effect.

Section 11.3 Conditions to the Obligations of Seller. The obligations of Sellers to consummate the transactions contemplated by this Agreement are subject to the fulfillment at or prior to the Closing of each of the following conditions (any or all of which may be waived in whole or in part by Sellers):

(a) Representations and Warranties. The representations and warranties of Buyer set forth in this Agreement shall be true and correct in all material respects (in the case of any representation or warranty without any materiality qualification) or in all respects (in the case of any representation or warranty containing any materiality qualification) as of the Closing except (i) for the warranties that address matters as of a particular date which need be true in all material respects (in the case of any representation or warranty without any materiality qualification) or in all respects (in the case of any representation or warranty containing any materiality qualification) only as of the particular date in question or (ii) where the failure of such representations and warranties of Buyer to be so true and correct would not reasonably be expected to prevent or materially delay the consummation of the Contemplated Transactions.

(b) Performance of Obligations of Buyer. Buyer shall have performed in all material respects all covenants and agreements required to be performed by it hereunder on or prior to the Closing and shall have tendered the required documents at the Closing as set forth in Section 4.2(b).

(c) Stock Purchase Agreement. The obligations of the Sellers to consummate the transactions contemplated by the Stock Purchase Agreement have been satisfied or waived, other than those conditions which by their nature are satisfied concurrently with the consummation of such transactions, including, without limitation, the Closing under this Agreement, in which case, such conditions shall be reasonably expected to be satisfied upon or immediately following Closing.

ARTICLE XII
TERMINATION, AMENDMENT AND WAIVER

Section 12.1 Termination. Notwithstanding anything to the contrary in this Agreement, this Agreement may be terminated and the transactions contemplated hereby abandoned at any time prior to the Closing:

(a) by mutual written consent of Sellers and Buyer;

(b) by either Sellers, on the one hand, or Buyer, on the other hand, upon written notice to the other if there shall be in effect any Law which makes illegal or permanently prohibits or enjoins the consummation of the transactions contemplated by this Agreement;

(c) by either Sellers, on the one hand, or Buyer, on the other hand, upon notice to the other if the Closing shall not have occurred on or before ****; provided, however, that the right to terminate this Agreement pursuant to this Section 12.1(c) shall not be available to such Party whose failure to fulfill any obligation under this Agreement has caused, or resulted in, the failure of the Closing to occur on or before such date;

(d) by Buyer, if Sellers have materially breached or failed to comply with their respective warranties, representations or obligations under this Agreement such that the conditions set forth in Section 11.2 would not reasonably be expected to be satisfied, and such breach or failure to comply shall not have been cured within a period of **** after Buyer shall have given written notice to Sellers of such breach or failure to comply;

(e) by Sellers, if Buyer has materially breached or failed to comply with its warranties, representations or obligations under this Agreement such that the conditions set forth in Section 11.3 would not reasonably be expected to be satisfied, and such breach or failure to comply shall not have been cured within a period of **** after Buyer shall have given written notice to Sellers of such breach or failure to comply.

Section 12.2 Effect of Termination. In the event of termination by either Seller, on the one hand, or Buyer, on the other hand, pursuant to Section 12.1, written notice thereof will forthwith be given to the other Party and the transactions contemplated by this Agreement will be terminated, without further action by any Party. If the transactions contemplated by this Agreement are terminated as provided herein:

(a) this Agreement shall become null and void and have no further force and effect and all obligations of the Parties under this Agreement shall terminate and there shall be no liability of any Party to any other Party except (i) Section 9.3, this Section 12.2 and Article XIV shall survive any termination of this Agreement pursuant to Section 12.1 and (ii) that nothing herein will relieve or release any Party from liability arising from any intentional and willful breach by such Party of this Agreement. For a breach to be intentional and willful, it must be the consequence of an act undertaken by the breaching Party with the knowledge that the taking of such act would, or would reasonably be expected to, cause a breach of this Agreement.

(b) subject to the provisions of Section 9.3, Buyer will return all documents and other material received from Sellers relating to Fanapt and the Transferred Assets and to the Contemplated Transactions, whether so obtained before or after the execution hereof, to Sellers; and

(c) all confidential information received by Buyer with respect to Sellers, Fanapt or the Transferred Assets will be treated in accordance with the Confidentiality Agreement, which will remain in full force and effect notwithstanding the termination of this Agreement.

ARTICLE XIII
INDEMNIFICATION

Section 13.1 Survival. (i) All representations and warranties of Sellers and Buyer contained herein or made pursuant hereto will survive ****

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****; provided, however, that the representations and warranties set forth in Sections 5.1, 5.2, 5.3(i) and (ii), 5.4, 5.14, 6.1, 6.2 and 6.5 shall survive ****, (ii) the representations and warranties set forth in Section 5.11 shall survive ****, (iii) the covenants and agreements of the Parties contained in this Agreement will survive ****, and (iv) the indemnification obligations contained in Section 13.2(a)(iii) will survive **** (as applicable, the "**Survival Period**"). Any right of indemnification pursuant to Article XIII hereof with respect to a claimed breach of a representation, warranty or covenant will expire on the last day of the applicable Survival Period of the representation, warranty or covenant claimed to be breached, and no indemnification or other claim may be brought by a Party alleging misrepresentation or breach of the applicable representation, warranty, covenant or agreement. Notwithstanding the foregoing, any breach of representation, warranty, covenant or agreement in respect of which an indemnity claim is properly brought under this Agreement shall survive the time at which it would otherwise terminate pursuant to the preceding sentence (solely with respect to such claim), if notice (specifying in reasonable detail) of the inaccuracy or breach thereof giving rise to such right of indemnity shall have been given to the Party against whom such indemnity is brought prior to such time. The representations and warranties of Sellers set forth in Sections 5.1, 5.2, 5.3(i), 5.3(ii), and 5.4 are collectively referred to as "**Sellers' Fundamental Representations**". The representations and warranties of Buyer set forth in Sections 6.1, and 6.2 are collectively referred to as "**Buyer's Fundamental Representations**".

Section 13.2 Indemnification by Sellers.

(a) From and after Closing, each Seller hereby agrees to, jointly and severally, indemnify Buyer and its Affiliates and their respective officers, directors, agents and employees (the "**Buyer Indemnified Parties**") against, and agrees to hold them harmless from, any Loss to the extent such Loss results or arises, whether or not due to a Third-Party Claim, from the following:

(i) any failure of any representation or warranty made by Sellers in this Agreement or the Ancillary Agreements or a certification required to be delivered hereby or thereby, in each case, to be true and correct as of the Closing Date;

(ii) any breach by any Seller of any of its covenants or agreements contained in this Agreement or the Ancillary Agreements; or

(iii) any Excluded Liability (collectively, the claims made under clauses (i), (ii) and (iii), "**Buyer Claims**").

(b) Notwithstanding the foregoing, other than in the case of fraud committed by the Sellers, the indemnification in favor of the Buyer Indemnified Parties contained in Section 13.2(a) above shall be limited to Buyer Claims as to which Buyer has given written notice to the Sellers within the applicable time period set forth in Section 13.1, in each case setting forth therein in reasonable detail the basis for such Buyer Claim, including a reasonable estimate for the amount of Losses to the extent known by Buyer at such time****

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****

(c) Notwithstanding anything to the contrary contained herein, for purposes of this Section 13.2, each of the representations and warranties made by Sellers in this Agreement, the Ancillary Agreements or any certificate or other instrument delivered pursuant hereto or thereto shall be deemed to have been made without the inclusion of limitations or qualifications as to materiality, including the words "immaterial," "material" and "in all material respects" or words of similar import but not the term "Material Adverse Effect."

Section 13.3 Indemnification by Buyer.

(a) From and after the Closing, Buyer hereby agrees to indemnify Sellers and their respective Affiliates and their respective officers, directors and employees (the "**Sellers Indemnified Parties**") against, and agrees to hold them harmless from, any Loss to the extent such Loss results or arises from, whether or not due to a Third-Party Claim, with the following:

(i) any failure of any representation or warranty made by Buyer in this Agreement or the Ancillary Agreements or a certification to be delivered hereby or thereby, in each case, as of the Closing Date;

(ii) any breach by Buyer of any of its covenants contained in this Agreement; or

(iii) any Assumed Liability (collectively, the claims made under clauses (i), (ii) and (iii), "**Sellers' Claims**").

(b) Notwithstanding the foregoing, other than in the case of fraud committed by Buyer, the indemnification in favor of the Seller Indemnified Parties contained in Section 13.3 shall be limited to Sellers' Claims as to which the Sellers have given written notice to Buyer within the applicable time period set forth in Section 13.1, in each case setting forth therein in reasonable detail the basis for such Sellers' Claim, including a reasonable estimate for the amount of Losses to the extent known by Sellers at such time.

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Section 13.4 ****

Section 13.5 Other Indemnification Limitations. The amount of any Loss incurred shall be net of any amounts recovered by the Indemnified Party from any Third Party and each Party agrees to use commercially reasonable efforts to pursue and collect such amounts; provided that the Indemnified Party shall not be required to seek payment of or recover any amounts under any insurance policy.

Section 13.6 Procedure.

(a) In order for the party seeking indemnification under this Article XIII (an "**Indemnified Party**") to be entitled to any indemnification provided for under this Agreement, such Indemnified Party will, promptly following the discovery of the matters giving rise to any Loss, notify the party against whom indemnity is to be sought under this Article XIII (the "**Indemnifying Party**") in writing of its claim for indemnification for such Loss, specifying in reasonable detail the nature of such Loss and the amount of the liability estimated to accrue therefrom; provided, however, that failure to give such prompt notification will not affect the indemnification provided hereunder except to the extent the Indemnifying Party will have been actually prejudiced as a result of such failure (except that the Indemnifying Party will not be liable for any expenses incurred during the period in which the Indemnified Party failed to give such notice). Thereafter, the Indemnified Party will deliver to the Indemnifying Party, within **** after the Indemnified Party's receipt of such request, all information and documentation reasonably requested by the Indemnifying Party with respect to such Loss, subject to mutually agreed upon non-disclosure and non-use requirements.

(b) If the indemnification sought pursuant hereto involves a claim made by a Third Party against the Indemnified Party (a "**Third Party Claim**"), the Indemnifying Party will be entitled to participate in the defense of such Third Party Claim and, if it so chooses, to assume the defense of such Third Party Claim with counsel selected by the Indemnifying Party. Should the Indemnifying Party so elect to assume the defense of a Third Party Claim, the Indemnifying Party will not be liable to the Indemnified Party for any legal expenses subsequently incurred by the Indemnified Party in connection with the defense thereof. If the Indemnifying Party assumes such defense, the Indemnified Party will have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnifying Party, it being understood that the Indemnifying Party will control such defense. The Indemnifying Party will be liable for the reasonable fees and expenses of counsel employed by the Indemnified Party for any period during which the Indemnifying Party has not assumed the

defense thereof (other than during any period in which the Indemnified Party will have failed to give notice of the Third Party Claim as provided above). If the Indemnifying Party chooses to defend or prosecute a Third Party Claim, all of the Parties will cooperate in the defense or prosecution thereof. Such cooperation will include the retention and (upon the Indemnifying Party's request) the provision to the Indemnifying Party of records and information which are reasonably relevant to such Third Party Claim, and making employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnifying Party will not settle, compromise or discharge such Third Party Claim, to the extent that it involves any agreement, performance or observance by the Indemnified Party, without the Indemnified Party's prior written consent (which shall not be unreasonably withheld, conditioned or delayed). Whether or not the Indemnifying Party will have assumed the defense of a Third Party Claim, the Indemnified Party will not admit any liability with respect to, or settle, compromise or discharge, such Third Party Claim without the Indemnifying Party's prior written consent (which shall not be unreasonably withheld, conditioned or delayed).

ARTICLE XIV
GENERAL PROVISIONS

Section 14.1 Non-Recourse. This Agreement may only be enforced against, and any claims or causes of action that may arise out of this Agreement, or the negotiation, execution or performance of this Agreement may only be made against, the Persons that are parties to this Agreement in their capacities as such, and no former, current or future equityholders, controlling persons, directors, officers, employees, agents or Affiliates of any Party, or any former, current or future equityholder, controlling person, director, officer, employee, agent or Affiliate of any of the foregoing shall have any liabilities for any obligations or liabilities of the parties to this Agreement for any claims or causes of action arising out of this Agreement or the negotiation, execution or performance of this Agreement.

Section 14.2 Expenses. Except as otherwise specified in this Agreement or the Ancillary Agreements, all costs and expenses, including fees and disbursements of counsel, financial advisors and accountants, incurred in connection with this Agreement or the Ancillary Agreements and the transactions contemplated hereby or thereby will be paid by the Party incurring such costs and expenses.

Section 14.3 Notices. All notices, requests, demands, waivers and communications required or permitted to be given under this Agreement or of the Ancillary Agreements shall be in writing and shall be deemed to have been duly given if delivered (i) by hand (including by reputable overnight courier), or (ii) by telecopy facsimile transmission (receipt of which is confirmed):

(a) if to Buyer, to:

Vanda Pharmaceuticals Inc.
2200 Pennsylvania Avenue, NW, Suite 300E
Washington, DC 20037
Attention: Chief Executive Officer
Fax: ****

with copies to (which shall not constitute notice hereunder):

Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP
One Marina Park Drive
Suite 900
Boston, MA 02210
Attn: ****
Fax: ****

and

Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019
Attn: ****
Fax: ****

if to Novartis Pharma AG, to:

Novartis Pharma AG
Forum 1
Novartis Campus
CH-4056 Basel, Switzerland
Attn: General Counsel
Fax: ****

Novartis Pharma AG
Forum 1
Novartis Campus
CH-4056 Basel, Switzerland
Attn: Head BD&L
Fax: ****

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with a copy to (which shall not constitute notice hereunder):

Kaye Scholer LLP
250 West 55th Street
New York, NY 10019
Attn: ****
Facsimile: ****

(b) if to Novartis AG, to

Novartis AG
Forum 1
Novartis Campus
CH-4056 Basel, Switzerland
Attn: General Counsel
Fax: ****

Novartis AG
Forum 1
Novartis Campus
CH-4056 Basel, Switzerland
Attn: Head BD&L
Fax: ****

with a copy to (which shall not constitute notice hereunder):

Kaye Scholer LLP
250 West 55th Street
New York, NY 10019
Attn: ****
Facsimile: ****

or to such other person or address as any party shall specify by notice in writing to the other party. All such notices, requests, demands, waivers and communications shall be deemed to have been given on the date on which (i) so hand-delivered whether in person or by reputable overnight courier, or (ii) telecopied and confirmed. If requested, each party shall confirm receipt of any notice that it receives by either of the methods of delivery in the prior sentence.

Section 14.4 Headings. The table of contents and headings contained in this Agreement and the Ancillary Agreements are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement or of the Ancillary Agreements.

Section 14.5 Severability. If any term or other provision of this Agreement or of the Ancillary Agreements is invalid, illegal or incapable of being enforced under any Law or public policy, all other terms and provisions of this Agreement and the Ancillary Agreements will nevertheless remain in full force and effect so long as the economic or legal substance of the

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transactions contemplated hereby is not affected in any manner materially adverse to any party. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the Parties will negotiate in good faith to modify this Agreement or the Ancillary Agreements so as to effect the original intent of the Parties as closely as possible in an acceptable manner in order that the transactions contemplated hereby are consummated as originally contemplated to the greatest extent possible.

Section 14.6 Counterparts. This Agreement and the Ancillary Agreements and any amendments thereto may be executed in one or more counterparts, all of which will be considered one and the same agreement and will become effective when one or more counterparts have been signed by each of the Parties and delivered to the other Parties, it being understood that all Parties need not sign the same counterpart. Any individual signing this Agreement or the Ancillary Agreements or any amendment thereto represents and warrants that he or she has full authority to do so.

Section 14.7 Entire Agreement; No Third Party Beneficiaries. This Agreement (together with the Schedules and Exhibits attached thereto and any Ancillary Agreements, term sheets or other documents or requirements contemplated thereby) constitutes the entire agreement among, and supersedes all prior agreements and understandings, both written and oral, between or among, the Parties with respect to the subject matter hereof. Except as specifically provided herein, no provision of this Agreement or of the Ancillary Agreements is intended to confer upon any Person other than the Parties any rights or remedies hereunder or thereunder.

Section 14.8 Amendments, Waivers and Drafting. This Agreement and the Ancillary Agreements may be amended only by an instrument in writing signed on behalf of each of the Parties. By an instrument in writing, Buyer, on the one hand, or Sellers, on the other hand, may waive compliance by the other party with any term or provision of this Agreement or of the Ancillary Agreements that such other party was or is obligated to comply with or perform. Absent such an instrument in writing, no failure by a Party to enforce its rights under any provision of this Agreement or the Ancillary Agreements shall be construed to be a waiver of such provision or the right of the Party to enforce such provision. The Parties acknowledge and agree that they have mutually participated in the drafting of this Agreement and the Ancillary Agreements, and that no provision of this Agreement or the Ancillary Agreements or any amendment thereto will be construed against or interpreted to the disadvantage of any Party by reason of such Party or its representatives having or being deemed to have structured or drafted such provision.

Section 14.9 Governing Law; Jurisdiction. This Agreement and the Ancillary Agreements shall be deemed to have been made and entered into within the State of New York and shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to the principles or rules of conflict of laws of the State of New York or of any other jurisdiction to the extent such principles or rules would require or permit the application of the laws of any jurisdiction other than the State of New York. Each of the Parties irrevocably agrees that any legal action or proceeding arising out of or relating to this Agreement and Ancillary Agreements brought by any other Party or its successors or assigns shall be brought and determined in the federal courts located in the State of New York, or, if such federal

courts lack jurisdiction, in the state courts of the State of New York located in Manhattan, and each of the Parties hereby irrevocably submits to the exclusive jurisdiction of the aforesaid courts for itself and with respect to its property, generally and unconditionally, with regard to any such action or proceeding arising out of or relating to this Agreement and the transactions contemplated hereby. Each of the Parties agrees not to commence any action, suit or proceeding relating thereto except in the courts described above in New York, other than actions in any court of competent jurisdiction to enforce any judgment, decree or award rendered by any such court. Each of the Parties further agrees that notice as provided herein shall constitute sufficient service of process and the Parties further waive any argument that such service is insufficient. Each of the Parties hereby irrevocably and unconditionally waives, and agrees not to assert, by way of motion or as a defense, counterclaim or otherwise, in any action or proceeding arising out of or relating to this Agreement, of the Ancillary Agreements or the transactions contemplated hereby or thereby, (i) any claim that it is not personally subject to the jurisdiction of the courts described herein for any reason, (ii) that it or its property is exempt or immune from jurisdiction of any such court or from any legal process commenced in such courts (whether through service of notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise) and (iii) that (A) the suit, action or proceeding in any such court is brought in an inconvenient forum, (B) the venue of such suit, action or proceeding is improper or (C) this Agreement, the Ancillary Agreements or the subject matter hereof or thereof, may not be enforced in or by such courts.

Section 14.10 WAIVER OF JURY TRIAL. EACH OF THE PARTIES IRREVOCABLY AND UNCONDITIONALLY WAIVES TRIAL BY JURY IN ANY LEGAL ACTION OR PROCEEDING RELATING TO THIS AGREEMENT, THE ANCILLARY AGREEMENTS, THE AGREEMENTS, INSTRUMENTS AND DOCUMENTS CONTEMPLATED HEREBY OR THEREBY OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY AND FOR ANY COUNTERCLAIM THEREIN.

Section 14.11 Binding Effect; Assignment. This Agreement and the Ancillary Agreements shall inure to the benefit of and be binding upon the Parties and the respective successors and permitted assigns of the Parties and such Persons. No rights or obligations under this Agreement or of the Ancillary Agreements may be assigned by any Party without the prior written consent of each of the other parties; provided, that after the Closing, a Seller may assign its rights hereunder to an Affiliate thereof so long as such Seller remains liable for performance under this Agreement and the Ancillary Agreements.

[signature page follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be signed by their respective representatives thereunto duly authorized, all as of the date first written above.

NOVARTIS PHARMA AG

By: /s/ Matt Owens
Name: Matt Owens
Title: Head Legal GBS & Strategy

By: /s/ Marc Ceulemans
Name: Marc Ceulemans
Title: Head Strategic Venture Capital Fund & Pharma Entities

NOVARTIS AG

By: /s/ Matt Owens
Name: Matt Owens
Title: Head Legal GBS & Strategy

By: /s/ Marc Ceulemans
Name: Marc Ceulemans
Title: Head Strategic Venture Capital Fund & Pharma Entities

VANDA PHARMACEUTICALS INC.

By: /s/ Mihael H. Polymeropoulous, M.D.
Name: Mihael H. Polymeropoulous, M.D.
Title: CEO, Vanda

CONFIDENTIAL TREATMENT REQUESTED

Exhibit A

CONFIDENTIAL TREATMENT REQUESTED

Exhibit B

CONFIDENTIAL TREATMENT REQUESTED

Exhibit C

EXHIBIT 10.58

CONFIDENTIAL TREATMENT REQUESTED

AMENDMENT NO. 1 TO SUBLICENSE AGREEMENT

This Amendment is made as of the 30th day of November 1998, between TITAN PHARMACEUTICALS, INC., a corporation organized under the laws of the State of Delaware and having its principal offices at 400 Oyster Point Blvd., Suite 505, South San Francisco, CA 94080 U.S.A. (hereinafter "TITAN"), and NOVARTIS PHARMA A.G., a corporation organized under the laws of Switzerland and having its principal offices at Lichtstrasse 35, CH 4002, Basel, Switzerland (hereinafter "NOVARTIS").

WITNESSETH

WHEREAS, the parties have entered into that certain Sublicense Agreement, effective as of November 20. 1997 (the "Principal Agreement"), whereby, among other things, TITAN granted to NOVARTIS an exclusive sublicense relating to a compound known as Iloperidone; and

WHEREAS, by this Amendment the parties desire to amend the Principal Agreement.

NOW THEREFORE, in consideration of the premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound, the pasties hereto agree as follows:

1. The term "Agreement", as used and defined in the Principal Agreement, shall mean the Principal Agreement as amended by this Amendment. Terms defined in the Principal Agreement and not otherwise defined herein are used herein as defined in the Principal Agreement.

2. Except as otherwise provided herein, the terms and provisions of the Principal Agreement shall be unchanged and shall continue in full force and effect.

3. Appendix A to the Principal Agreement is hereby amended in its entirety to be and read in the form attached as Appendix A to this Amendment.

4. This Amendment may be executed in any number of counterparts, each of which should be deemed to be an original, but all of which together shall constitute one and the same Amendment.

IN WITNESS WHEREOF, the parties hereby intending to be legally bound have caused this Amendment to be executed and delivered by their proper and duly authorized officers as of the day and year first above written.

NOVARTIS PHARMA A.G.

By: /s/ Olivier Bassi /s/ James S. New

Date: August 27, 1999

TITAN PHARMACEUTICALS, INC.

By: /s/ Louis R. Bucalo

Date: November 30, 1998

CONFIDENTIAL TREATMENT REQUESTED

APPENDIX A

PATENTS AND PATENT APPLICATIONS (PER SECTION 1.17)

(As amended per Amendment No. 1 to Sublicense Agreement)

Country	Patent Appl. No.	Filing Date	Type	Status	Patent No.	Issue Date	Expiration Date

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

Country	Patent Appl. No.	Filing Date	Type	Status	Patent No.	Issue Date	Expiration Date

****

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CONFIDENTIAL TREATMENT REQUESTED

Country	Patent Appl. No.	Filing Date	Type	Status	Patent No.	Issue Date	Expiration Date

****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

EXHIBIT 10.59

CONFIDENTIAL TREATMENT REQUESTED

AMENDMENT NO. 2 TO SUBLICENSE AGREEMENT

THIS AMENDMENT to the Sublicense Agreement effective as of November 20, 1997 (the "Sublicense Agreement") is made as of April 10, 2001 by and between TITAN PHARMACEUTICALS, INC., a corporation organized under the laws of the State of Delaware and having its principal office at 400 Oyster Point Blvd., Suite 505, South San Francisco, CA 94080 (hereinafter "TITAN"), and NOVARTIS PHARMA A.G., a corporation organized under the laws of Switzerland and having its principal office at Lichtstrasse 35, CH 4002 Basel, Switzerland (hereinafter "NOVARTIS"). Capitalized terms used in this Amendment shall have the same meanings set forth in the Sublicense Agreement.

WITNESSETH:

WHEREAS, TITAN and NOVARTIS desire to amend the Sublicense Agreement to add Japan to the scope of the sublicense and to incorporate certain related modifications to the terms and conditions thereof.

NOW THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth, the parties hereby agree as follows:

1. Definitions. Section 1.21 of the Sublicense Agreement is hereby deleted in its entirety and replaced with the following:

"1.21 "TERRITORY" shall mean all countries and territories of the world; provided that any country(ies) in which this Sublicense Agreement is terminated shall be removed from the scope of this definition."

2. Grant. Section 2.1(f) is hereby deleted in its entirety and replaced with the following

"2.1(f) TITAN and its AFFILIATES and SUBLICENSEES shall be entitled to utilize the PATENTS and KNOW-HOW in the FIELD within the TERRITORY for the development and manufacture of COMPOUND and PRODUCT for marketing, distribution and sale outside of the TERRITORY (those countries where NOVARTIS' rights under this Sublicense Agreement have been terminated).

3. Payments and Royalties.

a. Section 3.1 of the Sublicense Agreement is hereby amended by deleting subsection (d) in its entirety and adding the following new subsections (d), (e) and (f):

"(d) An upfront license fee of **** shall be paid by NOVARTIS to TITAN in cash within **** of both parties execution of this Amendment Agreement. An additional license fee of **** shall be payable by NOVARTIS to TITAN within **** after submission by TITAN to

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

NOVARTIS of an Invoice one time only upon annual NET SALES in **** reaching ****.

"(e) Upon submission by TITAN to NOVARTIS of an Invoice therefor, a milestone payment of **** shall be payable one time only by NOVARTIS to TITAN as follows: (i) **** shall be paid in cash upon receipt by NOVARTIS, its AFFILIATE or SUBLICENSEE of notification from the **** that PRODUCT is approved for **** in **** by NOVARTIS, its AFFILIATE or SUBLICENSEE (or their designee) for schizophrenia or other psychiatric disorders; and (ii) **** shall be paid in cash within **** after receipt of such notification. The **** payment provided for herein shall, unless otherwise expressly provided for herein, be non-refundable.

"(f) NOVARTIS shall notify TITAN in writing **** prior to NOVARTIS' estimated achievement of each milestone event described in Sections 3.1(b), 3.1(c)(i) and 3.1(e) above. Upon the receipt of such notification, TITAN shall send NOVARTIS an Invoice for the milestone payment due as a result of the achievement of such milestone event, and NOVARTIS shall make each such payment within **** of the achievement of the milestone event for which payment is due.

b. Section 3.3 of the Sublicense Agreement is hereby deleted in its entirety and replaced with the following:

"3.3(a) As consideration for the sublicense granted to NOVARTIS in this Sublicense Agreement with respect to all of the TERRITORY ****, NOVARTIS shall pay to TITAN, in those countries where, and for the period, PATENTS claiming a priority date of May 19,1989 and December 29, 1989 in a particular country in the TERRITORY **** for which a patent had been granted validly claiming Iloperidone or the manufacture, formulation or the use thereof for use in the FIELD exist: (i) a **** percent (****%) royalty on annual NET SALES of PRODUCT in the TERRITORY **** up to ****, and (ii) a **** percent (****%) royalty on annual NET SALES of PRODUCT in the TERRITORY **** in excess of ****; in each case on NOVARTIS', its AFFILIATES' and SUBLICENSEES' annual NET SALES of PRODUCT in the TERRITORY ****.

(b) As consideration for the sublicense granted to NOVARTIS in this Sublicense Agreement with respect to ****, NOVARTIS shall pay to TITAN: (i) a **** percent (****%) royalty on annual NET SALES of PRODUCT in **** up to Twenty Million Dollars ($20,000,000), and (ii) a **** percent (****%) royalty on annual NET SALES of PRODUCT in **** in excess of ****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

****; in each case on NOVARTIS', its AFFILIATES' and SUBLICENSEES' annual NET SALES of PRODUCT in ****.

4. Development. Section 5.5 of the Sublicense Agreement is hereby amended by deleting the second sentence of the paragraph.

5. Exchange of Information and Confidentiality. Section 6.3 of the Sublicense Agreement is hereby amended by deleting the second sentence of the paragraph.

6. Appendix A. The following patents shall be added to Appendix A:

****	****	****	****	****	****	****
****	****	****	****			

7. Effectiveness. This Amendment shall be deemed effective as of the date hereof.

8. Miscellaneous.

a. Agreement Amended. Subject to the provisions of this Section 7, this Amendment shall be deemed to be an amendment to the Sublicense Agreement. All references to the Sublicense Agreement in any other document, instrument, agreement or writing hereafter shall be deemed to refer to the Sublicense Agreement as amended hereby.

b. Successors and Assigns. This Amendment shall be binding upon and inure to the benefit of TITAN and NOVARTIS and their respective successors and assigns.

c. Governing Law. This Amendment shall be deemed to have been made in the State of New York and its form, execution, validity, construction and effect shall be determined in accordance with the laws of the State of New York (without regard to New York's or any other jurisdictions's conflict of laws principles).

CONFIDENTIAL TREATMENT REQUESTED

IN WITNESS WHEREOF, the parties hereby have executed this Agreement by proper persons thereunto duly authorized.

NOVARTIS PHARMA A.G.

By:	/s/ Markus Goebel	/s/ Gisela Schelling
Name:	Markus Goebel	Gisela Schelling
Title:	Head Nervous System BD&L	Legal Counsel

TITAN PHARMACEUTICALS, INC.

By:	/s/ Louis R. Bucalo M.D.
Name:	Louis R. Bucalo, M.D.
Title:	Chairman, President and CEO

EXHIBIT 10.60

CONFIDENTIAL TREATMENT REQUESTED

AMENDMENT NO. 3 TO SUBLICENSE AGREEMENT

THIS CONSENT' AND AMENDMENT AGREEMENT (this "Amendment Agreement") is made as of June 4, 2004 by and among, Titan Pharmaceuticals, Inc., a corporation having its principal office at 400 Oyster Point Blvd., Suite 505, South San Francisco, CA 94080 ("Titan"), and Novartis Pharma AG, a corporation having its principal office at Lichtstrasse 35, CH 4002, Basel, Switzerland ("NOVARTIS").

WITNESSETH:

WHEREAS, Aventis (formerly Hoechst Marion Rousel, Inc. ("HMRI")) and Titan are parties to that certain License Agreement effective as of December 31, 1996 (the "License Agreement"): and

WHEREAS, Titan and Novartis are parties to that certain Sublicense Agreement effective as of November 20, 1997 as. amended, (the "Sublicense Agreement"); and

WHEREAS, Novartis desires to sublicense its rights and obligations under .the Sublicense Agreement to Vanda Pharmaceuticals, Inc., a corporation organized under the laws of Delaware ("Vanda"), pursuant to a sublicense agreement (the 'Vanda Sublicense Agreement") and the parties hereto desire to facilitate the execution of the Venda Sublicense Agreement by pleading certain of the tennis of the Sublicense Agreement. Terms not otherwise defined in this Amendment Agreement shall have the meanings set forth in the Sublicense Agreement.

NOW THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth and for other good and valuable consideration the receipt of which is hereby acknowledged, the parties hereby agree as follows:

1. Definitions. The definition of "Field" set forth in Section 1.12 of the Sublicense Agreement is hereby deleted in its entirety and replaced with the following:

> "Field" shall mean the treatment in humans of psychiatric disorders, including psychotic disorders and analgesia; provided, however, that for purposes solely of the Vanda Sublicense Agreement warty approved sublicense thereunder, "Field" shall mean the application to all conditions, disorders and &cases in humans".

2. For purposes of the Vanda Sublicense Agreement or any approved sublicense thereunder, Section 2.2 of the Sublicense Agreement shall be deleted in its entirety.

3. For purposes of the Vanda Sublicense Agreement or any approved sublicense. thereunder, Section 2.3 of the Sublicense Agreement shalt be deleted in its entirety.

4. Grant. Section 2.5 of the Sublicense Agreement is modified to provide that each of Aventis, Titan and Novartis will have **** after notification thereof in accordance with the Sublicense Agreement to inform Vanda of any objection tai the trademark. selections).

5. Subsection 3.4(a) of the Sublicense Agreement shall be deleted in its entirety and replaced by the following:

3.4 (a) In order to spread royalty payments hereunder, over a. sufficient period of time, in each of those countries in the TERRITORY where the PATENTS claiming a priority date of May 19, 1989 and December 29, 1989 in a particular country for which a patent had been granted validly claiming Iloperidone or the manufacture, formulation or use hereof for use in the FIELD have expired, NOVARTIS' obligations to pay royalties for use of PATENTS in such country shell cease, and NOVARTIS and/or any of its SUBLICENSEES shall pay directly to HMRI a royalty for **** of **** percent (****%) on NOVARTIS', its AFFILIATES' and any SUBLICENSEES' annual NET SALES of the PRODUCT in each such country for **** after the expiration of the final remaining PATENT in each such country. After the end of such ****, no further royalties arising from sales of the PRODUCT in such country shall be due to HMRI and NOVARTIS, its AFFILIATES and any SUBLICENSEES shall be entitled to continue to use **** on a fully-paid, irrevocable basis in accordance with Section 10.3.

6. Subsection 3.4(b) of the Sublicense Agreement shall be del in its entirety and replaced by the following:

In the event a THIRD PART Y's generic version of Iloperidene is actively marketed in a process patent country (that is, any country in which only protection in relation to processes for the manufacture of Iloperidene has been obtained and not protection for Iloperidene as a new chemical entity per se) in the TERRITORY where a PATENT(s) has been granted validly claiming Iloperidene or the manufacture, formulation or use thereof for use in the FIELD exists, then subject to Sections 3,4(0) and (d) below, the royalty rate that NOVARTIS, shall pay to TITAN on NOVARTIS' or its AFFILLIATE's or SUBLICENSEE's annual NET SALES of PRODUCT in that process patent country shall be **** percent (****%) until such PATENT(s) expires, provided:

(i) ****

(ii) **** Unless otherwise agreed to by the PARTIES, ****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

****

7. For purposes of the Venda Sublicense Agreement or any approved sublicense thereunder, Subsection 5.6 of the Sublicense Agreement shall be deleted in its entirety.

8. Exchange-of Information and Confidentiality. The first sentence of Section 6.4 of the Sublicense Agreement is amended by deleting the words "and for ****"

9. Intellectual Property. The Sublicense Agreement is hereby amended to include the following provision:

Notwithstanding anything to the contrary in this Agreement, in the event that the Venda Sublicense Agreement expires or terminates, in its entirety or with respect to any country, (except as a result of material breach of that agreement by Novartis), then,

A. Novartis shall make certain and take all action necessary so that Venda delivers all inventions-or discoveries or improvements which arise from Venda's, its Affiliates' and Sublicensees' work relating to the development and/or manufacture of the Compound and/or Product (the "Venda IP") to Than or Aventis **** of the termination or expiration of the Venda Sublicense Agreement: and

B. Novartis will make certain that Titan or Aventis has full access, at Titan's or Aventis' request, to all Venda IP in the possession of Novartis (as the case may be).

If the Venda Sublicense Agreement expires or terminates with respect to a particular country, then the requirements set forth in Sections A and B above, and Titan's or Aventis' rights to the Venda IP, shall be limited to such country.

Titan shall grant a license in the Venda IP to Novartis as set forth in Section 2.1 of the Sublicense Agreement.

10. For purposes of the Venda Sublicense Agreement or any approved sublicense thereunder, Subsection 8.5 of the Sublicense Agreement shall be deleted in its entirety and replaced with the following:

> 8.5 Except as other Wise expressly provided in this. Sublicense Agreement, under.ne circumstances shall a party hereto, as a result of this Sublicense Agreement, obtain any ownership interest in or Other right to any technology, KNOW-HOW, patents pending patent applications, products, or biological material of the other party, or HMRI, including items owned, controlled, discovered, invented or developed by the other party, or HMRI, or transferred by the other party or HMRI to said party, at any time pursuant to this Sublicense Agreement which is not a direct result of the study, KNOW-HOW and experimentation of COMPOUND and PRODUCT.

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

11. The last two paragraphs of Section 17.1 of the Sublicense Agreement shall be deleted in their entirety and replaced with the following:

With copies to; Titan Pharmaceuticals, Inc.
****
Attention: ****
Telephone: ****
Facsimile: ****

and

****
Telephone: ****
Facsimile: ****

12. Effectiveness. This Amendment Agreement shall be deemed effective as of the date hereof.

13. Miscellaneous.

a. Agreement Amended. Subject to the provisions of this Section 13, this Amendment Agreement shall be deemed to be an amendment to the Sublicense Agreement. All references to the Agreements in any other document, instrument, agreement or writing hereafter shall be deemed to refer to the Agreements as amended hereby.

b. Representation. Titan represents as of the date of this Amendment Agreement that Titan has received the prior written consent as required by Section 12.1 (e)of the Sublicense Agreement to have the legal power, right and authority to enter into this Amendment Agreement.

c. Successors and Assigns. This Amendment Agreement shall be binding Upon and inure to the benefit of Titan and Novartis and their respective successors and assigns.

d. Governing Law. This Amendment Agreement shall be deemed tore been made in the State of New York and its form, execution, validity, construction and effect shall be determined in accordance with the laws of the State of New York (without regard to New York's or any other jurisdictions conflict of laws principles).

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

IN WITNESS WHEREOF, the panics hereby have executed this Agreement by proper persons thereunto duly authorized.

TITAN PHARMACEUTICALS, INC.

By: /s/ Sunil Bmonsel
Name: Sunil Bmonsel
Title: Exec. Vice President & COO

NOVARTIS PHARMA AG

By: /s/ Signatory Unknown
Name: _____
Title: _____

By: /s/ Hevre Girsault
Name: Hevre Girsault
Title: Head Global Partnering Business Development & Licencsing

By: /s/ Dr. Tom Chakraborti
Name: Dr. Tom Chakraborti
Title: Senior Legal Counsel

Exhibit 10.61

Confidential

FINAL VERSION

STOCK PURCHASE AGREEMENT

This STOCK PURCHASE AGREEMENT (the "**Agreement**"), is made as of December 22, 2014, by and between Vanda Pharmaceuticals Inc., a Delaware corporation (the "**Company**"), and Novartis Pharma AG, a corporation organized under the laws of Switzerland (the "**Purchaser**").

WHEREAS, the parties have entered into the Settlement Agreement, dated as of the date hereof, by and between the Company and the Purchaser (the "**Settlement Agreement**");

WHEREAS, in connection with the Settlement Agreement, the Purchaser wishes to purchase at the Closing (as defined below), upon the terms and conditions stated in this Agreement, US$25,000,000 of common stock of the Company, par value US$0.001 per share (the "**Common Stock**"), in cash as set forth herein;

WHEREAS, the Shares (as defined below) have been registered on a registration statement on Form S-3, File No. 333-191434 (the "**Registration Statement**"), under the Securities Act of 1933, as amended (the "**Securities Act**"), which was declared effective by the U.S. Securities and Exchange Commission (the "**SEC**") and remains effective as of the date hereof; and

WHEREAS, the Company and the Purchaser wish to agree to certain other rights and obligations in connection with the purchase, ownership, transfer and sale of the shares of Common Stock as set forth herein.

NOW THEREFORE, in consideration of the covenants and promises set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

Article I

PURCHASE AND SALE OF SHARES

1.1 Purchase of the Shares. Subject to the terms and conditions of this Agreement, the Purchaser agrees to purchase at the Closing (as defined below), and the Company agrees to sell and issue to the Purchaser, 1,808,973 shares of Common Stock, free and clear of any liens and encumbrances (the "**Shares**"), at a price per share equal to US $13.82, for an aggregate purchase price of US$25,000,000 (the "**Aggregate Purchase Price**").

1.2 Closing Date. The purchase and sale of the Shares shall take place at the offices of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, One Marina Park Drive, Boston, MA 02210 on December 31, 2014 or at such other time and place as Company and Purchaser may mutually agree after the satisfaction or waiver of the conditions set forth in Article VII (the "**Closing**"). The date and time of the Closing is hereafter referred to as the "**Closing Date**."

1.3 Form of Payment; Delivery of Shares. On the Closing Date, (i) the Purchaser shall pay the Aggregate Purchase Price to the Company by wire transfer of immediately available funds denominated in U.S. dollars to the account of the Company previously designated in writing to the Purchaser, and (ii) the Company shall have executed and delivered a copy of irrevocable instructions (the "**Irrevocable Transfer Agent Instructions**") to the transfer agent for the Company (the "**Transfer Agent**") and caused the Transfer Agent to deliver to the Purchaser the Shares, represented in a restricted, electronic book-entry account (the "**Restricted Electronic Shares**") maintained by the Transfer Agent on behalf of the Purchaser, with such evidence of such Restricted Electronic Shares delivered to the Purchaser within three Trading Days of the Closing. The Shares (and, if any stock certificates are subsequently issued representing the Shares, such stock certificates (any such stock certificates, together with any Restricted Electronic Shares or unrestricted book entry electronic shares, the "**Stock Certificates**")) shall be subject to the legends required pursuant to Section 2.9 hereof. The Company agrees that, except as may be required pursuant to Section 5.5, no instruction other than the Irrevocable Transfer Agent Instructions referred to in this Section 1.3 will be given by the Company to its Transfer Agent with respect to the Shares

Article II

REPRESENTATIONS AND WARRANTIES OF THE PURCHASER

The Purchaser represents and warrants to the Company that, as of the date hereof:

2.1 Due Organization. The Purchaser is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or ownership of its properties requires such qualification and failure to be so qualified would prevent such party from performing its obligations under this Agreement. The Purchaser is not in violation of any of the provisions of its certificate of incorporation, bylaws or other organizational or charter documents.

2.2 Due Authorization; Enforceability. The Purchaser has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement, and otherwise to carry out its obligations hereunder. The execution, delivery and performance of this Agreement by the Purchaser has been duly authorized by all necessary corporate action of the Purchaser, and no other act or proceeding on the part of or on behalf of the Purchaser or its stockholders is necessary to approve the execution and delivery of this Agreement, the performance by the Purchaser of its obligations hereunder and the consummation of the transactions contemplated hereby. This Agreement has been duly executed and delivered by the Purchaser and constitutes a legal, valid and binding obligation of the Purchaser, enforceable against the Purchaser in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium and similar laws relating to or affecting creditors generally, by general equity principles or by limitations on indemnification pursuant to public policy.

2.3 No Conflicts; No Consents. The execution, delivery and performance of this Agreement by the Purchaser (i) will not infringe any law, regulation, judgment or order

applicable to the Purchaser, (ii) is not and will not be contrary to the provisions of the constitutional documents of the Purchaser, and (iii) will not (with or without notice, lapse of time or both) result in any breach of the terms of, or constitute a default under, any instrument or agreement to which the Purchaser is a party or by which it or its property is bound, except in the case of clauses (i) and (iii) above, for such infringement, breach or defaults which would not prevent the Purchaser from performing its obligations hereunder. No consents or approvals are required to be obtained by the Purchaser in connection with the purchase of the Shares by the Purchaser, except where the failure to obtain such consents or approvals would not prevent the Purchaser from performing its obligations hereunder.

2.4 Common Stock. As of the date hereof, the Purchaser does not own any Common Stock or any securities convertible into or exchangeable or exercisable for Common Stock.

2.5 Investment Decision. In making its investment decision with respect to the purchase of the Shares hereunder, the Purchaser has relied solely on the Company's public filings as filed with the SEC.

2.6 Investment Intent. The Purchaser is acquiring the Shares in the ordinary course of its business and for its own account, and has no present intention of distributing any of the Shares nor any arrangement or understanding with any other Persons regarding the distribution of such Shares within the meaning of Section 2(11) of the Securities Act.

2.7 Broker-Dealer. The Purchaser is not a broker-dealer registered under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**").

2.8 Prospectus Delivery. The Purchaser consents to receipt of the Company's the prospectus supplement required by the Registration Statement pursuant to Rule 424(b) under the Securities Act (the "**Prospectus Supplement**"), to be filed following the execution of this Agreement, and the accompanying base prospectus forming part of the Registration Statement (the "**Prospectus**"), dated October 6, 2013, including the documents incorporated by reference therein, in portable document format, or PDF, via electronic mail.

2.9 No Brokers or Finders. The Purchaser is not a party to any contract, agreement or understanding with any person that would give rise to a valid claim against the Purchaser or the Company for a brokerage commission, finder's fee or like payment in connection with the transactions contemplated by this Agreement.

Article III

REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents and warrants to the Purchaser that, as of the date hereof, except as set forth in the SEC Reports (as defined below), which exceptions shall be deemed to be representations and warranties as if made hereunder:

3.1 Due Organization. The Company is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business

or ownership of its properties requires such qualification and failure to be so qualified would prevent the Company from performing its obligations under this Agreement, with the requisite corporate authority to own and use its properties and assets and to carry on its business as currently conducted.

3.2 Due Authorization; Enforceability. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement, and otherwise to carry out its obligations hereunder. The execution, delivery and performance of this Agreement by the Company has been duly authorized by all necessary action of the Company, and no other act or proceeding on the part of or on behalf of the Company or its stockholders is necessary to approve the execution and delivery of this Agreement, the performance by the Company of its obligations hereunder and the consummation of the transactions contemplated hereby. This Agreement has been duly executed and delivered by the Company and constitutes a legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium and similar laws relating to or affecting creditors generally, by general equity principles or by limitations on indemnification pursuant to public policy.

3.3 No Conflicts; No Consents. The execution, delivery and performance of this Agreement by the Company (i) will not infringe any law, regulation (including the rules and regulations of any self-regulatory organization to which the Company or its subsidiaries or securities are subject, including The NASDAQ Global Market ("**Nasdaq**"), judgment or order applicable to the Company or its subsidiaries, (ii) is not and will not be contrary to the provisions of the certificate of incorporation or bylaws of the Company, and (iii) will not (with or without notice, lapse of time or both) result in any breach of the terms of, or constitute a default under, any instrument or agreement to which the Company or its subsidiaries is a party or by which it or its property is bound, except in the case of clauses (i) and (iii) above, for such infringement, breach or defaults which would not materially impact the ability of the Company to perform any of its obligations hereunder or materially impact the transactions contemplated hereby. No consents, filings, notices or approvals are required to be obtained by the Company or its subsidiaries in connection with the sale of the Shares by the Company, except for (i) the filings required in accordance with Section 7.3(e) of this Agreement and (ii) those that have been made or obtained prior to the date of this Agreement.

3.4 Registration Statement and Prospectus. The issuance by the Company of the Shares has been registered under the Securities Act, the Shares are being issued pursuant to the Registration Statement and, subject to the Transfer restrictions set forth in Sections 5.1 and 5.2, all of the Shares are freely transferable and freely tradable by the Purchaser without restriction. The Registration Statement is effective and available for the issuance of the Shares thereunder and the Company has not received any written notice that the SEC has issued or intends to issue a stop-order with respect to the Registration Statement or that the SEC otherwise has suspended or withdrawn or intends to suspend or withdraw the effectiveness of the Registration Statement, either temporarily or permanently. Upon receipt of the Shares, subject to the Transfer restrictions set forth in Sections 5.1 and 5.2, the Purchaser will have good and marketable title to the Shares. The Registration Statement and any prospectus included therein, including the Prospectus and the Prospectus Supplement, complied in all material respects with the

requirements of the Securities Act and the rules and regulations of the SEC promulgated thereunder. At the time the Registration Statement and any amendments thereto became effective, at the date of this Agreement and at each deemed effective date thereof pursuant to Rule 430B(f)(2) of the Securities Act, the Registration Statement and any amendments thereto complied and will comply in all material respects with the requirements of the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus and any amendments or supplements thereto (including, without limitation the Prospectus Supplement), at the time the Prospectus or any amendment or supplement thereto was issued and at the Closing Date, complied, and will comply, in all material respects with the requirements of the Securities Act and did not, and will not, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The Company meets all of the requirements for the use of Form S-3 under the Securities Act for the offering and sale of the Shares contemplated by this Agreement, and the SEC has not notified the Company of any objection to the use of the form of the Registration Statement pursuant to Rule 401(g)(1) under the Securities Act.

3.5 SEC Filings. The Company is subject to and in compliance in all material respects with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. Since January 1, 2013, the Company has filed all reports required to be filed by it under the Exchange Act on a timely basis, including pursuant to Section 13(a) or 15(d) thereof. Such reports required to be filed by the Company under the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, together with any materials filed by the Company under the Exchange Act, whether or not any such reports were required to be filed (but not including any materials furnished), being collectively referred to herein as the "**SEC Reports**." As of their respective dates, the SEC Reports filed by the Company complied in all material respects with the requirements of the Exchange Act and the rules and regulations of the SEC promulgated thereunder, and none of the SEC Reports, when filed by the Company, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

3.6 Issuance of Securities. The Shares and the issuance and sale thereof are duly authorized and, upon payment for the Shares and issuance at the Closing pursuant to the terms of this Agreement, will (i) be duly and validly issued, fully paid and non-assessable, and shall be free and clear of all liabilities, debts, obligations, encumbrances, leases, indebtedness, liens, charges, security interests, and pledges, of whatever nature, whether fixed or contingent, disclosed or undisclosed, foreseen or unforeseen, except for restrictions on transfer set forth in this Agreement or imposed by applicable securities laws, (ii) have been issued in compliance with all applicable federal and state securities laws (assuming the accuracy of the Purchaser's representations and warranties in Section 5 herein) and (iii) will not have been issued in violation of any preemptive right, anti-dilution right, resale right, right of first refusal or similar right.

3.7 The NASDAQ Global Market. The Company's Common Stock is registered pursuant to Section 12(b) of the Exchange Act and is listed on Nasdaq. The Company is in compliance with applicable Nasdaq continued listing requirements, and to the Company's

knowledge there are no proceedings pending or threatened against the Company to revoke or suspend such listing. The Company has not received any notice of the delisting of the Common Stock from Nasdaq and has no knowledge of any facts or circumstances which would reasonably be expected to lead to delisting or suspension of the Common Stock in the next twelve months. The Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from Nasdaq, nor has the Company received any notification that the SEC, FINRA or the Nasdaq Stock Exchange LLC (inclusive with Nasdaq) is currently contemplating terminating such registration or listing. No consent, approval, authorization or order of, or filing, notification or registration with, Nasdaq is required for the listing and trading of the Shares on Nasdaq, except for (i) a Notification Form: Listing of Additional Shares; and (ii) a Notification Form: Change in the Number of Shares Outstanding.

3.8 No Integrated Offering. None of the Company nor, to the Company's knowledge, any of its Affiliates, nor any Person acting on their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Shares to require approval of stockholders of the Company under any applicable stockholder approval provisions, including, without limitation, under the rules and regulations of any exchange or automated quotation system on which any of the securities of the Company are listed or designated for quotation.

3.9 Application of Takeover Protections; Rights Agreement. No control share acquisition, interested stockholder, business combination, poison pill (including, without limitation, any distribution under a rights agreement) of the Company or other similar anti-takeover provision under its certificate of incorporation or bylaws or the laws of the jurisdiction of its incorporation is or would become applicable to the Purchaser solely as a result of the transactions contemplated by this Agreement.

3.10 No Brokers or Finders. The Company is not a party to any contract, agreement or understanding with any person that would give rise to a valid claim against the Company or the Purchaser for a brokerage commission, finder's fee or like payment in connection with the transactions contemplated by this Agreement.

3.11 Manipulation of Price. Neither the Company nor, to the knowledge of the Company, any Person acting on its behalf has, directly or indirectly, (i) taken any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Shares, (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Shares, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company.

Article IV

COVENANTS

4.1 Prospectus Supplement and Blue Sky. Immediately prior to execution of this Agreement, the Company shall have delivered, and as soon as practicable after execution of this

Agreement the Company shall file, the Prospectus Supplement with respect to the Shares as required under, and in conformity with, the Securities Act, including Rule 424(b) thereunder. If required, the Company, on or before the Closing Date, shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to, qualify the Shares for sale to the Purchaser at the Closing pursuant to this Agreement under applicable securities or "Blue Sky" laws of the states of the United States (or to obtain an exemption from such qualification), and shall provide evidence of any such action so taken to the Purchaser on or prior to the Closing Date. Without limiting any other obligation of the Company under this Agreement, the Company shall timely make all filings and reports relating to the offer and sale of the Shares required under all applicable securities laws (including, without limitation, all applicable federal securities laws and all applicable "Blue Sky" laws), and the Company shall comply with all applicable federal, state and local laws, statutes, rules, regulations and the like relating to the offering and sale of the Shares to the Purchaser.

4.2 Listing. The Company shall promptly secure the listing of all of the Shares upon Nasdaq (subject to official notice of issuance) (but in no event later than the Closing Date). The Company shall use its commercially reasonable efforts to maintain the Common Stock's listing on Nasdaq. The Company shall not take any action which would be reasonably expected to result in the delisting or suspension of the Common Stock on Nasdaq. The Company further agrees, if the Company applies to have the Common Stock traded on any other Eligible Market, it will then include in such application all of the Shares, and will take such other action as is necessary to cause all of the Shares to be listed or quoted on such other Eligible Market as promptly as possible. The Company shall pay all fees and expenses in connection with satisfying its obligations under this Section 4.2.

4.3 Expenses; Fees. Except as otherwise set forth in this Agreement, the Company and the Purchaser shall each pay their own expenses in connection with the transactions contemplated by this Agreement.

4.4 No Integrated Offering. The Company shall not, and shall use its commercially reasonable efforts to ensure that no Affiliate of the Company, nor any Person acting on their behalf shall, directly or indirectly, make any offers or sales of any security or solicit any offers to buy any security, under circumstances that would cause this offering of the Shares to require approval of stockholders of the Company under any applicable stockholder approval provisions, including, without limitation, under the rules and regulations of any exchange or automated quotation system on which any of the securities of the Company are listed or designated for quotation.

4.5 Disclosure of Transactions and Other Material Information. The Company shall, no later than 9:00 a.m., New York time, on the fourth Trading Day following the date of this Agreement, (i) issue a press release (the "**Press Release**") reasonably acceptable to the Purchaser disclosing all the material terms of the transactions contemplated by this Agreement and (ii) file a Current Report on Form 8-K describing all the material terms of the transactions contemplated by this Agreement in the form required by the Exchange Act (the "**8-K Filing**"). From and after the 8-K Filing, the Company shall have disclosed all material, non-public information (if any) delivered to the Purchaser by the Company or any of its subsidiaries, or any of their respective officers, directors, employees or agents in connection with the transactions contemplated by this

Agreement. For so long as the Purchaser continues to hold own any of the Shares, the Company shall not, and the Company shall cause each of its subsidiaries and each of its and their respective officers, directors, employees and agents, not to, provide the Purchaser with any material, non-public information regarding the Company or any of its subsidiaries from and after the issuance of the 8-K Filing without the express prior written consent of the Purchaser; it being acknowledged by the Purchaser, that information may be provided to the Purchaser or its Affiliates pursuant to the terms of one or more agreements now or hereafter existing by and between the Company and the Purchaser or its Affiliates. In the event of a breach of the covenant contained in the preceding sentence by the Company, any of its subsidiaries, or any of its or their respective officers, directors, employees and agents (as determined in the reasonable good faith judgment of the Purchaser), in addition to any other remedy provided herein, the Purchaser shall have the right to make a public disclosure, in the form of a press release, public advertisement or otherwise, of such material, non-public information without the prior approval by the Company, any of its subsidiaries, or any of its or their respective officers, directors, employees or agents. The Purchaser shall not have any liability to the Company, any of its subsidiaries, or any of its or their respective officers, directors, employees, stockholders or agents, for any such disclosure. Subject to the foregoing, neither the Company, its subsidiaries nor the Purchaser shall issue any press releases or any other public statements with respect to the transactions contemplated hereby; provided, however, the Company shall be entitled, without the prior approval of the Purchaser, to make any press release or other public disclosure with respect to such transactions (A) in substantial conformity with the 8-K Filing and contemporaneously therewith or following the closing of the transactions disclosed therein and (B) as is required by applicable law and regulations.

4.6 Further Assurances. The Company and the Purchaser agree to cooperate with each other and their respective officers, employees, attorneys, accountants and other agents, and, generally, do such other reasonable acts and things in good faith as may be necessary to effectuate the intents and purposes of this Agreement, subject to the terms and conditions hereof and compliance with applicable law, including, without limitation, taking reasonable action to facilitate the preparation and filing of any document or notice, or the taking of reasonable action to assist the other party hereto in complying with the terms hereof.

4.7 Indemnification of Purchaser. Subject to the provisions of this Section 4.7, the Company will indemnify and hold the Purchaser and its directors, officers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls the Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a "**Purchaser Party**") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such Purchaser Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or (b) any action instituted against the Purchaser Parties in any capacity, or any of them or their respective Affiliates, by any stockholder of the Company who is not an Affiliate of the Purchaser

Parties, with respect to any of the transactions contemplated by this Agreement (unless such action is based upon a breach of the Purchaser Party's representations, warranties or covenants under this Agreement or any agreements or understandings the Purchaser Parties may have with any such stockholder or any violations by the Purchaser Parties of state or federal securities laws or any conduct by the Purchaser Parties which constitutes fraud, gross negligence, willful misconduct or malfeasance). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, the Purchaser Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of the Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in the reasonable judgment of counsel to such Purchaser Party, representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by the Purchaser Party in this Agreement. The indemnification required by this Section 4.7 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred. The indemnity agreements contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

Article V

TRANSFER RESTRICTIONS

5.1 Restrictions on Transfer of Shares within Transfer Restriction Period. The Purchaser agrees not to sell, assign, transfer, pledge, hypothecate, or otherwise encumber or dispose of in any way (each, a "**Transfer**"), all or any part of or any interest in the Shares during the period beginning on the Closing Date and ending on January 27, 2015 (the "**Transfer Restriction Period**"). The Purchaser agrees that the foregoing restrictions preclude the Purchaser from engaging in any hedging or other transaction which is designed to or which reasonably could be expected to lead to or result in a sale or disposition of the Shares even if the Shares would be disposed of by someone other than the Purchaser. Such prohibited hedging or other transactions would include without limitation any short sale or any purchase, sale or grant of any right (including without limitation any put or call option) with respect to any of the Shares or with respect to any security that includes, relates to, or derives any significant part of its value from the Shares (any such transaction, a "**Hedging Transaction**"). Any Transfer of the Shares made within the Transfer Restriction Period shall be null and void, shall not be recorded on the books of the Company and shall not be recognized by the Company.

5.2 Restrictions on Transfer of Shares after Transfer Restriction Period. After the Transfer Restriction Period has expired, the Purchaser agrees that, until such time that the

Purchaser no longer owns any Shares, (i) the Purchaser shall not engage in any Hedging Transaction and (ii) any Transfer or Transfers of the Shares on any Trading Day shall not exceed fifteen percent (15%) of the average daily trading volume for the twenty (20) Trading Days immediately preceding such Trading Day (the "**Transfer Volume Limitation**"). Any Transfer of the Shares made in violation of the Transfer Volume Limitation shall be null and void, shall not be recorded on the books of the Company and shall not be recognized by the Company.

5.3 Lapse of Transfer Restrictions. Notwithstanding anything else under this Article V (but subject to the requirements of Section 2.9), all restrictions on Transfers under this Article V shall lapse and no longer be under effect if there has been a Change in Control.

5.4 Legends. The Purchaser understands that the Stock Certificates or other instruments representing the Shares will contain a legend (or be subject to a notation on the books and records of the Transfer Agent reflecting such the restrictions imposed by such legend) reading as follows until such time as the restrictions set forth in Section 5.1 and 5.2 of this Agreement are no longer required or until such time as such legend may be removed pursuant to Section 5.5, as applicable:

THE SHARES EVIDENCED HEREBY ARE SUBJECT TO A STOCK PURCHASE AGREEMENT (A COPY OF WHICH MAY BE OBTAINED FROM THE COMPANY) WHICH IMPOSES CERTAIN TRANSFER RESTRICTIONS ON THE HOLDER OF SUCH SHARES, AND BY ACCEPTING ANY INTEREST IN SUCH SHARES THE PERSON HOLDING SUCH INTEREST SHALL BE DEEMED TO AGREE TO AND SHALL BECOME BOUND BY SUCH TRANSFER RESTRICTIONS.

5.5 Removal of Legends. The legend (or notation) set forth in Section 5.4 shall be removed and the Company shall or shall cause the Transfer Agent to issue a Stock Certificate (either in physical certificated form or by electronic delivery at the applicable balance account at the Depository Trust Company) free from any legend or notation restricting in any way the Transfer of such Shares, to the holder of the Shares subject to such legend (or notation), promptly, but in any event no later than three (3) Trading Days following the delivery by such holder to the Company and the Transfer Agent of reasonable assurances and evidence that such sale, assignment or transfer of such Shares does not violate the Transfer restrictions set forth in this Article V. Upon the delivery of such [reasonable assurances and evidence] to the Company, the Company shall provide the Transfer Agent with such documentation as required by the Transfer Agent for it to effect the removal of such legend (or notation) and the issuance of such Shares. The Company and the Purchaser agree to cooperate with each other, and with the Transfer Agent, in order to facilitate the orderly and efficient removal of any legends upon Transfers of the Shares in compliance with this Agreement.

Article VI
STANDSTILL AGREEMENT

6.1 Standstill Agreement. Purchaser agrees that, from and after the date hereof until the date that is six (6) months after the Closing Date, it shall not, unless specifically invited in writing by the Company's Board of Directors, directly or indirectly: (i) effect or seek (including, without limitation, enter into any discussions, negotiations, agreements or understandings with any Third Party), offer or propose (whether publicly or otherwise) to effect, or cause or participate in, or in any way assist or facilitate any other Person to effect or seek, offer or propose (whether publicly or otherwise) to effect or participate in, (A) any acquisition of any securities (or beneficial ownership thereof), or rights or options to acquire any securities (or beneficial ownership thereof), or any assets or businesses, of the Company, (B) any tender or exchange offer, merger, acquisition or other business combination involving the Company, (C) any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to the Company, or (D) any "solicitation" of "proxies" (as such terms are used in the proxy rules of the SEC) or consent to vote any voting securities of the Company; (ii) form, join or in any way participating in a "group" (as defined under the Exchange Act) with respect to the Company; (iii) otherwise act, alone or in concert with others, to seek to control or influence the management, Board of Directors or policies of the Company or initiate or take any action to obtain representation on the Board of Directors of the Company; (iv) take any action which would or would reasonably be expected to force the Company to make a public announcement regarding any of the types of matters set forth in (i) through (iii) above; or (v) enter into any discussions or arrangements with any Third Party with respect to any of the foregoing. The Purchaser also agrees that it shall not request, directly or indirectly, any amendment or waiver of any provision of this Section 6.1 (including this sentence) by the Company or any of the Company's representatives.

Article VII

CONDITIONS PRECEDENT

7.1 Conditions to Each Party's Obligations. The respective obligations of the Company and the Purchaser to consummate the transactions contemplated by this Agreement shall be subject to the satisfaction at or before the Closing Date of each of the following conditions:

(a) no provision of any applicable law or regulation and no judgment, injunction, order or decree shall prohibit the Closing or shall prohibit (i) the Company from selling the Shares to the Purchaser or (ii) the Purchaser from acquiring the Shares from the Company;

(b) all notices to, filings with and consents of government agencies or regulatory bodies required to be made or obtained under any applicable law in connection with the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby and by the Settlement Agreement shall have been made or obtained; and

(c) the Closing (as defined in the Asset Transfer Agreement, dated as of the date hereof, by and between the Parties, the "**Asset Transfer Agreement**") shall have occurred.

7.2 Conditions to the Company's Obligation to Sell. The obligation of the Company hereunder to issue and sell the Shares to the Purchaser at the Closing is subject to the satisfaction, at or before the Closing Date of each of the following conditions, provided that these conditions are for the Company's sole benefit and may be waived by the Company at any time by providing the Purchaser with prior written notice thereof:

(a) the Purchaser shall have executed and delivered to the Company the Settlement Agreement, and such agreement shall be in full force and effect consistent with its terms;

(b) the Purchaser shall have delivered to the Company the Aggregate Purchase Price for the Shares being purchased by the Purchaser at the Closing by wire transfer of immediately available funds pursuant to the wire instructions provided by the Company; and

(c) the representations and warranties of the Purchaser shall be true and correct in all material respects (except for those representations and warranties which are qualified as to materiality, in which case such representations and warranties shall be true and correct in all respects) as of the date hereof and as of the Closing Date, as though made on and as of such date, except for such representations and warranties that speak as of a specific date, and the Purchaser shall have performed, satisfied and complied in all material respects with the covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Purchaser at or prior to the Closing Date; and the Purchaser shall have delivered to the Company a certificate, dated as of the Closing Date of an executive officer of the Purchaser to such effect.

7.3 Conditions to the Purchaser's Obligation to Purchase. The obligation of the Purchaser hereunder to purchase the Shares at the Closing is subject to the satisfaction, at or before the Closing Date of each of the following conditions, provided that these conditions are for the Purchaser's sole benefit and may be waived by the Purchaser at any time by providing the Company with prior written notice thereof:

(a) the Company shall have executed and delivered to the Purchaser the Settlement Agreement, and such agreement shall be in full force and effect consistent with its terms;

(b) the representations and warranties of the Company shall be true and correct in all material respects (except for those representations and warranties which are qualified as to materiality, in which case such representations and warranties shall be true and correct in all respects) as of the date when made and as of the Closing Date, as though made on and as of such date, except for such representations and warranties that speak as of a specific date; the Company shall have performed, satisfied and complied in all material respects with the covenants, agreements and conditions required by this Agreement to be performed, satisfied or complied with by the Company at or prior to the Closing Date; and the Company shall have

delivered to the Purchaser a certificate, dated as of the Closing Date of an executive officer of the Company to such effect;

(c) no statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction that prohibits the consummation of any of the transactions contemplated hereunder.

(d) the Common Stock shall not have been suspended, as of the Closing Date, by the SEC or Nasdaq from trading on Nasdaq nor shall suspension by the SEC or Nasdaq have been threatened, as of the Closing Date, either (A) in writing by the SEC or Nasdaq or (B) by falling below the minimum listing maintenance requirements of Nasdaq.

(e) Nasdaq shall have approved the listing of additional shares application for the Shares and the Company shall have delivered to Nasdaq a duly completed and executed Notification Form: Change in the Number of Shares Outstanding.

(f) the Company shall have obtained in a timely fashion any and all consents, permits, approvals, registrations and waivers necessary for consummation of the purchase and sale of the Shares, all of which shall be and remain so long as necessary in full force and effect.

(g) the Company shall deliver to the Purchaser on the Closing Date each of the following:

(i) a copy of the Irrevocable Transfer Agent Instructions, in the form previously provided to the Purchaser, that have been delivered to and acknowledged in writing by the Company's transfer agent.

(ii) a certificate evidencing the good standing of the Company in its jurisdiction of formation issued by the Secretary of State (or comparable office) of such jurisdiction of formation as of a date within ten (10) days of the Closing Date.

(iii) a certified copy of the Certificate of Incorporation as certified by the Secretary of State of the Company's jurisdiction of formation within ten (10) days of the Closing Date.

(iv) a certificate, in the form previously provided to the Company, executed by an officer of the Company and dated as of the Closing Date, certifying (i) the resolutions authorizing the execution, delivery and performance of the transaction contemplated under this Agreement as adopted by the Company's board of directors in a form reasonably acceptable to the Purchaser, (ii) the Certificate of Incorporation and (iii) the Bylaws, each as in effect at the Closing.

Article VIII

TERMINATION.

8.1 Termination. This Agreement shall automatically terminate, and be of no further force or effect, without liability to either Party, immediately upon the termination of the Asset Transfer Agreement.

Article IX

MISCELLANEOUS

9.1 Transfer Agent Fees and Expenses. The Company shall pay all transfer agent fees, stamp taxes and other taxes and duties levied in connection with the sale and issuance of the Shares to the Purchaser.

9.2 Governing Law; Jurisdiction. This Agreement shall be deemed to have been made and entered into within the State of New York and shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to the principles or rules of conflict of laws of the State of New York or of any other jurisdiction to the extent such principles or rules would require or permit the application of the laws of any jurisdiction other than the State of New York. Each of the Parties irrevocably agrees that any legal action or proceeding arising out of or relating to this Agreement brought by any other Party or its successors or assigns shall be brought and determined in the federal courts located in the State of New York, or, if such federal courts lack jurisdiction, in the state courts of the State of New York located in Manhattan, and each of the Parties hereby irrevocably submits to the exclusive jurisdiction of the aforesaid courts for itself and with respect to its property, generally and unconditionally, with regard to any such action or proceeding arising out of or relating to this Agreement and the transactions contemplated hereby. Each of the Parties agrees not to commence any action, suit or proceeding relating thereto except in the courts described above in New York, other than actions in any court of competent jurisdiction to enforce any judgment, decree or award rendered by any such court. Each of the Parties further agrees that notice as provided herein shall constitute sufficient service of process and the Parties further waive any argument that such service is insufficient. Each of the Parties hereby irrevocably and unconditionally waives, and agrees not to assert, by way of motion or as a defense, counterclaim or otherwise, in any action or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby, (i) any claim that it is not personally subject to the jurisdiction of the courts described herein for any reason, (ii) that it or its property is exempt or immune from jurisdiction of any such court or from any legal process commenced in such courts (whether through service of notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise) and (iii) that (A) the suit, action or proceeding in any such court is brought in an inconvenient forum, (B) the venue of such suit, action or proceeding is improper or (C) this Agreement or the subject matter hereof, may not be enforced in or by such courts.

9.3 Survival. The representations, warranties, agreements and covenants contained herein shall survive until the 12 (twelve) month anniversary of the Closing.

9.4 Waiver of Breach. Except as otherwise expressly provided in this Agreement, any term of this Agreement may be waived only by a written instrument executed by a duly authorized representative of the party waiving compliance. The delay or failure of either party at any time to require performance of any provision of this Agreement shall in no manner affect such party's rights at a later time to enforce the same. No waiver by either party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

9.5 Modification. No amendment or modification of any provision of this Agreement shall be effective unless in writing signed by a duly authorized representative of each party. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by a duly authorized representative of each party.

9.6 Severability. In the event any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

9.7 Entire Agreement. This Agreement, together with the Settlement Agreement, constitutes the entire agreement between the parties relating to its subject matter and supersedes all prior or contemporaneous agreements, understandings or representations, either written or oral, between the Company and the Purchaser with respect to such subject matter.

9.8 Notices. Unless otherwise agreed by the parties or specified in this Agreement, all communications between the parties relating to, and all written documentation to be prepared and provided under, this Agreement shall be in the English language. Any notice required or permitted under this Agreement, unless otherwise specified herein, shall be: (a) delivered personally; (b) sent by registered or certified mail (return receipt requested and postage prepaid); (c) sent by express courier service providing evidence of receipt, postage pre-paid where applicable; or (d) sent by facsimile (receipt verified and a copy promptly sent by another permissible method of providing notice described in paragraphs (a), (b) or (c)), to the following addresses of the parties or such other address for a party as may be specified by like notice:

If to the Company:

Vanda Pharmaceuticals Inc.
2200 Pennsylvania Avenue, NW, Suite 300E
Washington, DC 20037
Telephone: (202) 734-3428
Facsimile: (202) 296-1450
Attention: Chief Financial Officer

With a copy, which shall not constitute notice, to:

Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP
One Marina Park Drive
Boston, MA 02210
Telephone: (617) 648-9100
Facsimile: (617) 648-9199
Attention: Gregg A. Griner

If to the Purchaser:

Novartis Pharma AG
Forum 1
Novartis Campus
CH-4056 Basel, Switzerland
Telephone: +41 61 324 0888
Facsimile: +41 61 324 2100
Attention: General Counsel
Email: sean.reilly@novartis.com

With a copy, which shall not constitute notice, to:

Kaye Scholer LLP
250 West 55th Street
New York, NY, 10019-9710
Telephone: 212-836-8032
Attention: Derek Stoldt
Email: Dstoldt@kayescholer.com

Unless otherwise specified herein, any notice required or permitted to be given concerning this Agreement shall be effective upon receipt by the party to whom it is addressed or within seven days of dispatch whichever is earlier.

9.9 Assignment. This Agreement shall not be assignable by either party to any Affiliate (as defined below) or Third Party hereto without the written consent of the other party hereto. Subject to the foregoing, this Agreement shall inure to the benefit of each party, its successors and permitted assigns. Any assignment of this Agreement in contravention of this Section 9.9 shall be null and void.

9.10 Headings; Interpretation. The captions to the several Articles and Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression; (b) the singular shall include the plural and vice versa; (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable; and (d) references to Nasdaq shall include any successor or other national securities exchange or market on which the Common Stock is then listed.

9.11 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument.

9.12 No Third Party Beneficiaries. Unless otherwise expressly stated herein, nothing in this Agreement, express or implied, is intended to confer upon any Person (as defined below) other than the parties hereto or their respective permitted assignees and successors in interest any rights or remedies under or by reason of this Agreement.

9.13 Public Disclosures and Statements. The Company and the Purchaser agree that neither party nor any of their Affiliates will make any public disclosure regarding this Agreement except as set forth in Section 4.5 above or as contemplated by the Settlement Agreement; provided, however, that this provision will not limit either party's right to effect any public disclosure that it is or may be required to make under applicable law, or the rules of applicable securities exchanges, in each case upon advice of legal counsel, including that the Company will be entitled to file a copy of this Agreement as an exhibit to the Company's reports filed with the SEC.

9.14 Specific Performance and Injunctive Relief. The Company and the Purchaser agree that if any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached, irreparable damage would occur, no adequate remedy at law would exist and damages would be difficult to determine, and that the parties shall be entitled to specific performance of the terms hereof and injunctive relief, in addition to any other remedy at law or equity.

9.15 Certain Definitions.

(a) "**Affiliate**" of a party shall mean any Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such party, as the case may be, for as long as such control exists. As used herein, "control" shall mean: (a) to possess, directly or indirectly, the power to direct the management and policies of such Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of at least 50% (or such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital in such Person.

(b) "**Change in Control**" shall mean the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events: (a) there is consummated a sale of all or substantially all of the assets of the Company and its subsidiaries in one or a series of integrated transactions not in the ordinary course of business to a Third Party; (b) any Person or group of Persons within the meaning of Section 13(d)(3) of the Exchange Act becomes the beneficial owner, directly or indirectly, of 50% or more of the then outstanding Common Stock of the Company; or (c) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the

surviving entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their ownership of the outstanding Common Stock of the Company immediately prior to such transaction; or (d) individuals who, on the date of this Agreement, are members of the board of directors of the Company (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the members of the board of directors; provided, however, that if the appointment or election (or nomination for election) of any new member of the board of directors was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Agreement, be considered as a member of the Incumbent Board.

(c) "**Eligible Market**" means each of The New York Stock Exchange, the NYSE Amex, Nasdaq or the Nasdaq Global Select Market.

(d) "**Person**" means any individual, corporation, partnership, firm, association, joint venture, joint stock company, trust or other entity, or any government or regulatory administrative or political subdivision or agency, department or instrumentality thereof.

(e) "**Third Party**" shall mean any Person other than the Company, the Purchaser and their respective Affiliates.

(f) "**Trading Day**" shall mean a day on which the Common Stock is traded for a regular trading session on Nasdaq.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

VANDA PHARMACEUTICALS INC.

By: /s/ Mihael H. Polymeropoulos, M.D.
Name: Mihael H. Polymeropoulos, M.D.
Title: Chief Executive Officer

NOVARTIS PHARMA AG

By: /s/ Matt Owens
Name: Matt Owens
Title: Head Legal GBS & Strategy

By: /s/ Marc Ceulemans
Name: Marc Ceulemans
Title: Head Strategic Venture Capital Fund & Pharma Equities

EXHIBIT 10.62

CONFIDENTIAL TREATMENT REQUESTED

FINAL VERSION

LICENSE AGREEMENT

between

NOVARTIS PHARMA AG

and

VANDA PHARMACEUTICALS INC.

Table of Contents

CONFIDENTIAL TREATMENT REQUESTED

LICENSE AGREEMENT

This LICENSE AGREEMENT ("**License Agreement**") is made as of this 22nd day of December, 2014, by and between Novartis Pharma AG, a company organized under the laws of Switzerland and located at Lichtstrasse 35, 4056 Basel, Switzerland ("**Novartis**") and Vanda Pharmaceuticals Inc., a company organized under the laws of the State of Delaware, United States with its principal executive offices located at 2200 Pennsylvania Avenue, NW, Suite 300E, Washington, D.C. 20037 ("**Vanda**"). Novartis and Vanda are each referred to individually as a "**Party**" and together as the "**Parties**."

RECITALS

WHEREAS, Novartis and/or its Affiliates own or control the Licensed IP;

WHEREAS, Novartis and/or its Affiliates desire to grant to Vanda, and Vanda desires to obtain rights to, the Licensed IP exclusively related to Product in the Territory; and

WHEREAS, Vanda desires to develop, market, sell, distribute, manufacture, have manufactured and commercialize Product in the Territory.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the Parties hereby agree as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 **Definitions.** The capitalized terms used in this License Agreement shall have the meanings as defined below:

"**Accounting Standards**" means with respect to Vanda, US GAAP (United States Generally Accepted Accounting Principles), as generally and consistently applied throughout Vanda's organization. Vanda shall promptly notify Novartis in the event that it changes the Accounting Standards pursuant to which its records are maintained, it being understood that Vanda may only use internationally recognized accounting principles (e.g. International Financial Reporting Standards, US GAAP, etc.).

"**Affiliate**" means, with respect to a Party, any Person that directly or indirectly controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "**control**" shall mean: (a) direct or indirect, ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation; (b) fifty percent (50%) or more of the equity interest in the case of any other type of legal entity or status as a general partner in any partnership; (c) any other arrangement whereby the entity or Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity; (d) if a Party is exposed, or has rights, to variable returns from its involvement with an entity or Person and has the ability to affect its returns through its power over such entity or Person; or (e) the ability to cause the direction of the management or policies of a corporation or other entity. In the case of entities organized under the Laws of certain countries, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity.

"**Auditor**" shall have the meaning set forth in Clause 10.4(b) of this License Agreement.

"**Business Day**" means a day (other than a Saturday, Sunday or a public holiday) on which the banks are open for business in Basel, Switzerland and New York, New York.

"**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

"**Calendar Year**" means a period of twelve (12) consecutive calendar months ending on December 31.

"**Commercialize**" means to use, market, promote, distribute, import, offer to sell and/or sell Product, and "**Commercialization**" means commercialization activities relating to the Product, including activities relating to using, marketing, promoting, distributing, importing, offering for sale and/or selling the Product.

"**Commercially Reasonable Efforts**" means efforts ****

"**Competition Law**" means the Sherman Act, as amended, the Clayton Act, as amended, the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, the Federal Trade Commission Act, as amended, and all other federal, state or foreign statutes, rules, regulations, orders, decrees, administrative and judicial doctrines and other Laws, including any antitrust, competition or trade regulation Laws that are designed or intended to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade or lessening competition through merger, acquisition or otherwise.

"**Contract**" means any agreement, contract, purchase order, sales order, tender or other legally binding commitment or arrangement.

"**Develop**" or "**Development**" means drug development activities, including, without limitation, research, test method development and stability testing, assay development and audit development, toxicology, formulation, quality assurance/quality control development, statistical analysis, clinical studies, packaging development, regulatory affairs, and the preparation, filing and prosecution of NDAs.

"**Development & Regulatory Report**" means a written report or reports providing a summary of Vanda's Development and regulatory activities for the Product, sufficient to permit Novartis to evaluate Vanda's adherence to the terms of this License Agreement.

"**Drug Substance**" means the active pharmaceutical ingredient known as AQW051, ****.

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

"**Effective Date**" means the Closing Date as that term is defined in the Asset Transfer Agreement signed contemporaneously with this License Agreement between the Parties and Novartis AG.

"**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

"**Field**" shall mean ****.

"**First Commercial Sale**" means, with respect to the Product, the first arm's length sale to a Third Party in the Territory.

"**Force Majeure**" means any event which is beyond the reasonable control of the Party affected, including but not limited to the following events: earthquake, storm, flood, fire or other acts of nature, epidemic, war, riot, public disturbance, strike or lockouts, government actions, terrorist attack or the like.

"**Generic Entry**" means, with respect to a Product in a country, the following has occurred ****.

"**Generic Equivalent**" means a product with the same active ingredient and administration route as the Product.

"**Global Medical Information**" shall mean any medical or clinical information, adverse event reports and/or safety information related to the Product and/or the Drug Substance owned or controlled by or on behalf of Novartis and/or its Affiliates in the Field, and including but not limited to clinical study reports, pre-clinical data and toxicity data that are in existence on the Effective Date.

"**cGCP**" means the current good clinical practices.

"**cGLP**" means the current good laboratory practices.

"**Good Manufacturing Practice**" or "**GMP**" means the current good manufacturing practices (cGMP) and all applicable governmental rules and regulations as applied at the site(s) of manufacture and control, as amended from time to time and in effect during the term of this License Agreement.

"**Governmental Authorizations**" means any approval, permit, license, certificate, franchise, permission, clearance, registration, qualification or other authorization issued, granted, given or otherwise made available by or under the authority of any Governmental Entity or pursuant to any Law.

"Governmental Entity" means any court, agency, authority, department, legislative or regulatory body or other instrumentality of any (a) government, (b) country, (c) national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country, (d) supranational organization of which any such government or country is a member, or (e) quasi-governmental authority or self-regulatory organization of competent authority.

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"**IND**" means an Investigational NDA in the Territory filed with the FDA.

"**Information**" means all Licensed IP and other proprietary information and data of a financial, commercial or technical nature which the disclosing Party or any of its Affiliates (in the case of Novartis) has supplied or otherwise made available to the other Party or Affiliates (in the case of Novartis), under this License Agreement and whether made available orally, in writing or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae in relation to this License Agreement.

"**Infringement**" has the meaning ascribed to such term in Clause 14.1.

"**Insolvency Event**" means, in relation to Vanda, any one of the following: (a) Vanda is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against Vanda (except for involuntary bankruptcy proceedings which are dismissed within one-hundred and twenty (120) days); (b) an administrative receiver, receiver and manager, interim receiver, custodian, sequestrator or similar officer is appointed for substantially all of the assets of Vanda; (c) a resolution to wind up Vanda shall have been passed other than a resolution for the solvent reconstruction or reorganization of Vanda; or (d) a resolution shall have been passed by Vanda's board of directors to make an application for an administration order or to appoint an administrator for substantially all of the assets of Vanda.

"**Know-How**" means all existing and available technical information, know-how and data, including inventions (whether patentable or not), discoveries, trade secrets, package specifications, chemical specifications, analytical test methods, stability data, testing data, product specifications, instructions, processes, formulation information, validation documents, materials, drawings, formulae, reports, and other technology and techniques in each case to the extent related to the Product or to the Drug Substance in the Field including all biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical safety, safety data, manufacturing and quality control, preclinical and clinical data to the extent relevant to the manufacture, registration, use or commercialization of the Product but excluding Manufacturing Technology, and that are in existence and owned or controlled by Novartis and/or its Affiliates on the Effective Date.

"**Law**" means any statute, law, ordinance, requirement, regulatory rule, code or order of a Governmental Entity.

"**Legal Proceeding**" means any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Entity or any arbitrator or arbitration panel.

"**Licensed IP**" means any Global Medical Information, Know How, Information, Patent Rights and Manufacturing Technology (and any intellectual property rights in the foregoing) in each case to the extent reasonably useful or necessary for the Development and/or Commercialization of Product in the Field in the Territory and in each case that is in existence and owned or controlled by Novartis and/or its Affiliates or which Novartis and/or its Affiliates have a right to license as of the Effective Date. Without limiting the foregoing, the Licensed IP includes the Patent Rights set forth in **Schedule B**.

"**Losses**" shall have the meaning set forth in Clause 13.1 hereof.

"**Manufacturing Technology**" means all technology, trade secrets, know-how and proprietary information in each case to the extent reasonably useful or necessary for the manufacture, validation, packaging, release testing, stability and/or shelf life of the Product and/or the Drug Substance in the Field, including the Product's formulation and/or other records related to the manufacturing process and that are in existence and owned or controlled by Novartis and/or its Affiliates on the Effective Date.

"**NDA**" means a New Drug Application filed with the FDA in the Territory for authorization to market the Product, as defined in the applicable Laws and regulations.

"**Net Sales**" means the net sales on behalf of Vanda and any of its Affiliates ****

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****

"**Novartis Indemnitees**" shall have the meaning set forth in Clause 13.2 hereof.

"**Patent Rights**" means all patents and patent applications, including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, extensions, registrations, and supplemental protection certificates and the like of any of the foregoing.

"**Person**" means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization or other entity.

"**Product**" means any product for use in the Field in the Territory containing the Drug Substance which is Developed or Commercialized using the Licensed IP.

"**Regulatory Approval**" means, with respect to the Product, any approval (notwithstanding the indication), registration, license or authorization from the FDA to market and sell such Product in the Territory.

"**Regulatory Filings**" means, with respect to the Drug Substance or Product, any submission to the FDA of any appropriate regulatory application, and shall include any IND or NDA.

"**Royalty(ies)**" shall have the meaning set forth in Clause 9.1.

"**Royalty Term**" shall have the meaning set forth in Clause 9.1.

"**Sales, Royalty & Commercialization Report**" means a written report or reports showing each of: **** For the avoidance of doubt such written report shall also show details on the aforementioned (a) and (c) items for: (i) Vanda, its Affiliates and authorized sub-licensees; (ii) last Calendar Quarter and year to date data, for example, up to the last month of the last Calendar Quarter; and (iii) for each Product.

"**Territory**" means worldwide.

"**Third Party**" shall mean any Person other than a Party or an Affiliate of a Party.

"**USD**" **or "US Dollars"** means the lawful currency of the United States of America.

"**Valid Claim**" means a claim of an issued patent that has not expired or been revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period).

"**Vanda Indemnitees**" shall have the meaning set forth in Clause 13.1.

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1.2 **Interpretation.** In this License Agreement unless otherwise specified:

(a) "includes" and "including" shall mean respectively includes and including without limitation;

(b) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;

(c) the Schedules and other attachments form part of the operative provision of this License Agreement and references to this License Agreement shall, unless the context otherwise requires, include references to the Schedules and attachments;

(d) references to Clauses and subclauses are to Clauses and subclauses of this License Agreement unless otherwise specified;

(e) the headings in this License Agreement are for information only and shall not be considered in the interpretation of this License Agreement;

(f) any reference to "writing" or "written" includes faxes and any legible reproduction of words delivered in permanent and tangible form (but does not include email);

(g) the words "hereof", "herein" and "hereunder" and words of like import used in this License Agreement shall refer to this License Agreement as a whole and not to any particular provision of this License Agreement;

(h) references to any Contract are to that Contract as amended, modified or supplemented from time to time in accordance with the terms hereof and thereof; and

(i) the Parties agree that the terms and conditions of this License Agreement are the result of negotiations between the Parties and that this License Agreement shall not be construed in favor of or against any Party by reason of the extent to which any Party participated in its preparation.

2. LICENSE

2.1 **License Grant from Novartis to Vanda.** Subject to the terms and conditions of this License Agreement, Novartis grants to Vanda an exclusive (including as to Novartis), perpetual, irrevocable (other than as set forth in Clause 15), royalty-bearing, sublicensable (subject to Clause 2.2 below), assignable (subject to Clause 18.2 below) license under the Licensed IP to use the Licensed IP solely to Develop and Commercialize the Product in the Field in the Territory and to manufacture or have manufactured the Product for use in the Field in the Territory.

2.2 **Sublicensing.**

(a) **By Vanda.** Subject to Clause 2.2(b) below, Vanda may sublicense the rights granted to it under Clause 2.1 of this License Agreement without the prior written consent of Novartis.

(b) **Sublicense Requirements.** Any sublicense by Vanda will be subject to a written agreement that ****

2.3 **Reservation of Rights by Novartis.** Vanda agrees that Novartis retains all rights under the Licensed IP not expressly granted to Vanda in Clause 2.1. Vanda acknowledges and agrees that as between the Parties, Novartis and/or its Affiliates are the sole owner(s) of all right, title and interest in and to the Licensed IP, and Vanda has not acquired, and shall not acquire, any right, title or interest in or to the Licensed IP pursuant to this License Agreement other than the rights expressly set forth in Clause 2.1.

3. TRANSFER OF LICENSED IP

3.1 **Transfer**. Novartis shall provide to Vanda (a) within **** from the Effective Date all tangible documentation and records embodying the Licensed IP owned or controlled by Novartis and its Affiliates, which if in electronic form shall be readily useable with off-the-shelf commercially available software and equipment, (b) until **** following Novartis' delivery of all materials under Clause 3.1(a), reasonable access to the personnel at Novartis and its Affiliates to provide instructions and answer questions regarding the application of the Licensed IP (to the extent known by Novartis and its Affiliates), and (c) upon Vanda's request, reasonable access to the manufacturing sites of Novartis or of its Affiliates within the Territory used for the manufacturing and/or packaging of the Product (subject to any policies and guidelines reasonably imposed by Novartis and its Affiliates).

4. DEVELOPMENT AND REGULATORY REGARDING PRODUCT

4.1 **Development**. Subject to Clause 4.2, Vanda will be responsible for conducting, without cost to Novartis, such research and preclinical, clinical, regulatory and other Development of the Drug Substance and/or Product as it determines appropriate in its sole discretion and at its sole risk. Novartis shall not have any obligation to provide any support to Vanda regarding the Development of the Product in the Field in the Territory (except as strictly described in this License Agreement).

4.2 **Development Diligence, Semi-Annual Reports**. Notwithstanding anything to the contrary, Vanda shall itself, or through its Affiliates or authorized sublicensees, **** Develop the Product in the Field in the Territory. ****, Vanda shall provide Novartis with a Development & Regulatory Report ****.

4.3 **Regulatory**.

(a) Vanda will, as it determines appropriate in its sole discretion but subject to Clause 4.2, (i) determine the regulatory plans and strategies for the Drug Substance and Product, (ii) (either itself or through its authorized sublicensees) make all Regulatory Filings with respect to the Product and (iii) will be responsible for obtaining and maintaining Regulatory Approval in the Territory in the name of Vanda or its authorized sublicensees.

(b) Without prejudice to Clause 4.1 above, Novartis shall reasonably cooperate with and provide assistance to Vanda solely by providing reasonable access to the Licensed IP in connection with Regulatory Filings to the FDA for a Product.

4.4 **Compliance**. Vanda agrees that in performing its obligations under this License Agreement, in particular with regard to the Product: (a) it shall comply with all applicable current international regulatory standards, including cGMP, cGLP, cGCP and other rules, regulations and requirements; and (b) it will not knowingly employ or use any Person that has been debarred under Section 306(a) or 306(b) of the U.S. Federal Food, Drug and Cosmetic Act.

5. MANUFACTURING AND COMMERCIALIZATION OF THE PRODUCT

5.1 **Manufacturing**. Vanda (or their designated authorized sublicensee(s)) hereby acknowledge and agree that they will be solely responsible for the manufacture and supply of the Drug Substance and the Product and for the Commercialization of the Product under this License Agreement as Vanda determines appropriate in Vanda's sole discretion.

5.2 **Commercialization**. Vanda will be solely responsible for all aspects of Commercialization of the Product in the Territory, including planning and implementation, distribution, booking of sales, pricing and reimbursement as they determine appropriate in their sole discretion and at their sole risk. Notwithstanding anything to the contrary, following Regulatory Approval in a particular country within the Territory, Vanda shall themselves, or through their authorized sublicensees, **** Commercialize the Product in the Field in the Territory. Novartis shall not have any obligation to provide any support to Vanda regarding the Commercialization of the Product in the Field in the Territory (except as strictly described in this License Agreement).

6. QUALITY CONTROL AND APPROVAL PROCEDURES

6.1 **Standards of Quality**. Vanda agrees to, and to cause its Affiliates to, strictly comply, at least, with applicable Good Manufacturing Practice in the manufacture of Product(s), as well as to comply with applicable Laws and regulations in the marketing, sale, and distribution of Product(s).

7. OWNERSHIP OF INVENTIONS & PROSECUTION

7.1 **Ownership of Inventions**. Novartis shall have no rights in any inventions, Know-How or similar intellectual property rights created and developed by Vanda arising from Vanda's activities under this License Agreement, including any patent applications and patents covering such inventions, all of which shall be owned by Vanda.

7.2 **Prosecution**. **** will be responsible for filing, prosecuting and maintaining the Licensed IP ****. ****

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****, it being understood and agreed that **** shall make all decisions relating thereto. **** will notify **** of any decision not to file applications for, or to cease prosecution and/or maintenance of, or not to continue to pay the expenses of prosecution and/or maintenance of, any Licensed IP. **** will provide such notice at least **** prior to any filing or payment due date, or any other due date that requires action, in connection with such Licensed IP. In such event, **** shall permit ****, at its sole discretion and expense, to file or to continue prosecution or maintenance of such Licensed IP. **** shall co-operate with **** in applying for patent term extensions for Licensed IP where applicable in any country of the Territory (including but not limited to Supplementary Protection Certificates). **** shall have full responsibility and authority in the decisions regarding filing for the foregoing patent term extensions at its own expense.

8. INTENTIONALLY OMITTED

9. FINANCIAL PROVISIONS

9.1 **Royalty Payments**.

(a) In consideration of the licenses and rights granted to Vanda hereunder, during the Royalty Term (as defined below), Vanda will make royalty payments to Novartis on aggregate Net Sales of Product(s) in the Territory **** by Vanda and its authorized sublicensees at the rate of ("**Royalty**"):

Annual Net Sales (USD)	*Percentage*
****	****
****	****
****	****

(b) Royalties will be payable on a Product-by-Product and country-by-country basis from First Commercial Sale of the Product in the Territory and shall continue to be paid until **** ("**Royalty Term**").

(c) In the event of a Generic Entry in a country, then the royalty rates applicable to Net Sales of such Product in such country shall be ****

10. REPORTS AND PAYMENT TERMS

10.1 **Payment Terms**.

(a) Within **** following the First Commercial Sale of a Product (on a Product-by-Product

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basis), Vanda will provide to Novartis a Sales, Royalty & Commercialization Report. Novartis shall submit an invoice to Vanda substantially in the form provided by Novartis with respect to the Royalty amount shown therein. Vanda shall pay such Royalty amount within **** after the date of its receipt of the invoice.

(b) All payments from Vanda to Novartis shall be made by wire transfer of immediately available funds in US Dollars to the credit of such bank account or accounts as may be designated by Novartis in this License Agreement or in writing to Vanda from time to time. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

10.2 **Currency**. All payments under this License Agreement shall be payable in US Dollars. When conversion of payments from any foreign currency is required to be undertaken by Vanda, the USD equivalent shall be calculated using **** then-current standard exchange rate methodology as applied in its external reporting.

10.3 **Taxes**. Any taxes paid or required to be withheld by Vanda on account of royalties payable by such party under this License Agreement shall be indicated on the accounting described in Clause 10.1(a) hereof and deducted from the amount of royalties otherwise due. Vanda shall secure and send to Novartis proof of any such taxes withheld and paid by Vanda.

10.4 **Records and Audit Rights**.

(a) Vanda shall keep complete, true and accurate books and records in accordance with its Accounting Standards in relation to this License Agreement, including in relation to Net Sales and Royalties. Vanda will keep such books and records for at least ****.

(b) Novartis shall have the right for a period of **** after receiving each Sales, Royalty & Commercialization Report to appoint an internationally-recognized independent accounting firm ("**Auditor**") to inspect the relevant records of Vanda or its authorized sublicensees to verify such reports, statements, records or books of accounts, as applicable. No records for any given year may be audited more than once and Vanda and its Affiliates will not be audited more than once per year.

(c) In order to initiate an audit, Novartis must provide written notice to Vanda, which notice shall include one or more proposed dates for the audit and which notice shall be given not less than sixty (60) days prior to the first proposed audit date. Vanda will reasonably accommodate the scheduling of such audit. Prior to commencing the work, the Auditor will enter into an appropriate confidentiality agreement with Vanda. The Auditor will have the right to disclose to Novartis its conclusions regarding any payments owed under this License Agreement. For the avoidance of doubt, notwithstanding the foregoing, the Auditor shall not disclose to Novartis any more detailed information that Novartis would have otherwise been entitled to receive pursuant to this License Agreement. Novartis agrees to hold in confidence all information received and all information learned in the course of any audit or inspection, except to the extent that such information is not confidential and/or it is necessary to disclose it to enforce its rights under this License Agreement or if disclosure is required by Law.

(d) Vanda and Vanda's authorized sublicensees shall make their records available for inspection by the Auditor during regular business hours at such place or places where such records are customarily kept, to verify the accuracy of the Sales & Royalty Reports and compliance with this License Agreement

(e) Novartis shall pay for such audits, as well as its own expenses associated with enforcing its rights with respect to any payments hereunder, except that, if an underpayment of **** is discovered, the reasonable fees and expenses charged by or incurred by the Auditor shall be paid by Vanda.

(f) In the event that the final result of the inspection reveals an undisputed underpayment or overpayment by Vanda, the underpaid or overpaid amount shall be ****.

11. FURTHER OBLIGATIONS

11.1 **Actions**. No Party shall do or omit to do anything that would substantially diminish or impair the rights of Novartis or Vanda in the Licensed IP, provided however, that the foregoing shall not restrict Vanda's discretion as to the Development and Commercialization of the Product so long as Vanda comply with their obligation ****. If any Party becomes aware of any claim or challenge to, the validity of the Licensed IP, it shall promptly inform the other Parties.

11.2 **Further Assurances**.

(a) The Parties shall, and shall cause their Affiliates to, promptly cooperate with each other and their Affiliates and provide such information and assistance as may be reasonably requested by the other in connection with any filings or other actions contemplated by any Competition Law. In connection with and without limiting the foregoing, the Parties shall and shall cause their respective Affiliates to, subject to applicable Law and except as prohibited by any applicable Governmental Entity, and solely in respect of compliance with Competition Law:

(i) promptly notify the other Party of any written communication to that party or its Affiliates from any Governmental Entity, including regulatory authorities, concerning this License Agreement or the transactions contemplated hereby, and permit the other Party to review in advance (and to consider any comments made by the other Party in relation to) any proposed written communication to any of the foregoing;

(ii) not agree to participate or participate in any substantive meeting with any Governmental Entity in respect of any filings, investigation or inquiry concerning this License Agreement or the transactions contemplated hereby unless it consults with the other Party in advance and, to the extent permitted by such Governmental Entity, gives the other Party the opportunity to attend and participate; and

(iii) furnish the other Party (through outside counsel) with copies of all correspondence, filings and written communications (and memoranda setting forth the substance thereof) between it and its Affiliates and their respective representations on the one hand, and any

Governmental Entity, including regulatory authority, or members of their respective staffs on the other hand, with respect to this License Agreement and the transactions contemplated hereby.

(b) Each Party shall execute and deliver to the other Parties, upon any Party's request, all documents that are reasonably necessary or desirable to secure, preserve or implement each Party's rights pursuant to this License Agreement.

11.3 **Regulatory Actions**. In the event that any assets, businesses or licenses are required to be divested, assigned or sublicensed by order of any Governmental Entity or court of competent jurisdiction, Vanda may assign its rights under this License Agreement to a Third Party****.

12. REPRESENTATIONS AND WARRANTIES

12.1 **Representations and Warranties by Each Party**. Each Party represents and warrants to the other Party as of the Effective Date that:

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

(b) it has full corporate power and authority to execute, deliver, and perform this License Agreement, and has taken all corporate action required by Law and its organizational documents to authorize the execution and delivery of this License Agreement and the consummation of the transactions contemplated by this License Agreement; and

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

12.2 **Novartis Representation and Warranty**. ****

12.3 **Vanda Representation and Warranty**. Vanda represents and warrants to Novartis that as at the Effective Date and subject to such exceptions as are disclosed in the disclosure letter dated as of the date hereof and delivered herewith to Novartis, provided that the disclosure in any Clause or subclause of Vanda' disclosure letter shall constitute an exception to the corresponding Clause or subclause of this Clause 12.3 and shall not constitute an exception to any other Clause or subclause of this Clause 12.3 unless (and solely to the extent) the applicability of such disclosure to such other Clause or subclause is clear solely from a reading of the text of such disclosure:

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

(a) Vanda, nor, any employee, agent or subcontractor of Vanda, involved or to be involved in the Development and/or Commercialization of the Drug Substance or the Product has been debarred under Subsection (a) or (b) of Section 306 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 335a); (ii) no Person who is known by Vanda to have been debarred under Subsection (a) or (b) of Section 306 of said Act will be employed by Vanda in the performance of any activities hereunder; and (iii) to the actual knowledge, following reasonable inquiry, of Vanda, no Person on any of the FDA clinical investigator enforcement lists (including, but not limited to, the (1) Disqualified/Totally Restricted List, (2) Restricted List and (3) Adequate Assurances List will participate in the performance of any activities hereunder.

(b) Vanda is a well-established and licensed pharmaceutical company which, together with its Affiliates and distributors, has the necessary resources and expertise (or the resources to acquire the expertise) to carry out its obligations hereunder and to cause Vanda to carry out its obligations hereunder.

(c) Vanda is not and has not been (and has no Affiliates that are or have been) subject to any litigation by customers or investigation by local and/or regulatory authorities which would materially negatively impact Vanda's obligations hereunder.

(d) There is no suit, action, investigation or proceeding pending or threatened against Vanda that challenges or seeks to prevent or enjoin the transactions contemplated by this License Agreement.

(e) Vanda has received all the information it considers necessary for deciding whether to enter into this License Agreement and obtain rights to the Licensed IP in the Territory.

(f) Vanda has no knowledge that any representations or warranty of Novartis made in this License Agreement are not true and correct.

12.4 **Special, Indirect and Other Losses**. NO PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR FOR ANY ECONOMIC LOSS, DIMINUTION IN VALUE OR LOSS OF PROFITS SUFFERED BY ANY OTHER PARTY. NO REPRESENTATIONS OR WARRANTIES ARE MADE, INCLUDING AS TO FITNESS FOR PURPOSE, MERCHANTABILITY AND/OR NON-INFRINGEMENT, EXCEPT AS EXPRESSLY STATED HEREIN.

****

12.5 **Survival**. The representations and warranties made by the Parties and contained in this License Agreement shall survive the Effective Date for, and all claims for indemnification in connection therewith shall be asserted not later than, **** following the Effective Date. ****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

****

13. INDEMNIFICATION

13.1 **Indemnification Obligations of Novartis**. Novartis shall indemnify and hold Vanda, their Affiliates and their respective officers, directors, agents and employees ("**Vanda Indemnitees**") harmless from and against any and all costs, charges, Third Party claims, Third Party damages or expenses (including attorneys' fees and expenses) against or incurred by them ("**Losses**") to the extent arising or resulting from ****.

13.2 **Indemnification Obligations of Vanda**. Vanda shall indemnify and hold Novartis, its Affiliates and their respective officers, directors, agents and employees ("**Novartis Indemnitees**") harmless from and against any and all Losses to the extent arising or resulting from:

****

13.3 **Indemnification Procedure**. Novartis or Vanda, as applicable, (the "**Indemnified Party**") shall:

(a) promptly notify the other Party or Parties (the "**Indemnifying Party**") of anything which could lead to a Loss;

(b) permit the Indemnifying Party to participate in or lead the conduct, defense and/or settlement of such claim, proceeding, inquiry or investigation; provided, however, that Indemnifying Party shall not compromise or otherwise settle the same without the prior written consent of the Indemnified Party, which consent shall not be unreasonably withheld or delayed; and

(c) reasonably assist at the cost of the Indemnifying Party in the investigation and defense of such claim, proceeding, inquiry or investigation.

****

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14. INFRINGEMENT OF LICENSED IP BY THIRD PARTIES

14.1 **Infringement**. Each Party shall promptly notify the other Parties of any actual, suspected or threatened infringement, violation or misappropriation within the Territory of the Licensed IP ("**Infringement**") that comes to its attention, provided that if either Party receives a notice under 21 U.S.C.§355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) ("**Paragraph IV Notice**") concerning Licensed IP, then it shall provide a copy of such notice to the other Party within **** of receipt thereof.

14.2 **Right to Bring Action**. Except as set forth in Clause 14.3 below, **** shall have the sole right to send notices and bring and conduct actions in relation to any Infringement in the Territory. **** will co-operate fully with **** in taking all reasonable steps requested by **** in connection with any Infringement action, including joining in Legal Proceedings. **** shall bear the costs of any such Legal Proceedings, and **** shall be entitled to any damages, account of profits and/or awards of costs recovered.

14.3 **Exception**. In the event that **** does not take reasonable steps to prevent any individual Infringement within **** of becoming aware or receiving written notice thereof, **** shall hereafter have the sole right (but shall not be under any obligation in this regard) to send notices and bring and conduct actions in relation to such Infringement. **** will co-operate fully with **** in taking all reasonable steps requested by **** in connection with any such Infringement action, including joining in Legal Proceedings. **** shall bear the costs of any such Legal Proceedings, and shall be entitled to any damages, account of profits and/or awards of costs recovered.

14.4 **Settlements**. The Parties shall reasonably consult with each other before accepting any settlement or any judicial finding which is reviewable by a higher authority.

TERM AND TERMINATION

14.5 **Term**. This License Agreement shall come into force on the Effective Date and, subject only to earlier termination pursuant to this Clause 15, shall continue in full force and effect in perpetuity.

14.6 **Novartis Termination**. Novartis has the right to terminate the license granted hereunder by serving written notice on Vanda only upon the occurrence of the following events:

(a) Vanda fails to and Vanda also does not pay any undisputed amount due hereunder and Vanda fails to remedy such failure within **** of receipt of a written notice from Novartis specifying such failure;

(b) An Insolvency Event occurs; or

(c) Vanda materially breaches its obligation to **** and fails to cure such breach within a period of **** of receipt of a written notice from Novartis specifying such breach.

14.7 **Effect of Termination**. If this License Agreement is terminated pursuant to Clause 15.2:

****

14.8 **Survival**. The termination of this License Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the forgoing the provisions of Clauses 13, 15, 16 and 18 shall survive the termination of this License Agreement.

14.9 **Termination Not Sole Remedy**. Termination is not the sole remedy under this License Agreement, and, whether or not termination is effected and notwithstanding anything contained in this License Agreement to the contrary, all other remedies will remain available except as otherwise agreed to herein.

15. CONFIDENTIALITY

15.1 **Duty of Confidence**. The Parties acknowledge and agree that the Licensed IP will be deemed to be the confidential and proprietary information of Vanda on and after the Effective Date and shall be deemed to be Information of Vanda for purposes of this Clause 16. Subject to the other provisions of this Clause 16, all Information will be maintained by the Parties in confidence and otherwise safeguarded by all Parties. Each Party may only use the Information strictly for the purposes of this License Agreement and pursuant to the rights and obligations of such Party under this License Agreement. Subject to the other provisions of this Clause 16, each Party shall hold as confidential such Information of the other Party or its Affiliates (in the case of Novartis, where Affiliates of Novartis disclose information) in the same manner and with the same protection as such recipient Party maintains its own confidential information. Subject to the other provisions of this Clause 16, a Party may only disclose Information to employees, agents, contractors, consultants and advisers of such Party and its Affiliates and their employees, agents and contractors, and in the case of Vanda, Vanda may also disclose to its authorized sublicensees to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this License Agreement; provided that such Persons are bound to maintain the confidentiality of the Information in a manner consistent with the confidentiality provisions of this License Agreement.

15.2 **Exceptions**. The obligations under this Clause 16 shall not apply to any information to the extent the recipient Party can demonstrate by competent evidence that such information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this License Agreement by the recipient Party or, including in the case of Novartis its Affiliates or in the case of Vanda, through their authorized sublicensees;

(b) with respect to Vanda, was known to, or was otherwise in the possession of, Vanda, prior to the time of disclosure by Novartis or any of its Affiliates;

(c) is disclosed to the recipient Party (or an Affiliate, in the case of Novartis) on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party (or any of its Affiliates in the case of Novartis); or

(d) is independently developed by or on behalf of the recipient Party (or its Affiliates, in the case of Novartis), as evidenced by its written records, without reference to the Information disclosed by the disclosing Party (or its Affiliates in the case of Novartis) under this License Agreement.

Specific aspects or details of Information shall not be deemed to be within the public domain or in the possession of the recipient Party merely because the Information is embraced by more general information in the public domain or in the possession of the recipient Party. Further, any combination of Information shall not be considered in the public domain or in the possession of the recipient Party merely because individual elements of such Information are in the public domain or in the possession of the recipient Party unless the combination and its principles are in the public domain or in the possession of the recipient Party.

15.3 **Authorized Disclosures**.

(a) In addition to disclosures allowed under Clause 16.1 and 16.2, Vanda may disclose Information belonging to Novartis or its Affiliates to the extent such disclosure is necessary in connection with the Regulatory Filings for a Product.

(b) In addition to disclosures allowed under Clause 16.1 and 16.2, either Party may disclose Information belonging to the other Party (and/or its Affiliates in the case of Novartis) to the extent such disclosure is necessary to: (i) prosecute or defend litigation as permitted by this License Agreement; and/or (ii) comply with applicable court orders or governmental regulations.

(c) In the event the recipient Party is required to disclose Information of the disclosing Party by Law or in connection with bona fide legal process, such disclosure shall not be a breach of this License Agreement; provided that the recipient Party (i) informs the disclosing Party as soon as reasonably practicable of the required disclosure; (ii) limits the disclosure to the required purpose; and (iii) at the disclosing Party's request and expense, assists in an attempt to object to or limit the required disclosure.

15.4 **Ongoing Obligation for Confidentiality**. Upon early termination of this License Agreement for any reason, each Party and its Affiliates (in the case of Novartis) shall immediately return to the other Party or destroy any Information disclosed by the other Party, except for (i) such copies as must be retained pursuant to applicable Law, and (ii) one copy which may be retained in its confidential files for archive purposes.

16. PRESS RELEASE

16.1 **Press Releases**. Vanda's proposed press release for the transaction contemplated by this License Agreement is attached as Schedule C. Aside from Schedule C, neither Party shall issue any press release, trade announcement or make any other public announcement or statement with regard to the transactions contemplated by this License Agreement without the other Party's prior written consent, which shall not be unreasonably withheld or delayed. Where consent is forthcoming, the Parties agree to consult with each other regarding the content of any such press release or other announcement. The aforementioned restriction shall not apply to announcements required by any Regulatory Authority or Governmental Entity under applicable Law provided that in such event the Parties shall, to the extent reasonably practicable, coordinate and work in good faith to create mutually acceptable announcements and each Party shall take into consideration and comply with any reasonable comments or requests of the other Party. Each Party hereto acknowledges that Vanda and Novartis shall have the right to disclose a brief summary of the transaction, including the amounts payable by Vanda under this License Agreement, in its official financial reports, provided, however, that Novartis shall provide drafts of such reports sufficiently in advance of disclosing or providing such reports to any Third Party to permit Vanda to review and comment on such reports and the Parties shall, to the extent reasonably practicable, coordinate and work in good faith to create a mutually acceptable financial report and Novartis shall take into consideration and comply with any reasonable comments or requests of Vanda. Novartis acknowledges that Vanda shall have the right to disclose a brief summary of the material terms of transactions contemplated by this License Agreement on a Current Report on Form 8-K no later than **** following the date of this License Agreement, and file a copy of this License Agreement with the United States Securities and Exchange Commission (**"SEC"**), provided, however, that Vanda shall provide drafts of such Current Report on Form 8-K sufficiently in advance of filing to permit Novartis to review and comment on such Current Report on Form 8-K and the Parties shall, to the extent reasonably practicable, coordinate and work in good faith to create a mutually acceptable Current Report on Form 8-K and Vanda shall take into consideration and comply with any reasonable comments or requests of Novartis. To the extent that any Party is required to make a filing or any other public disclosure (other than as set forth in the preceding sentence) pursuant to applicable Law or any Governmental Entity with respect to this License Agreement or the terms or existence hereof or thereof to comply with the requirements, rules, laws or regulations of any applicable stock exchange, The NASDAQ Global Market or any Governmental Entity, including without limitation the SEC (collectively, the **"Disclosure Obligations"**), such Party shall promptly inform the other Parties thereof and shall use reasonable efforts to maintain the confidentiality of the other Parties' confidential information in any such filing or disclosure. To the extent that any Party is required to file a copy of this License Agreement to comply with the Disclosure Obligations, such Party shall promptly inform the other Parties thereof. Prior to making any such filing of a copy of this License Agreement, the Parties shall mutually agree on the provisions of this License Agreement, as applicable, for which the Parties shall seek confidential treatment, it being understood that if one Party determines to seek confidential treatment for a provision for which the another Party does not, then the Parties will use reasonable efforts in connection with such filing to seek the confidential treatment of any such provision. The Parties shall cooperate, each at its own expense, in such filing, including without limitation such confidential treatment request, and shall execute all documents reasonably required in connection therewith. The Parties shall agree with each other as to the substance of any such filing. Each Party shall have the right to review in advance, and shall consult with the other Party on, all information relating to this License Agreement, that appear in any such filing. In furtherance of the foregoing, the Parties will agree as promptly as practicable after the date of this License Agreement on the confidential treatment request to be filed with the SEC and the

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redacted form or forms of this License Agreement, as applicable, related thereto. In furtherance thereof, any redaction reasonably requested by any Party shall be included in such filing. The Parties will reasonably cooperate in responding promptly to any comments received from the SEC with respect to such filing in an effort to achieve confidential treatment of such redacted form; provided, however, that a Party shall be relieved of such obligation to seek confidential treatment for a provision requested by the another Party if such treatment is not achieved after the second round of responses to comments from the SEC.

17. MISCELLANEOUS

17.1 **Governing Law; Venue**. This License Agreement shall be governed by and construed under the Laws of the State of New York USA, without giving effect to the conflicts of Laws provision thereof, and with the exclusion of the Vienna Convention on the International Sale of Goods. Any Legal Proceeding relating to this License Agreement or the enforcement of any provision of this License Agreement shall be brought or otherwise commenced in, and each Party expressly and irrevocably consents and submits to the jurisdiction of, any state or federal court located in the State, City and County of New York.

17.2 **Assignment**. No Party may assign its rights and obligations under this License Agreement without the other Parties' prior written consent, except that any Party may (i) assign its rights and obligations under this License Agreement or any part hereof to one or more of its Affiliates without the consent of the other Party; and (ii) assign this License Agreement in its entirety to a successor to all or substantially all of its business or assets to which this License Agreement relates; provided in all cases, that any permitted assignee shall assume all obligations of its assignor under this License Agreement (or related to the assigned portion in case of a partial assignment), and no permitted assignment shall relieve the assignor of liability hereunder. Any attempted assignment in contravention of the foregoing shall be void. Subject to the terms of this License Agreement, this License Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

17.3 **Injunctive Relief**. The Parties understand and agree that monetary damages may not be a sufficient remedy for breach of this License Agreement and that each Party will be entitled to seek equitable relief, including injunction and specific performance for any such breach. Nothing contained in this License Agreement shall be construed as limiting a Party's right to any other remedies it may have under this License Agreement or in Law, including, without limitation, the recovery of damages for breach of this License Agreement.

17.4 **Force Majeure**. If and to the extent that any Party is prevented or delayed by Force Majeure from performing any of its obligations under this License Agreement and promptly so notifies in writing the other Parties, specifying the matters constituting Force Majeure together with such evidence in verification thereof as it can reasonably give and specifying the period for which it is estimated that the prevention or delay will continue, then the Party so affected shall be relieved of liability to the other for failure to perform or for delay in performing such obligations (as the case may be), but shall nevertheless **** resume full performance thereof.

17.5 **Notices**. All notices, consents, waivers, and other communications under this License Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt); or (b) sent by when received by the

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addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and fax numbers set forth below (or to such other addresses and fax numbers as a Party may designate by written notice):

If to Vanda:

Vanda Pharmaceuticals Inc.
2200 Pennsylvania Avenue, NW, Suite 300E
Washington, DC 20037
****

with copies to (which shall not constitute notice hereunder):

Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP
One Marina Park Drive
Suite 900
Boston, MA 02210
****

If to Novartis:

Novartis Pharma AG
Lichtstrasse 35
CH-4056 Basel, Switzerland
****

With a copy to:

Novartis Pharma AG
Lichtstrasse 35
CH-4056 Basel, Switzerland
****

17.6 **Waiver and Amendments**. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this License Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this License Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

17.7 **Severability**. Without prejudice to any other rights that the Parties have pursuant to this License Agreement, every provision of this License Agreement is intended to be severable. If any provision of this License Agreement shall be invalid or unenforceable, such invalidity or unenforceability shall not affect the other provisions of this License Agreement, which shall remain in full force and effect. The Parties hereto agree to consult each other and to agree upon a new stipulation which is permissible under the Law and which comes as close as possible to the original purpose and intent of the invalid, void or unenforceable provision.

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17.8 **Entire Agreement**. This License Agreement constitutes the entire agreement and supersedes all prior agreements and understandings, both written and oral, between the Parties with respect to the subject matter hereof.

17.9 **Relationship of the Parties**. Nothing contained in this License Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between Novartis and Vanda, or to constitute one as the agent of the other. Moreover, each Party agrees not to construe this License Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this License Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other.

17.10 **Expenses**. Except as otherwise expressly provided in this License Agreement, each Party shall pay the fees and expenses of its respective lawyers and other experts and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution and delivery of this License Agreement.

17.11 **Extension to Affiliates**. Each Party shall have the right to extend the rights, immunities and obligations granted in this License Agreement to one or more of its Affiliates. All applicable terms and provisions of this License Agreement shall apply to any such Affiliate to which this License Agreement has been extended to the same extent as such terms and provisions apply to original Party, who shall remain primarily liable for any acts or omissions of its Affiliates.

17.12 **Further Assurances**. Novartis and Vanda hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary to carry out the intent and purposes of this License Agreement.

17.13 **Compliance with Law**. Each Party shall perform its obligations under this License Agreement in accordance with all applicable Laws. No Party shall, or shall be required to, undertake any activity under or in connection with this License Agreement which violates, or which it believes, in good faith, may violate, any applicable Law.

17.14 **English Language**. This License Agreement is written and executed in the English language. Any translation into any other language shall not be an official version of this License Agreement and in the event of any conflict in interpretation between the English version and such translation, the English version shall prevail.

17.15 **Counterparts**. This License Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Remainder of Page Intentionally Left Blank; Signature Page Follows]

The Parties to this License Agreement have caused this License Agreement to be executed and delivered as of the date first written above.

NOVARTIS PHARMA AG

By: /s/ Matt Owens

Name: Matt Owens

Title: Head Legal GBS & Strategy

Date: 12/22/2014

By: /s/ Marc Ceulemans

Name: Marc Ceulemans

Title: Head Strategic Venture Capital Fund & Pharma Entities

Date: 12/22/2014

VANDA PHARMACEUTICALS INC.

By: /s/ Mihael H. Polymeropoulous, M.D.

Name: Mihael H. Polymeropoulous, M.D.

Title: CEO, Vanda

Date: 12/22/2014

CONFIDENTIAL TREATMENT REQUESTED

SCHEDULE A

DRUG SUBSTANCE

****	****
****	****
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****	****
****	****

**** CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

CONFIDENTIAL TREATMENT REQUESTED

SCHEDULE B

PATENT RIGHTS

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****

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CONFIDENTIAL TREATMENT REQUESTED

****

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CONFIDENTIAL TREATMENT REQUESTED

****

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CONFIDENTIAL TREATMENT REQUESTED

SCHEDULE C

PRESS RELEASE

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-133368, No. 333-138070, No. 333-141571, No. 333-148924, No. 333-156995, No. 333-164567, No. 333-171962, No. 333-179265, No. 333-186509, No. 333-193614 and No. 333-201754) and on Form S-3 (No. 333-191434) of Vanda Pharmaceuticals Inc. of our report dated March 13, 2015 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

McLean, Virginia
March 13, 2015

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mihael H. Polymeropoulos, certify that:

1. I have reviewed this annual report on Form 10-K of Vanda Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 13, 2015

/s/ Mihael H. Polymeropoulos, M.D.

Mihael H. Polymeropoulos, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James P. Kelly, certify that:

1. I have reviewed this annual report on Form 10-K of Vanda Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 13, 2015

/s/ James P. Kelly

James P. Kelly
Senior Vice President, Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Vanda Pharmaceuticals Inc., (the "Company"), does hereby certify, to the best of such officer's knowledge, that:

The Annual Report on Form 10-K for the year ended December 31, 2014 (the Form 10-K) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the consolidated financial condition and results of operations of the Company.

March 13, 2015

/s/ Mihael H. Polymeropoulos, M.D.

Mihael H. Polymeropoulos, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

March 13, 2015

/s/ James P. Kelly

James P. Kelly
Senior Vice President, Chief Financial Officer, Secretary and Treasurer (Principal Financial Officer and Principal Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission (SEC) or its staff upon request. This certification "accompanies" the Form 10-K to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.