Vanda Pharmaceuticals Inc.
Form 10-K
March 13, 2015
Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 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 þ

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

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

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

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

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

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

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

As of June 30, 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.

Table of Contents

Vanda Pharmaceuticals Inc.

Form 10-K

Table of Contents

Table of Contents

PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements throughout this report are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may appear throughout this report. Words such as, but not limited to, believe, expect, anticipate, estimate, intend, plan, project, target, goal, likely, will, would, and could, or the negative of these terms and similar expressions or words, forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in our forward-looking statements include, among others:

our ability to successfully commercialize 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;

Table of Contents

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.

Table of Contents

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.

Table of Contents

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®	Non-24	United States	FDA approval in January 2014;
(tasimelteon)			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)	Schizophrenia	United States	FDA approval in May 2009;
(iloperidone)			

	Commercial launch in January 2010; U.S. and Canada rights sublicensed to Novartis in October 2009; Reacquired by Vanda in December 2014

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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;

Table of Contents

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