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

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2015

or

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

For the transition period from _____ to _____

Commission File Number: 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, N.W., Suite 300 E Washington, D.C.	**20037**
(Address of principal executive offices)	**(Zip Code)**

(202) 734-3400
(Registrant's telephone number, including area code)

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 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.

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

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

As of July 24, 2015, there were 42,285,426 shares of the registrant's common stock issued and outstanding.

Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended June 30, 2015

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Part I — FINANCIAL INFORMATION

ITEM 1 Financial Statements (Unaudited)

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except for share and per share amounts)	June 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 48,337	$ 60,901
Marketable securities	98,300	68,921
Accounts receivable, net	15,818	3,654
Inventory	4,962	5,170
Prepaid expenses and other current assets	6,956	3,084
Total current assets	174,373	141,730
Property and equipment, net	3,869	2,437
Intangible assets, net	44,638	26,724
Restricted cash and other	813	813
Total assets	$ 223,693	$ 171,704
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,631	$ 835
Accrued and other current liabilities	43,562	6,951
Total current liabilities	45,193	7,786
Milestone obligation under license agreement	25,000	—
Other non-current liabilities	3,753	3,101
Total liabilities	73,946	10,887
Commitments and contingencies (Notes 13 and 14)		
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; 42,270,426 and 41,486,361 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	42	41
Additional paid-in capital	453,269	448,744
Accumulated other comprehensive income	27	16
Accumulated deficit	(303,591)	(287,984)
Total stockholders' equity	149,747	160,817
Total liabilities and stockholders' equity	$ 223,693	$ 171,704

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

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(in thousands, except for share and per share amounts)	Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Revenues:				
Product sales, net	$ 27,582	$ 1,559	$ 49,732	$ 1,559
Royalty revenue	—	1,539	—	3,230
Licensing revenue	—	7,764	—	15,216
Total revenues	27,582	10,862	49,732	20,005
Operating expenses:				
Cost of goods sold	5,766	198	10,781	198
Research and development	5,946	3,514	10,424	10,777
Selling, general and administrative	18,386	28,139	37,192	56,032
Intangible asset amortization	2,942	617	7,086	1,182
Total operating expenses	33,040	32,468	65,483	68,189
Loss from operations	(5,458)	(21,606)	(15,751)	(48,184)
Other income	72	31	144	76
Net loss	$ (5,386)	$ (21,575)	$ (15,607)	$ (48,108)
Basic and diluted net loss per share	$ (0.13)	$ (0.64)	$ (0.37)	$ (1.42)
Weighted average shares outstanding, basic and diluted	41,991,578	33,874,625	41,868,944	33,777,207

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

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS) (Unaudited)

(in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2015	June 30, 2014	June 30, 2015	June 30, 2014
Net loss	$(5,386)	$(21,575)	$(15,607)	$(48,108)
Other comprehensive income (loss):				
Change in net unrealized income (loss) on marketable securities	—	2	11	(11)
Tax provision on other comprehensive income (loss)	—	—	—	—
Other comprehensive income (loss), net of tax	—	2	11	(11)
Comprehensive loss	$(5,386)	$(21,573)	$(15,596)	$(48,119)

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

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (Unaudited)

(in thousands, except for share amounts)	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Total
Balances at December 31, 2014	41,486,361	$ 41	$448,744	$ 16	$ (287,984)	$160,817
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	809,012	1	794	—	—	795
Shares withheld upon settlement of equity awards	(24,947)	—	(282)	—	—	(282)
Stock-based compensation expense	—	—	4,013	—	—	4,013
Net loss	—	—	—	—	(15,607)	(15,607)
Other comprehensive income, net of tax	—	—	—	11	—	11
Balances at June 30, 2015	42,270,426	$ 42	$453,269	$ 27	$ (303,591)	$149,747

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

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(in thousands)	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Cash flows from operating activities		
Net loss	$(15,607)	$(48,108)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization of property and equipment	263	264
Stock-based compensation expense	4,013	2,836
Amortization of discounts and premiums on marketable securities	426	96
Intangible asset amortization	7,086	1,182
Changes in assets and liabilities:		
Accounts receivable	(12,164)	(345)
Prepaid expenses and other current assets	(3,872)	(1,463)
Inventory	208	(1,093)
Accounts payable	796	(413)
Accrued and other liabilities	36,193	1,691
Deferred revenue	314	(15,216)
Net cash provided by (used in) operating activities	17,656	(60,569)
Cash flows from investing activities		
Acquisition of intangible assets	—	(8,000)
Purchases of property and equipment	(939)	(378)
Purchases of marketable securities	(81,348)	(20,544)
Proceeds from sale of marketable securities	999	8,198
Maturities of marketable securities	50,555	31,235
Change in restricted cash	—	245
Net cash provided by (used in) investing activities	(30,733)	10,756
Cash flows from financing activities		
Obligations paid in connection with settlement of equity awards	(282)	(436)
Proceeds from exercise of stock options	795	2,479
Net cash provided by financing activities	513	2,043
Net decrease in cash and cash equivalents	(12,564)	(47,770)
Cash and cash equivalents		
Beginning of period	60,901	64,764
End of period	$ 48,337	$ 16,994
Non-cash investing activities		
Acquisition of intangible asset included in non-current liabilities	$ 25,000	$ —
Purchases of property and equipment in current liabilities	759	20

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

VANDA PHARMACEUTICALS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

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), which was approved by the U.S. Food and Drug Administration (FDA) in January 2014 and launched commercially in the U.S. in April 2014. In July 2015, the European Commission (EC) granted centralized marketing authorization with unified labeling for HETLIOZ® for the treatment of Non-24 in totally blind adults. This authorization is valid in the 28 countries that are members of the European Union, as well as European Economic Area members Iceland, Liechtenstein and Norway. HETLIOZ® has potential utility in a number of circadian rhythm disorders.
- 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.
- 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 unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's consolidated financial statements for the fiscal year ended December 31, 2014 included in the Company's annual report on Form 10-K. The financial information as of June 30, 2015 and for the three and six months ended June 30, 2015 and 2014 is unaudited, but in the opinion of management, all adjustments, consisting only of normal recurring accruals, considered necessary for a fair statement of the results for these interim periods have been included. The condensed consolidated balance sheet data as of December 31, 2014 was derived from audited financial statements but does not include all disclosures required by GAAP.

The results of the Company's operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year. The financial information included herein should be read in conjunction with the consolidated financial statements and notes in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2014.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP 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.

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.

Net Product Sales

The Company's net product sales consist of sales of HETLIOZ® and, beginning in 2015, sales of Fanapt®. Net sales by product for the three and six months ended June 30, 2015 and 2014 were as follows:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2015	June 30, 2014	June 30, 2015	June 30, 2014
HETLIOZ® product sales, net	$10,017	$1,559	$17,477	$1,559
Fanapt® product sales, net	17,565	—	32,255	—
	$27,582	$1,559	$49,732	$1,559

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.

HETLIOZ® is only available in the U.S. for distribution through a limited number of specialty pharmacies, and is not available in retail pharmacies. Fanapt® is available in the U.S. for distribution through a limited number of wholesalers and is available in retail pharmacies. The Company invoices and records revenue when its customers, specialty pharmacies and wholesalers, receive product from the third-party logistics warehouse. Revenues and accounts receivable are concentrated with these customers. The top six customers represented 95% of total revenues for the six months ended June 30, 2015, and the top three customers represented 72% of accounts receivable at June 30, 2015. The Company has not experienced any losses relating to receivables from customers.

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 June 30, 2015, the Company recorded $0.5 million of deferred revenue related to Fanapt® sales.

Product Sales Discounts and Allowances

The Company's product sales are 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 and supplemental discounts under the Medicaid Drug Rebate Program as well as contracted rebate programs with other payors. 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 or contracted discount rates and expected utilization. Estimates for the expected utilization of rebates are based on historical activity and, where available, 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. If actual future invoicing varies from estimates, the Company may need to adjust accruals, which would affect net revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from specialty pharmacies and wholesalers. 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 or wholesaler, in turn, charges back the difference between the price initially paid by the specialty pharmacy or wholesaler and the discounted price paid to the specialty pharmacy or wholesaler by the contracted customer. The allowance for chargebacks is based on historical activity and, where available, 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 activity and, where available, 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.

Service Fees: The Company also incurs specialty pharmacy and wholesaler 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 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 sales and an estimate for pending sales based on either historical activity or pending sales for which the Company has validated the insurance benefits.

Prompt-pay: Specialty pharmacies and wholesalers are offered discounts for prompt payment. The Company expects that the specialty pharmacies and wholesalers 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 historical return activity, expiration dates of product shipped to specialty pharmacies, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors.

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. 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.

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 $0.9 million and $3.3 million for the three months ended June 30, 2015 and 2014, respectively, and $1.9 million and $4.3 million for the six months ended June 30, 2015 and 2014, respectively.

Segment Reporting

The Company operates in one reporting segment and, accordingly, no segment disclosures are presented herein.

Recent accounting pronouncements

In January 2015, the Financial Accounting Standards Board (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 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 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. At the time the new standard was issued, it was set to be effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. In July 2015, the FASB voted to defer the effective date by one year to December 15, 2017 for fiscal years, and interim periods within those fiscal years, beginning after that date. Early adoption of the standard is permitted, but not before the original effective date of December 15, 2016. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

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

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.

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 year ended 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 obligation 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 was included in gain on arbitration settlement in the consolidated statement of operations in the fourth quarter of 2014.

The Settlement Agreement provided for a 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 in the fourth quarter of 2014.

4. Earnings per Share

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

The following table presents the calculation of basic and diluted net loss per share of common stock for the three and six months ended June 30, 2015 and 2014:

(in thousands, except for share and per share amounts)	Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Numerator:				
Net loss	$ (5,386)	$ (21,575)	$ (15,607)	$ (48,108)
Denominator:				
Weighted average shares outstanding, basic and diluted	41,991,578	33,874,625	41,868,944	33,777,207
Net loss per share, basic and diluted:				
Net loss per share	$ (0.13)	$ (0.64)	$ (0.37)	$ (1.42)
Antidilutive securities excluded from calculations of diluted net loss per share	5,765,618	3,739,874	5,711,140	3,805,191

The Company incurred net losses for the three and six months ended June 30, 2015 and 2014 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.

5. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of June 30, 2015, which all have contract maturities of less than one year:

June 30, 2015 *(in thousands)*	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Market Value**
U.S. Treasury and government agencies	$ 54,628	$ 7	$ (2)	$54,633
Corporate debt	43,645	26	(4)	43,667
	$ 98,273	$ 33	$ (6)	$98,300

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2014:

December 31, 2014 *(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

6. 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 as of June 30, 2015 and December 31, 2014 consist of 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 and corporate notes that use as their basis readily observable market parameters. The Company did not transfer any assets between Level 2 and Level 1 during the six months ended June 30, 2015.

As of June 30, 2015, 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 June 30, 2015 Using		
(in thousands)	June 30, 2015	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	$98,300	$ 54,633	$ 43,667	$ —

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	$ —

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.

7. 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 June 30, 2015 and December 31, 2014:

(in thousands)	June 30, 2015	December 31, 2014
Raw materials	$ 128	$ 198
Work-in-process	1,778	1,326
Finished goods	2,646	3,394
Deferred cost of goods sold	410	252
	$4,962	$ 5,170

Deferred cost of goods sold represents the cost of product shipped to Probiomed, for which revenue recognition has been deferred. See Note 2, *Summary of Significant Accounting Policies*, for a discussion of Fanapt® revenue recognition.

8. Prepaid Expenses and Other Current Assets

The following is a summary of the Company's prepaid expenses and other current assets as of June 30, 2015 and December 31, 2014:

(in thousands)	June 30, 2015	December 31, 2014
Prepaid insurance	$ 928	$ 270
Prepaid manufacturing cost	346	358
Other prepaid expenses and vendor advances	5,363	2,302
Other current assets	319	154
	$6,956	$ 3,084

9. Intangible Assets

The following is a summary of the Company's intangible assets as of June 30, 2015:

		June 30, 2015		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	January 2033	$33,000	$ 2,600	$30,400
Fanapt®	November 2016	27,941	13,703	14,238
		$60,941	$ 16,303	$44,638

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

		December 31, 2014		
(in thousands)	Estimated Useful Life (Years)	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
		$35,941	$ 9,217	$26,724

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.

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. The likelihood of achieving the milestone and the related milestone obligation was determined to be probable during the six months ended June 30, 2015. As a result, the future obligation of $25.0 million was recorded as a non-current liability as of June 30, 2015 along with an addition of $25.0 million to capitalized intangible assets relating to HETLIOZ®. The $25.0 million was determined to be additional consideration for the acquisition of the HETLIOZ® intangible asset, which was created upon FDA approval on January 31, 2014. The actual payment of the $25.0 million will occur once the $250.0 million in cumulative worldwide sales of HETLIOZ® is realized. The $25.0 million is being amortized on a straight-line basis over the remaining life of the U.S. patent for HETLIOZ®, which is expected to be January 2033. Amortization of intangible assets relating to HETLIOZ® amounted to $2.1 million for the six months ended June 30, 2015 and includes a catch-up adjustment of $1.2 million to retroactively record cumulative amortization from January 31, 2014 to December 31, 2014 for the milestone obligation of $25.0 million. In future periods the Company expects annual amortization of capitalized intangible asset costs relating to HETLIOZ® will amount to $1.7 million until the expiration of the patent in 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. composition of matter patent for Fanapt® 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 additional Fanapt® patents solely owned by the Company with varying expiration dates, the latest of which is 2031. 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 $2.9 million and $0.6 million for the three months ended June 30, 2015 and 2014, respectively, and $7.1 million and $1.2 million for the six months ended June 30, 2015 and 2014, respectively. The following is a summary of the future intangible asset amortization schedule as of June 30, 2015:

(in thousands)	Total	Remainder of 2015	2016	2017	2018	2019	Thereafter
HETLIOZ®	$30,400	$ 860	$ 1,721	$1,721	$1,721	$1,721	$ 22,656
Fanapt®	14,238	5,025	9,213	—	—	—	—
	$44,638	$ 5,885	$10,934	$1,721	$1,721	$1,721	$ 22,656

10. Accrued Liabilities

The following is a summary of the Company's accrued liabilities as of June 30, 2015 and December 31, 2014:

(in thousands)	June 30, 2015	December 31, 2014
Accrued sales allowances	$28,738	$ 495
Accrued research and development expenses	1,953	1,759
Accrued consulting and other professional fees	4,475	2,522
Compensation and employee benefits	1,888	388
Royalties payable	5,000	602
Other accrued liabilities	1,508	1,185
	$43,562	$ 6,951

11. Deferred Revenue

The following is a summary of changes in total deferred revenue for the six months ended June 30, 2015 and 2014:

	Six Months Ended	
(in thousands)	June 30, 2015	June 30, 2014
Balance beginning of period	$ 174	$90,275
Deferred Fanapt® product revenue	314	—
Licensing revenue recognized	—	15,216
Balance end of period	$ 488	$75,059

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. 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 year ended December 31, 2014, the Company recognized revenue of $30.7 million related to the license agreement. In connection with the Settlement Agreement, the Company recognized the remaining deferred revenue balance of $59.5 million during the three months ended December 31, 2014, as part of the gain on arbitration settlement. See Note 3, *Settlement Agreement with Novartis*, for further discussion.

12. Income Taxes

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 June 30, 2015 and December 31, 2014. Changes in ownership may limit the amount of NOL carryforwards that can be utilized in the future to offset taxable income. Ownership changes did occur as of December 31, 2008 and December 31, 2014. The Company determined that there was sufficient Built-In-Gain as of December 31, 2008 to offset the Internal Revenue Code of 1986, as amended (IRC), Section 382 limitation generated by the ownership change. The Company believes that there is sufficient Built-In-Gain as of December 31, 2014 to offset the IRC Section 382 limitation generated by the ownership change. Any future ownership changes may cause the Company's existing tax attributes to have additional limitations.

13. Commitments and Contingencies

Operating leases

The following is a summary of the minimum annual future payments under operating leases as of June 30, 2015:

(in thousands)	Total	Remainder of 2015	2016	2017	2018	2019	Thereafter
Operating leases	$14,051	$ 736	$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). 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 was abated for the first nine months of the amended lease ending on June 30, 2015. The Landlord provided the Company with a cash allowance of $0.8 million for tenant improvements. The allowance for tenant improvements is reflected in the consolidated financial statements as an increase to the deferred rent liability for the six months ended June 30, 2015. 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 $0.5 million and $0.4 million for the three months ended June 30, 2015 and 2014, respectively, and $0.9 million and $0.8 million for the six months ended June 30, 2015 and 2014, respectively.

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 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. During the first quarter of 2015, the likelihood of achieving the milestone and the related milestone obligation was determined to be probable. As such, the $25.0 million milestone obligation was capitalized as an intangible asset and is being amortized over the expected HETLIOZ® patent life in the U.S. The actual payment of the $25.0 million will occur once the $250.0 million in cumulative worldwide sales of HETLIOZ® is realized. Additionally, the Company is obligated to make royalty payments on HETLIOZ® net sales to BMS in any territory where the Company commercializes HETLIOZ® for a period equal to the greater of 10 years following 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 the license agreement for HETLIOZ® to use its 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.

Fanapt®. Pursuant to the terms of the Settlement Agreement, 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 (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 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, 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 $200.0 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 (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.

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 generally 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.

14. 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 (ANDA) 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, 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. 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.

The two pending cases against Roxane were consolidated by agreement of the parties in April 2015 and are scheduled to be tried together in a four-day bench trial beginning on February 29, 2016.

In May 2015, the Company filed a lawsuit against Inventia Healthcare Pvt. Ltd. (Inventia) in the U.S. District Court for the District of Delaware. The suit seeks an adjudication that Inventia has infringed on one or more claims of one of the Company's patents by submitting to the FDA an ANDA for a generic version of Fanapt®. The relief requested by the Company includes a request for a permanent injunction preventing Inventia 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. The Company received Inventia's paragraph IV notice regarding the Patent on April 3, 2015.

15. 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 recognizes the expense over the award's vesting period.

The fair value of stock options granted and RSUs awarded are amortized using the straight-line method. As stock-based compensation expense recognized in the consolidated statements of operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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

Assumptions used in the Black-Scholes-Merton option pricing model for stock options granted during the six months ended June 30, 2015 and 2014 were as follows:

	Six Months Ended	
	June 30, 2015	June 30, 2014
Expected dividend yield	0%	0%
Weighted average expected volatility	61%	64%
Weighted average expected term (years)	5.99	5.83
Weighted average risk-free rate	1.61%	1.77%
Weighted average fair value per share	$ 6.15	$ 7.14

Total stock-based compensation expense related to stock-based awards for the three and six months ended June 30, 2015 and 2014 was comprised of the following:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2015	June 30, 2014	June 30, 2015	June 30, 2014
Research and development	$ 603	$ 454	$1,227	$ 935
Selling, general and administrative	1,465	989	2,786	1,901
	$ 2,068	$ 1,443	$4,013	$2,836

As of June 30, 2015, 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. There were 198,148 shares subject to outstanding options granted under the 2004 Plan as of June 30, 2015, and no additional options will be granted under the 2004 Plan. As of June 30, 2015, there were 11,829,472 shares of the Company's common stock reserved for issuance under the 2006 Plan, of which 7,641,146 shares were subject to outstanding options and RSUs and 1,713,842 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 June 30, 2015, $14.8 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.6 years. No option awards are classified as a liability as of June 30, 2015.

A summary of option activity for the 2004 Plan for the six months ended June 30, 2015 follows:

2004 Option Plan *(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, 2014	652,810	1.74	0.78	8,212
Exercised	(454,662)	0.44		4,559
Outstanding at June 30, 2015	198,148	4.73	0.50	4,455
Exercisable at June 30, 2015	198,148	4.73	0.50	1,577
Vested and expected to vest at June 30, 2015	198,148	4.73	0.50	1,577

A summary of option activity for the 2006 Plan for the six months ended June 30, 2015 follows:

2006 Option Plan *(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, 2014	6,227,112	11.58	6.71	28,523
Granted	721,500	11.35		
Forfeited	(166,606)	11.10		
Expired	(2,409)	11.70		
Exercised	(123,257)	5.32		794
Outstanding at June 30, 2015	6,656,340	11.68	6.52	19,773
Exercisable at June 30, 2015	4,151,650	12.20	5.02	14,830
Vested and expected to vest at June 30, 2015	6,456,458	11.69	6.43	19,516

Proceeds from the exercise of stock options amounted to $0.8 million for the six months ended June 30, 2015.

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 June 30, 2015, $9.2 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 2.0 years. No service RSUs are classified as a liability as of June 30, 2015.

A summary of RSU activity for the 2006 Plan for the six months ended June 30, 2015 follows:

RSUs	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Unvested at December 31, 2014	1,025,961	$ 9.94
Granted	253,000	11.23
Forfeited	(63,062)	10.88
Vested	(231,093)	7.96
Unvested at June 30, 2015	984,806	10.67

The grant date fair value for the 231,093 shares underlying RSUs that vested during the six months ended June 30, 2015 was $1.8 million.

ITEM 2 Management's Discussion and Analysis of Financial Condition and Results of Operations

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. and Europe;
- 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 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 agreements;
- the failure to obtain, or any delay in obtaining, regulatory approval for our products or to comply with ongoing regulatory requirements;
- the size and growth of the potential markets for our products and the ability to serve those markets;
- our expectations regarding trends with respect to our revenues, costs, expenses and liabilities;
- 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 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 timing and success of preclinical studies and clinical trials conducted by us and our development partners;
- a failure of our products to be demonstrably safe and effective;
- 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 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 unaudited condensed consolidated financial statements contained in this quarterly report on Form 10-Q. We also encourage you to read Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2014, which contains a discussion of the risks and uncertainties associated with our business. In addition to the risks described below and in Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2014, 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.

Overview

Vanda Pharmaceuticals Inc. (we, our, or Vanda) is 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® (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24), which was approved by the U.S. Food and Drug Administration (FDA) in January 2014 and launched commercially in the U.S. in April 2014. In July 2015, the European Commission (EC) granted centralized marketing authorization with unified labeling for HETLIOZ® for the treatment of Non-24 in totally blind adults. This authorization is valid in the 28 countries that are members of the European Union (EU), as well as European Economic Area members Iceland, Liechtenstein and Norway. HETLIOZ® has potential utility in a number of circadian rhythm disorders.
- 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 us. See *Settlement Agreement with Novartis* footnote to the condensed consolidated financial statements included in Part I of in this quarterly report on Form 10-Q for additional information. We expect to file for European regulatory approval of oral Fanapt® in the second half of 2015. 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.
- Trichostatin A, a small molecule histone deacetylase (HDAC) inhibitor.
- AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

Operational Highlights

HETLIOZ® (tasimelteon)

- HETLIOZ® U.S. net product sales grew to $10.0 million in the second quarter of 2015, a 34% increase compared to $7.5 million in the first quarter of 2015.
- In July 2015, the European Commission approved HETLIOZ® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in totally blind adults in the EU.
- HETLIOZ® life cycle management activities continue to progress with plans to initiate a Phase III study of HETLIOZ® for the treatment of jet lag during 2015.
- A HETLIOZ® interventional study for the treatment of Smith-Magenis Syndrome is expected to begin during the fourth quarter of 2015.
- During July 2015, HETLIOZ® patent number 9,060,995 (‘995) was listed in the U.S. Food and Drug Administration’s (FDA) Orange Book. The ‘995 patent expires in January 2033.

Fanapt® (iloperidone)

- Fanapt® U.S net product sales grew to $17.6 million in the second quarter of 2015, a 20% increase compared to $14.7 million in the first quarter of 2015.
- Vanda expects to file a supplemental New Drug Application for Fanapt® with the FDA in the second half of 2015 to include the results from the long-term maintenance REPRIEVE (Relapse prevention study in patients with schizophrenia) clinical study in the Fanapt® package insert.
- Vanda expects to file for European regulatory approval of oral Fanapt® in the second half of 2015.

Tradipitant (VLY-686)

- Vanda expects to initiate a Phase II study in chronic pruritus in patients with atopic dermatitis in the fourth quarter of 2015, seeking to confirm the exploratory efficacy findings reported in the Phase II proof of concept study (2101).

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 II of this quarterly report on Form 10-Q.

Critical Accounting Policies

The preparation of our condensed 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.

With the exception of accounting for inventory and net product sales from Fanapt®, there have been no significant changes in our critical accounting policies including estimates, assumptions and judgments from those described in Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations,* included in our annual report on Form 10-K for the fiscal year ended December 31, 2014.

A summary of our significant accounting policies appears in the notes to our audited consolidated financial statements included in our annual report on Form 10-K for the fiscal year ended December 31, 2014. 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.

Net Product Sales. Our net product sales consist of sales of HETLIOZ® and sales of Fanapt®. 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 June 30, 2015, we recorded $0.5 million of deferred revenue related to Fanapt® sales.

Product Sales Discounts and Allowances. Product sales are 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 and supplemental discounts under the Medicaid Drug Rebate Program as well as contracted rebate programs with other payors. 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 or contracted discount rates and expected utilization. Estimates for the expected utilization of rebates are based on historical activity and, where available, 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. If actual future invoicing varies from estimates, we may need to adjust accruals, which would affect net revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from specialty pharmacies and wholesalers. 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 or wholesaler, in turn, charges back the difference between the price initially paid by the specialty pharmacy or wholesaler and the discounted price paid to the specialty pharmacy or wholesaler by the contracted customer. The allowance for chargebacks is based on historical activity and, where available, 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 activity and, where available, 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 and wholesaler 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 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 sales and an estimate for pending sales based on either historical activity or pending sales for which we have validated the insurance benefits.

Prompt-pay: Specialty pharmacies and wholesalers are offered discounts for prompt payment. We expect that the specialty pharmacies and wholesalers 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 historical return activity, expiration dates of product shipped to specialty pharmacies, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors.

The following table summarizes sales discounts and allowance activity for the six months ended June 30, 2015:

(in thousands)	Rebates and Chargebacks	Discounts, Returns and Other	Total
Balances at December 31, 2014	$ 368	$ 268	$ 636
Provision related to current period sales	26,610	8,494	35,104
Adjustments for prior period sales	(142)	140	(2)
Credits/payments made	(594)	(5,546)	(6,140)
Balances at June 30, 2015	$ 26,242	$ 3,356	$29,598

The provision of $26.6 million for rebates and chargebacks for the six months ended June 30, 2015 primarily represents Medicaid rebates applicable to sales of Fanapt®.

License revenue. Our license revenues in 2014 and prior years 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, 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 condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for additional information.

Stock-based compensation. We use the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The determination of the fair value of stock options on the date of grant using an option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the expected stock price volatility over the expected term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatility rates are based on the historical volatility of our publicly traded common stock and other factors. The 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. Stock-based compensation expense 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.

Stock-based compensation expense related to stock-based awards for the three and six months ended June 30, 2015 and 2014 was comprised of the following:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2015	June 30, 2014	June 30, 2015	June 30, 2014
Research and development	$ 603	$ 454	$1,227	$ 935
Selling, general and administrative	1,465	989	2,786	1,901
	$ 2,068	$ 1,443	$4,013	$2,836

Research and development expenses

Research and development expenses consist primarily of fees for services provided by third parties in connection with the clinical trials, costs of contract manufacturing services, milestone payments made under licensing agreements prior to regulatory approval, costs of materials used in clinical trials and research and development, costs for regulatory consultants and filings, depreciation of capital resources used to develop products, related facilities costs, and salaries, other employee-related costs and stock-based compensation for research and development personnel. We expense research and development costs as they are incurred for products in the development stage, including manufacturing costs and milestone payments made under license agreements prior to FDA approval. Upon and subsequent to FDA approval, manufacturing and milestone payments made under license agreements are

capitalized. Milestone payments are accrued when it is deemed probable that the milestone event will be achieved. Costs related to the acquisition of intellectual property are expensed as incurred if the underlying technology is developed in connection with our research and development efforts and has no alternative future use.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of salaries, other related costs for personnel, including stock-based compensation, related to executive, finance, accounting, information technology, marketing, medical affairs and human resource functions. Other costs include facility costs not otherwise included in research and development expenses and fees for marketing, medical affairs, legal, accounting and other professional services. Selling, general and administrative expenses also include third party expenses incurred to support sales, business development, marketing and other business activities.

Intangible Assets

The following is a summary of our intangible assets as of June 30, 2015:

		June 30, 2015		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	January 2033	$33,000	$ 2,600	$30,400
Fanapt®	November 2016	27,941	13,703	14,238
		$60,941	$ 16,303	$44,638

In January 2014, the FDA 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.

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. The likelihood of achieving the milestone and the related milestone obligation was determined to be probable during the six months ended June 30, 2015. As a result, the future obligation of $25.0 million was recorded as a non-current liability as of June 30, 2015 along with an addition of $25.0 million to capitalized intangible assets relating to HETLIOZ®. The $25.0 million was determined to be additional consideration for the acquisition of the HETLIOZ® intangible asset, which was created upon FDA approval on January 31, 2014. The actual payment of the $25.0 million will occur once the $250.0 million in cumulative worldwide sales of HETLIOZ® is realized. The $25.0 million is being amortized on a straight-line basis over the remaining life of the U.S. patent for HETLIOZ®, which is expected to be January 2033. Amortization of intangible assets relating to HETLIOZ® amounted to $2.1 million for the six months ended June 30, 2015 and includes a catch-up adjustment of $1.2 million to retroactively record cumulative amortization from February 1, 2014 to December 31, 2014 for the milestone obligation of $25.0 million. In future periods the Company expects annual amortization of capitalized intangible asset costs relating to HETLIOZ® will amount to $1.7 million until the expiration of the patent in 2033.

In 2009, the FDA 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. composition of matter patent for Fanapt® 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 additional Fanapt® patents solely owned by us with varying expiration dates, the latest of which is 2031.

The following table summarizes our future intangible asset amortization schedule as of June 30, 2015:

(in thousands)	Total	Remainder of 2015	2016	2017	2018	2019	Thereafter
HETLIOZ®	$30,400	$ 860	$ 1,721	$1,721	$1,721	$1,721	$ 22,656
Fanapt®	14,238	5,025	9,213	—	—	—	—
	$44,638	$ 5,885	$10,934	$1,721	$1,721	$1,721	$ 22,656

Recent Accounting Pronouncements

See *Summary of Significant Accounting Policies* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q 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 $303.6 million as of June 30, 2015. Our total stockholders' equity was $149.7 million as of June 30, 2015, 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 in December 2014.

Three months ended June 30, 2015 compared to three months ended June 30, 2014

Revenues. Total revenues increased by $16.7 million, or 153%, to $27.6 million for the three months ended June 30, 2015 compared to $10.9 million for the three months ended June 30, 2014. Revenues were as follows:

	Three Months Ended		
(in thousands)	June 30, 2015	June 30, 2014	Change
HETLIOZ® product sales, net	$10,017	$ 1,559	$ 8,458
Fanapt® product sales, net	17,565	—	17,565
Fanapt® royalty revenue	—	1,539	(1,539)
Fanapt® licensing agreement	—	7,764	(7,764)
	$27,582	$10,862	$16,720

HETLIOZ® was commercially launched in the U.S. in April 2014.

Pursuant to the terms of the Settlement Agreement, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us in December 2014. We began selling Fanapt® commercially in the U.S. in January 2015. Fanapt® royalty revenue for the three months ended June 30, 2014 represented amounts due from Novartis based on quarterly U.S. sales of Fanapt® by Novartis, and Fanapt® license revenue for the three months ended June 30, 2014 represented amortization of deferred revenue from the $200.0 million up-front license fee received from Novartis. Pursuant to the Settlement Agreement, royalties from Novartis ceased, and the remaining balance of the deferred revenue as of December 31, 2014 related to the up-front license fee was recognized as part of gain on arbitration settlement in the consolidated statement of operations in the fourth quarter of 2014.

Cost of goods sold. Cost of goods sold for the three months ended June 30, 2015 was $5.8 million compared to $0.2 million for the three months ended June 30, 2014. HETLIOZ® was commercially launched in the U.S. in April 2014, and we began selling Fanapt® commercially in the U.S. in January 2015. Cost of goods sold includes third party manufacturing costs of product sold, third party royalty costs and distribution and other costs. Third party royalty costs for the three months ended June 30, 2015 were 10% of net U.S. sales of HETLIOZ® and 23% of net U.S sales of Fanapt®.

HETLIOZ® inventory manufactured prior to FDA approval on January 31, 2014 consisted of raw materials and work-in-process inventory, which was expensed as research and development costs as incurred. 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 June 30, 2015, we had approximately $0.3 million, $1.5 million and $0.0 million of reduced-cost HETLIOZ® finished goods, work-in-process inventory, and raw materials inventory, respectively, on hand.

The aggregate selling price of reduced-cost finished goods HETLIOZ® 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 HETLIOZ® inventory, or the timing of sales of finished goods HETLIOZ® manufactured with this inventory. We expect our HETLIOZ® 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 HETLIOZ® 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.

HETLIOZ® cost of goods sold as a percentage of HETLIOZ® 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 costs included in cost of goods sold will be less than 2% of our net HETLIOZ® product sales.

Fanapt® work-in-process inventory and finished goods inventory acquired from Novartis as part of the acquisition of the Fanapt® business was recorded at fair value. The fair value of the inventory acquired from Novartis represents a higher cost than if new work-in-process inventory and finished goods inventory was manufactured at this time. We expect that, in the future, total Fanapt® manufacturing costs included in cost of goods sold will be less than 4% of our net Fanapt® product sales

Research and development expenses. Research and development expenses increased by $2.4 million, or 69%, to $5.9 million for the three months ended June 30, 2015 compared to $3.5 million for the three months ended June 30, 2014. The following table summarizes the costs of our product development initiatives for the three months ended June 30, 2015 and 2014. Included in this table are the research and development expenses recognized in connection with the clinical development of HETLIOZ®, Fanapt®, tradipitant and Trichostatin A.

	Three Months Ended	
(in thousands)	**June 30, 2015**	**June 30, 2014**
Direct project costs (1)		
HETLIOZ®	$ 1,763	$ 2,112
Fanapt®	1,870	(6)
Tradipitant	677	427
Trichostatin A	451	62
	4,761	2,595
Indirect project costs (1)		
Stock-based compensation	603	454
Other indirect overhead	582	465
	1,185	919
Total research and development expense	$ 5,946	$ 3,514

(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 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 decreased by $9.7 million, or 35%, to $18.4 million for the three months ended June 30, 2015 compared to $28.1 million for the three months ended June 30, 2014. The decrease is primarily due to the commercial launch of HETLIOZ® in the U.S. for the treatment of Non-24 in April 2014. Our sales and marketing effort included the addition of marketing programs, field-based sales and national account teams. We incurred costs associated with a HETLIOZ® branded advertising campaign and our Non-24 Disease Awareness campaign, which included radio and television advertisements broadcast nationwide. We added a medical affairs team in 2014 to support HETLIOZ® and Non-24 medical education. The decrease was partly offset by expenses for our launch of Fanapt® in the U.S. Our field sales force began promotion of Fanapt® in the U.S. in April 2015.

Intangible asset amortization. Intangible asset amortization increased by $2.3 million to $2.9 million for the three months ended June 30, 2015 compared to $0.6 million for the three months ended June 30, 2014. The increase reflects additional amortization of $2.1 million relating to Fanapt®. Pursuant to the terms of the Settlement Agreement, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us in December 2014 resulting in an increase in capitalized intangible assets of $15.9 million that is being amortized until November 2016.

Six months ended June 30, 2015 compared to six months ended June 30, 2014

Revenues. Total revenues increased by $29.7 million, or 149%, to $49.7 million for the six months ended June 30, 2015 compared to $20.0 million for the six months ended June 30, 2014. Revenues were as follows:

	Six Months Ended		
(in thousands)	June 30, 2015	June 30, 2014	Change
HETLIOZ® product sales, net	$17,477	$ 1,559	$ 15,918
Fanapt® product sales, net	32,255	—	32,255
Fanapt® royalty revenue	—	3,230	(3,230)
Fanapt® licensing agreement	—	15,216	(15,216)
	$49,732	$20,005	$ 29,727

HETLIOZ® was commercially launched in the U.S. in April 2014.

Pursuant to the terms of the Settlement Agreement, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us in December 2014. We began selling Fanapt® commercially in the U.S. in January 2015. Fanapt® royalty revenue for the six months ended June 30, 2014 represented amounts due from Novartis based on quarterly U.S. sales of Fanapt® by Novartis, and Fanapt® license revenue for the six months ended June 30, 2014 represented amortization of deferred revenue from the $200.0 million up-front license fee received from Novartis. Pursuant to the Settlement Agreement, royalties from Novartis ceased, and the remaining balance of the deferred revenue as of December 31, 2014 related to the up-front license fee was recognized as part of gain on arbitration settlement in the consolidated statement of operations in the fourth quarter of 2014.

Cost of goods sold. Cost of goods sold for the six months ended June 30, 2015 was $10.8 million compared to $0.2 million for the six months ended June 30, 2014. HETLIOZ® was commercially launched in the U.S. in April 2014, and we began selling Fanapt® commercially in the U.S. in January 2015. Cost of goods sold includes third party manufacturing costs of product sold, third party royalty costs and distribution and other costs. Third party royalty costs for the six months ended June 30, 2015 were 10% of net U.S. sales of HETLIOZ® and 23% of net U.S sales of Fanapt®.

HETLIOZ® inventory manufactured prior to FDA approval on January 31, 2014 consisted of raw materials and work-in-process inventory, which was expensed as research and development costs as incurred. 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 June 30, 2015, we had approximately $0.3 million, $1.5 million and $0.0 million of reduced-cost HETLIOZ® finished goods, work-in-process inventory, and raw materials inventory, respectively, on hand.

The aggregate selling price of reduced-cost finished goods HETLIOZ® 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 HETLIOZ® inventory, or the timing of sales of finished goods HETLIOZ® manufactured with this inventory. We expect our HETLIOZ® 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 HETLIOZ® 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.

HETLIOZ® cost of goods sold as a percentage of HETLIOZ® 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 costs included in cost of goods sold will be less than 2% of our net HETLIOZ® product sales.

Fanapt® work-in-process inventory and finished goods inventory acquired from Novartis as part of the acquisition of the Fanapt® business was recorded at fair value. The fair value of the inventory acquired from Novartis represents a higher cost than if new work-in-process inventory and finished goods inventory was manufactured at this time. We expect that, in the future, total Fanapt® manufacturing costs included in cost of goods sold will be less than 4% of our net Fanapt® product sales

Research and development expenses. Research and development expenses decreased by $0.4 million, or 4%, to $10.4 million for the six months ended June 30, 2015 compared to $10.8 million for the six months ended June 30, 2014. The following table summarizes the costs of our product development initiatives for the six months ended June 30, 2015 and 2014. Included in this table are the research and development expenses recognized in connection with the clinical development of HETLIOZ®, Fanapt®, tradipitant and Trichostatin A.

	Six Months Ended	
(in thousands)	**June 30, 2015**	**June 30, 2014**
Direct project costs (1)		
HETLIOZ®	$ 3,467	$ 7,802
Fanapt®	2,727	71
Tradipitant	1,078	1,014
Trichostatin A	799	70
	8,071	8,957
Indirect project costs (1)		
Stock-based compensation	1,227	935
Other indirect overhead	1,126	885
	2,353	1,820
Total research & development expense	$10,424	$10,777

(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 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 decreased by $18.8 million, or 34%, to $37.2 million for the six months ended June 30, 2015 compared to $56.0 million for the six months ended June 30, 2014. The decrease is primarily due to the commercial launch of HETLIOZ® in the U.S. for the treatment of Non-24 in April 2014. 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. We added a medical affairs team in 2014 to support HETLIOZ® and Non-24 medical education. The reduction was partly offset by expenses for our launch of Fanapt® in the U.S. Our field sales force began promotion of Fanapt® in the U.S. in April 2015.

Intangible asset amortization. Intangible asset amortization increased by $5.9 million to $7.1 million for the six months ended June 30, 2015 compared to $1.2 million for the six months ended June 30, 2014. The increase reflects additional amortization of $4.1 million relating to Fanapt®. Pursuant to the terms of the Settlement Agreement, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us in December 2014 resulting in an increase in capitalized intangible assets of $15.9 million that is being amortized until November 2016. The increase also reflects additional amortization of $1.8 million relating to HETLIOZ®. The likelihood of achieving a future milestone obligation that becomes payable to BMS when cumulative sales of HETLIOZ® equal $250.0 million was determined to be probable in the first quarter of 2015 resulting in an increase in capitalized intangible assets of $25.0 million and a corresponding increase in accrued non-current liabilities. The additional amortization relating to HETLIOZ® includes a catch-up adjustment of $1.2 million to retroactively record cumulative amortization from February 1, 2014 to December 31, 2014. We expect that annual amortization of capitalized intangible asset costs relating to HETLIOZ® will amount to $1.7 million in future years until the expiration of the patent in 2033.

Liquidity and Capital Resources

As of June 30, 2015, our total cash and cash equivalents and marketable securities were $146.6 million compared to $129.8 million at December 31, 2014. 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.

Our liquidity resources as of June 30, 2015 and December 31, 2014 are summarized as follows:

(in thousands)	June 30, 2015	December 31, 2014
Cash and cash equivalents	$ 48,337	$ 60,901
Marketable securities:		
U.S. Treasury and government agencies	54,633	30,618
Corporate debt	43,667	38,303
Total marketable securities	98,300	68,921
Total cash and cash equivalents	$146,637	$ 129,822

As of June 30, 2015, 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 throughout 2015 and beyond in connection with the continued U.S. commercial launch of HETLIOZ® and selling Fanapt® commercially in the U.S., while evaluating the commercial opportunity for HETLIOZ® in the European countries in which it has been approved. Additionally, we continue to pursue market approval of HETLIOZ® and Fanapt® in other regions. Because of the uncertainties discussed above, the costs to advance our research and development projects and the continued commercial launch of HETLIOZ® and selling Fanapt® commercially 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 and debt securities may be convertible into common stock. 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 six months ended June 30, 2015 and 2014:

	Six Months Ended	
	June 30, 2015	June 30, 2014
Net cash provided by (used in):		
Operating activities	$ 17,656	$(60,569)
Investing activities	(30,733)	10,756
Financing activities	513	2,043
Net decrease in cash and cash equivalents	$(12,564)	$(47,770)

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

Net cash provided by operating activities was $17.7 million for the six months ended June 30, 2015, an increase of $78.3 million from net cash used in operating activities of $60.6 million for the six months ended June 30, 2014. The increase resulted from a reduction in the net loss of $32.5 million and an increase of $7.4 million in non-cash charges. Non-cash charges resulting from the amortization of intangible assets increased $5.9 million, of which $4.1 million was for Fanapt® and $1.8 million was for HETLIOZ®. Non-cash charges for stock-based compensation increased by $1.2 million. In addition, the increase in net cash provided by operating activities reflects $34.5 million from a net increase in accrued liabilities primarily for sales allowances relating to initial sales of Fanapt® in the 2015 period. Net cash used in operating activities for the six months ended June 30, 2014 had included non-cash revenue of $15.2 million from the amortization of deferred revenue relating to Fanapt®. The increase in net cash provided by operating activities was partly offset by a net increase of $11.8 million in accounts receivable resulting from initial sales of Fanapt® in the 2015 period.

Net cash used in investing activities was $30.7 million for the six months ended June 30, 2015, a decrease of $41.5 million from net cash provided by investing activities of $10.8 million for the six months ended June 30, 2014. The decrease primarily resulted from net purchases of marketable securities of $29.8 million in the 2015 period compared with net sales of marketable securities of $18.9 million in the 2014 period. Net cash provided by investing activities for the six months ended June 30, 2014 had been reduced by a milestone payment of $8.0 million to BMS as a result of the FDA approval of HETLIOZ® in January 2014.

Net cash provided by financing activities was $0.5 million for the six months ended June 30, 2015, a decrease of $1.5 million, from net cash provided by financing activities of $2.0 million for the six months ended June 30, 2014. The decrease is due to a reduction in the amount of cash proceeds from the exercise of 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

There have been no material changes to our contractual obligations from the information provided in Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations*, included in our annual report on Form 10-K for the fiscal year ended December 31, 2014.

ITEM 3 Quantitative and Qualitative Disclosures about Market Risk

Interest rate risks

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.

Concentrations of credit risk

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.

Revenues and accounts receivable are concentrated with specialty pharmacies and wholesalers. The top six customers represented 95% of total revenues for the six months ended June 30, 2015, and the top three customers represented 72% of accounts receivable at June 30, 2015. We have not experienced any losses relating to receivables from customers.

Effects of inflation

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

ITEM 4 Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our 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 Exchange Act of 1934, as amended (Exchange Act)) as of June 30, 2015. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of June 30 , 2015, the end of the period covered by this quarterly report, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

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 capitalization of inventory relating to Fanapt®. Except for the expansion of our controls related to accounting for net product sales, accounts receivable and capitalization of inventory relating to Fanapt®, 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.

PART II — OTHER INFORMATION

ITEM 1 Legal Proceedings

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 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 (ANDA) 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, 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.

The two pending cases against Roxane were consolidated by agreement of the parties in April 2015 and are scheduled to be tried together in a four-day bench trial beginning on February 29, 2016.

In May 2015, we filed a lawsuit against Inventia Healthcare Pvt. Ltd. (Inventia) in the U.S. District Court for the District of Delaware. The suit seeks an adjudication that Inventia has infringed on one or more claims of one of our patents by submitting to the U.S. Food and Drug Administration (FDA) an ANDA for a generic version of Fanapt®. The relief requested by us includes a request for a permanent injunction preventing Inventia 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. We received Inventia's paragraph IV notice regarding the Patent on April 3, 2015.

ITEM 1A Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this quarterly report and our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, including the consolidated financial statements and the related notes appearing herein and therein, with respect to any investment in shares of our common stock. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment.

Risks related to our business and industry

We are heavily dependent on the commercial success of HETLIOZ®, which received marketing authorization in the U.S. in 2014 and in Europe in 2015.

Our future success is currently substantially dependent upon the commercial success of HETLIOZ® for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24). In January 2014, the 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®. In July 2015, the European Commission (EC) granted centralized marketing authorization with unified labeling for HETLIOZ® for the treatment of Non-24 in blind adults. This authorization is valid in the 28 countries that are members of the European Union, as well as European Economic Area members Iceland, Liechtenstein and Norway.

Because we have limited information with regard to the market acceptance of HETLIOZ® in the U.S. or elsewhere abroad, we may have to revise our estimates regarding the market acceptance of HETLIOZ® or our strategy to commercialize the product.

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

- cost of treatment;
- pricing and availability of alternative products;
- the cost and success of our Non-24 awareness campaign;
- our ability to obtain third-party coverage or reimbursement for HETLIOZ®;
- perceived efficacy relative to other available therapies;

- shifts in the medical community to new treatment paradigms or standards of care;
- relative convenience and ease of administration; and
- prevalence and severity of adverse side effects associated with treatment.

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® and our Non-24 awareness campaign in the U.S., evaluate foreign market opportunities for HETLIOZ® and continue to grow our operational capabilities, both domestically and abroad. This represents a significant investment in the commercial success of HETLIOZ®, which is uncertain.

If we do not successfully commercialize HETLIOZ® in the U.S., Europe or other jurisdictions 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 us;
- 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 June 30, 2015, we had 105 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 or applicable foreign agency 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 additional foreign jurisdictions, but we may not obtain any such approvals.

We intend to market our products, alone or with others, 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 June 30, 2015, our total cash and cash equivalents and marketable securities were $146.6 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;
- market acceptance of our products;
- costs involved in establishing manufacturing capabilities for commercial quantities of our products;
- 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;
- 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 FDA approved direct competitors. Sedative-Hypnotic treatments include, Ambien® (zolpidem) by Sanofi (including Ambien CR®), Lunesta® (eszopiclone) by Sunovion Pharmaceuticals Inc., Sonata® (zaleplon) by Pfizer Inc., Rozerem® (ramelteon) by Takeda Pharmaceuticals Company Limited, 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.

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 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 ANDA 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, 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.

The two pending cases against Roxane were consolidated by agreement of the parties in April 2015 and are scheduled to be tried together in a four-day bench trial beginning on February 29, 2016.

In May 2015, we filed suit against Inventia Healthcare Pvt. Ltd. (Inventia) in the U.S. District Court for the District of Delaware. The suit seeks an adjudication that Inventia has infringed one or more claims of one of our patents by submitting to the FDA an ANDA for a generic version of Fanapt®. The relief requested by us includes a request for a permanent injunction preventing Inventia 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.

FDA and foreign 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, as well as foreign regulatory authorities in jurisdictions in which we seek approval. 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 or foreign regulatory 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 or applicable foreign regulatory agency 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 or foreign agency may interpret data from pre-clinical and clinical trials in different ways than we or our partners do;
- the FDA or foreign agency 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 or foreign agency may change its approval policies or adopt new regulations;
- the FDA or foreign agency may not meet, or may extend, the Prescription Drug User Fee Act (PDUFA-V) date or its foreign equivalent with respect to a particular NDA or foreign application; and
- the FDA or foreign agency 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 or the applicable foreign agency, 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 the 31 countries in Europe covered by the recent centralized marketing authorization by the EC, 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 or the applicable foreign agency 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 and foreign agencies generally approve 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, local and foreign 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, the EC's grant of the centralized marketing authorization for HETLIOZ® in July 2015, 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 June 30, 2015, we had an accumulated deficit of $303.6 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. We are currently evaluating the commercial opportunity for HETLIOZ® in Europe. 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., Europe 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 Israel, Mexico and 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, 2008 and December 31, 2014. Our management determined that there was sufficient Built-In-Gain as of December 31, 2008 to offset the Internal Revenue Code of 1986, as amended (IRC), Section 382 limitation generated by the ownership change. Our management believes that there is sufficient Built-In-Gain as of December 31, 2014 to offset the IRC Section 382 limitation generated by the ownership change. 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, 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 $25.0 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 delay or prevent the commercial launch or impede the commercial success of HETLIOZ® in Europe and adversely affect our future results of operations.

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 legislature 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. Although we have received marketing authorization for HETLIOZ® from the EC, pricing negotiations with governmental authorities may take a considerable amount of time in those Member States that impose price controls. In addition, to obtain reimbursement or pricing approval for HETLIOZ® in some Member States, we may be required to conduct a clinical trial that compares the cost-effectiveness of HETLIOZ®, 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 may be subject to lengthy price regulations that delay or prevent the commercial launch of HETLIOZ® in a particular Member State and negatively impact the revenues that are generated from the sale of HETLIOZ® in that country. If reimbursement of HETLIOZ® is unavailable or limited in scope or amount, or if pricing for HETLIOZ® is set at unsatisfactory levels or takes too long to establish, or if there is competition from lower priced cross-border sales, our results of operations 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 results of operations.

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.

We are increasingly dependent on information technology systems, infrastructure and data.

We are increasingly dependent upon information technology systems, infrastructure and data. Our computer systems may be vulnerable to service interruption or destruction, malicious intrusion and random attack. Security breaches pose a risk that sensitive data, including intellectual property, trade secrets or personal information may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, denial-of service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Our key business partners face similar risks, and a security breach of their systems could adversely affect our security posture. While we continue to invest data protection and information technology, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm.

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®) 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, would 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.

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 patented methods, 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 extension for HETLIOZ®, and that we continue to have rights under our license agreement with respect to this product, we would have exclusive rights to the HETLIOZ® U.S. "new chemical entity" patent (the primary patent covering the product as a new composition of matter) until 2022. We also own two HETLIOZ® U.S. method of use patents (directed to the approved method of treatment as described in the HETLIOZ® label approved by the FDA). These patents expire normally in 2033. The Fanapt® U.S. "new chemical entity" patent has received the full five-year patent term extension under the Hatch-Waxman Act and so the term of this 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. Six additional U.S. patents directed to methods of treating patients with Fanapt®, with various expiration dates in 2030 and 2031, were issued to us in 2014 and 2015.

A directive in the European Union provides that companies that receive regulatory approval for a new medicinal product will have a 10-year period of market exclusivity for that product (with the possibility of a further one-year extension), 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 June 2014, we filed suit against Roxane Laboratories, Inc. (Roxane) in the U.S. District Court for the District of Delaware. The suit seeks 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 ANDA 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, 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.

The two pending cases against Roxane were consolidated by agreement of the parties in April 2015 and are scheduled to be tried together in a four-day bench trial beginning on February 29, 2016.

In May 2015, we filed suit against Inventia in the U.S. District Court for the District of Delaware. The suit seeks an adjudication that Inventia has infringed one or more claims of one of our patents by submitting to the FDA an ANDA for a generic version of Fanapt®. The relief requested by us includes a request for a permanent injunction preventing Inventia 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.

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, 2015 and June 30, 2015, the high and low sale prices of our common stock as reported on The NASDAQ Global Market varied between $8.80 and $15.00. Additionally, market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons that were unrelated to the operating performance of any one company.

The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our common stock:

- publicity regarding actual or potential testing or trial results relating to products under development by us or our competitors;
- the outcome of regulatory review relating to products under development by us or our competitors;
- regulatory developments in the U.S. and foreign countries;
- developments concerning any collaboration or other strategic transaction we may undertake;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- termination or delay of development or commercialization program(s) by our partners;
- safety issues with our products or those of our competitors;
- our or our partners' ability to successfully commercialize our products;
- our ability to successfully execute our commercialization strategies;
- announcements of technological innovations or new therapeutic products or methods by us or others;
- actual or anticipated variations in our quarterly operating results;
- changes in estimates of our financial results or recommendations by securities analysts or failure to meet such financial expectations;
- changes in government regulations or policies;
- changes in patent legislation or patent decisions or adverse changes to patent law;
- additions or departures of key personnel or members of our board of directors;
- financial guidance or business updates we may provide;
- announcements about our earnings that are not in line with analyst expectations or guidance we 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 private equity funds hold a significant number of shares of our common stock. Sales by these stockholders of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

In addition to our outstanding common stock, as of June 30, 2015 there were a total of 7,641,146 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 2 Unregistered Sales of Equity Securities and Use of Proceeds

None

ITEM 3 Defaults Upon Senior Securities

None

ITEM 4 Mine Safety Disclosures

Not applicable

ITEM 5 Other Information

None

ITEM 6 Exhibits

Exhibit Number	Description
10.63	Employment Agreement for Thomas E. Gibbs, Senior Vice President and Chief Commercial Officer, dated April 20, 2015.
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 (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2015formatted in XBRL (eXtensible Business Reporting Language) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of June 30, 2015 and December 31, 2014; (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2015 and 2014; (iii) Condensed Consolidated Statement of Comprehensive Income (Loss) for the three and six months ended June 30, 2015 and 2014; (iv) Condensed Consolidated Statement of Changes in Stockholders' Equity for the six months ended June 30, 2015; (v) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2015 and 2014; and (vi) Notes to Condensed Consolidated Financial Statements.

The certification attached as Exhibit 32.1 that accompanies this quarterly report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Vanda Pharmaceuticals Inc. 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 this quarterly report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Vanda Pharmaceuticals Inc.

July 31, 2015 /s/ Mihael H. Polymeropoulos, M.D.

Mihael H. Polymeropoulos, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

July 31, 2015 /s/ James P. Kelly

James P. Kelly
Senior Vice President, Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

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Exhibit 10.63

VANDA PHARMACEUTICALS INC.

EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement") was entered into as of April 20, 2015, by and between Thomas E. Gibbs (the "Executive") and **VANDA PHARMACEUTICALS INC.**, a Delaware corporation (the "Company").

1. **Duties and Scope of Employment.**

(a) **Position**. During his employment under this Agreement ("Employment"), the Company agrees to employ the Executive in the position of Senior Vice President, Chief Commercial Officer. The Executive shall be subject to the supervision of, and shall have such authority as is delegated to him by, the Company's Chief Executive Officer. The Executive hereby accepts such employment and agrees to undertake the duties and responsibilities normally inherent in such position and such other duties and responsibilities as the Company's Chief Executive Officer shall from time to time reasonably assign to him.

(b) **Obligations to the Company**. During his Employment, the Executive shall devote his full business efforts and time to the Company. In addition, during his Employment, without the prior written approval of the Company's Board of Directors (the "Board"), the Executive shall not render services in any capacity to any other person or entity and shall not act as a sole proprietor or partner of any other person or entity or as a shareholder owning more than five percent of the voting power of any other entity. The Executive shall comply with the Company's policies and rules, as they may be in effect from time to time during his Employment.

(c) **No Conflicting Obligations**. The Executive represents and warrants to the Company that he is under no obligations or commitments, whether contractual or otherwise, that are inconsistent with his obligations under this Agreement. The Executive represents and warrants that he will not use or disclose, in connection with his Employment, any trade secrets or other proprietary information or intellectual property in which the Executive or any other person has any right, title or interest and that his Employment as contemplated by this Agreement will not infringe or violate the rights of any other person or entity. The Executive represents and warrants to the Company that he has returned all property and confidential information belonging to any prior employers.

2. **Cash and Incentive Compensation.**

(a) **Salary**. The Company shall pay the Executive as compensation for his services a base salary at a gross annual rate of not less than $375,000. Such salary shall be payable in accordance with the Company's standard payroll procedures. (The annual compensation specified in this Subsection (a), together with any increases in such compensation that the Company may grant from time to time, is referred to in this Agreement as "Base Compensation.")

(b) **Incentive Bonuses**. The Executive shall be eligible for an annual incentive bonus with a target amount equal to 40% of his Base Compensation (the "Annual Target Bonus"). Such bonus (if any) shall be awarded based on objective or subjective criteria established in advance by the Board or the Compensation Committee of the Board (the "Compensation Committee"). Any bonus for the fiscal year in which Executive's employment begins shall not be prorated. Any incentive bonus for a fiscal year shall in no event be paid later than 2 ½ months after the close of such fiscal year. Except as provided in Section 6, such bonus shall be paid only if the Executive is employed by the Company at the time of payment. The determinations of the Board or the Compensation Committee with respect to such bonus shall be final and binding.

(c) **Stock Options**. On the date of this Agreement, the Company shall grant the Executive a nonstatutory stock option to purchase 175,000 shares of the Company's Common Stock (the "Option"). The per-share exercise price of the Option shall be equal to the closing price of one share of the Company's Common Stock on the date of grant as reported on the NASDAQ Global Market. The maximum term of the Option shall be 10 years, subject to earlier expiration in the event of the termination of the Executive's service with the Company. The grant of the Option shall be subject to the terms and conditions set forth in the Vanda Pharmaceuticals Inc. 2006 Equity Incentive Plan (the "Plan") and in the Company's standard form of Stock Option Agreement. The Option will become exercisable with respect to 25% of the shares on the first anniversary of the date of this Agreement and with respect to the remaining 75% of the shares in equal monthly installments over the next 3 years of continuous service thereafter. The Option shall become exercisable in full if (i) the Company is subject to a Change in Control before the Executive's service with the Company terminates and (ii) the Executive is subject to an Involuntary Termination within 24 months after such Change in Control. In addition, Section 6(c) shall apply to the Option. In addition, the Executive will be eligible to receive annual equity awards, if any, subject to the approval of the Board or the Compensation Committee in their sole discretion. The timing and size of the annual equity awards, if any, shall be determined in the sole discretion of the Board or the Compensation Committee based on the Executive's and/or the Company's performance.

(d) **Restricted Stock Units**. On the date of this Agreement, the Company shall award the Executive restricted stock units covering 60,000 shares of the Company's Common Stock (the "RSU Award"). The RSU Award shall be subject to the terms and conditions set forth in the Vanda Pharmaceuticals Inc. 2006 Equity Incentive Plan and in the Company's standard form of Restricted Stock Unit Award Agreement. The RSU Award will vest with respect to 25% of the shares on January 1, 2016, an additional 25% of the shares on January 1, 2017, an additional 25% of the shares on January 1, 2018, and the final 25% of the shares on January 1, 2019, provided that Executive's remains in continuous service with the Company on each applicable vesting date. The RSU Award shall vest in full if (i) the Company is subject to a Change in Control before the Executive's service with the Company terminates and (ii) the Executive is subject to an Involuntary Termination within 24 months after such Change in Control.

3. **Vacation and Employee Benefits**. During his Employment, the Executive shall be eligible for 25 paid vacation days each year. Vacation days shall accrue, and

may be taken, in accordance with the Company's standard policy for similarly situated employees, as it may be amended from time to time. During his Employment, the Executive shall be eligible to participate in any employee benefit plans maintained by the Company for similarly situated employees, subject in each case to the generally applicable terms and conditions of the plan in question and to the determinations of any person or committee administering such plan.

4. **Business Expenses**. During his Employment, the Executive shall be authorized to incur necessary and reasonable travel, entertainment and other business expenses in connection with his duties hereunder. The Company shall reimburse the Executive for such expenses upon presentation of an itemized account and appropriate supporting documentation, all in accordance with the Company's generally applicable policies. Any reimbursement shall (a) be paid promptly but not later than the last day of the calendar year following the year in which the expense was incurred, (b) not be affected by any other expenses that are eligible for reimbursement in any calendar year and (c) not be subject to liquidation or exchange for another benefit.

5. **Term of Employment**.

(a) **Employment at Will**. The Executive's Employment with the Company shall be "at will," meaning that either the Executive or the Company may terminate the Executive's Employment at any time and for any reason, with or without Cause. Any contrary representations which may have been made to the Executive shall be superseded by this Agreement. This Agreement shall constitute the full and complete agreement between the Executive and the Company on the "at will" nature of the Executive's Employment, which may only be changed in an express written agreement signed by the Executive and a duly authorized officer of the Company (other than the Executive). The termination of Executive's Employment shall not limit or otherwise affect his obligations under Section 7 below.

(b) **Termination**. The Company may terminate the Executive's Employment at any time and for any reason (or no reason), and with or without Cause, by giving the Executive notice in writing. The Executive may terminate his Employment by giving the Company 14 days' advance notice in writing. The Executive's Employment shall terminate automatically in the event of his death.

(c) **Rights Upon Termination**. Except as expressly provided in Section 6, upon the termination of the Executive's Employment pursuant to this Section 5, the Executive shall only be entitled to the compensation, benefits and expense reimbursements described in Sections 2, 3 and 4 for the period preceding the effective date of the termination. The payments under this Agreement shall fully discharge all responsibilities of the Company to the Executive.

6. **Termination Benefits**.

(a) **Preconditions**. Any other provision of this Agreement notwithstanding, the remaining Subsections of this Section 6 shall not apply unless each of the following requirements is satisfied:

(i) The Executive has executed a general release of all known and unknown claims that the Executive may then have against the Company or persons affiliated with the Company in a form prescribed by the Company, without alterations. The Executive shall execute and return the release on or before the date specified by the Company in the prescribed form (the "Release Deadline"). The Release Deadline shall in no event be later than 50 days after the Executive's Separation. If the Executive fails to return the release on or before the Release Deadline, or if the Executive revokes the release, then the Executive shall not be entitled to the benefits described in this Section 6.

(ii) The Executive has returned all property of the Company in the Executive's possession.

(b) **Severance Pay**. If, during the term of this Agreement, the Executive is subject to an Involuntary Termination, then the Company shall pay the Executive both of the following:

(i) **Base Compensation**. His Base Compensation for a period of 12 months following the Separation (the "Continuation Period"). Such severance payment shall be paid at the Base Compensation rate in effect at the time of the Separation and in accordance with the Company's standard payroll procedures. The severance payments shall commence within 60 days after the Executive's Separation and, once they commence (the "Payment Commencement"), shall include any unpaid amounts accrued from the date of the Employee's Separation. However, if the 60-day period described in the preceding sentence spans two calendar years, then the Payment Commencement shall in any event begin in the second calendar year.

(ii) **Target Bonus**. An amount equal to his Annual Target Bonus at the rate in effect at the time of the Separation. Such amount shall be payable in a lump sum on the Company's next regularly scheduled payroll that occurs following the Payment Commencement.

(c) **Options**. If, during the term of this Agreement, Executive is subject to an Involuntary Termination, then (i) the vested portion of the shares of the Company's Common Stock subject to all options held by the Executive at the time of his Separation shall be determined by adding three months to the actual period of service that he has completed with the Company and (ii) such options shall be exercisable for up to six months after the Executive's Separation (provided, however, that the Option shall remain subject to the terms of the Plan in the event the Company is subject to a Change in Control, and further provided that the Option in any event shall expire no later than the Expiration Date set forth in the Notice of Stock Option Grant evidencing the Option).

7. **Non-Solicitation, Non-Disclosure and Non-Competition.** The Executive has entered into a Proprietary Information and Inventions Agreement with the Company, which agreement is incorporated herein by reference.

8. **Successors.**

(a) **Company's Successors**. This Agreement shall be binding upon any successor (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets which becomes bound by this Agreement.

(b) **Executive's Successors**. This Agreement and all rights of the Executive hereunder shall inure to the benefit of, and be enforceable by, the Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

9. **Definitions**. For all purposes under this Agreement:

"**Cause**" shall mean:

(a) An unauthorized use or disclosure by the Executive of the Company's confidential information or trade secrets, which use or disclosure causes material harm to the Company;

(b) A material breach by the Executive of any agreement between the Executive and the Company;

(c) A material failure by the Executive to comply with the Company's written policies or rules;

(d) The Executive's conviction of, or plea of "guilty" or "no contest" to, a felony under the laws of the United States or any State thereof;

(e) The Executive's gross negligence or willful misconduct;

(f) A continuing failure by the Executive to perform assigned duties after receiving written notification of such failure from the Board; or

(g) A failure by the Executive to cooperate in good faith with a governmental or internal investigation of the Company or its directors, officers or employees, if the Company has requested the Executive's cooperation.

"**Change in Control**" shall mean:

(a) The consummation of a merger or consolidation of the Company with or into another entity or any other corporate reorganization, if persons who were not stockholders of the Company immediately prior to such merger, consolidation or other reorganization own immediately after such merger, consolidation or other reorganization 50% or more of the voting power of the outstanding securities of each of (i) the continuing or surviving entity and (ii) any direct or indirect parent corporation of such continuing or surviving entity;

(b) The sale, transfer or other disposition of all or substantially all of the Company's assets;

(c) A change in the composition of the Board, as a result of which fewer than 50% of the incumbent directors are directors who either:

(i) Had been directors of the Company on the date 24 months prior to the date of such change in the composition of the Board (the "Original Directors"); or

(ii) Were appointed to the Board, or nominated for election to the Board, with the affirmative votes of at least a majority of the aggregate of (A) the Original Directors who were in office at the time of their appointment or nomination and (B) the directors whose appointment or nomination was previously approved in a manner consistent with this Paragraph (ii); or

(d) Any transaction as a result of which any person is the "beneficial owner" (as defined in Rule 13d-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), directly or indirectly, of securities of the Company representing at least 50% of the total voting power represented by the Company's then outstanding voting securities. For purposes of this Subsection (d), the term "person" shall have the same meaning as when used in Sections 13(d) and 14(d) of the Exchange Act but shall exclude (i) a trustee or other fiduciary holding securities under an employee benefit plan of the Company or of a parent or subsidiary of the Company and (ii) a corporation owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of the Common Stock of the Company.

A transaction shall not constitute a Change in Control if its sole purpose is to change the State of the Company's incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

"**Code**" shall mean the Internal Revenue Code of 1986, as amended.

"**Good Reason**" shall mean Executive's resignation within 6 months after one of the following conditions has come into existence without Executive's consent: (i) a change in the Executive's position with the Company that materially reduces his level of authority or responsibility, (ii) a material reduction in his Base Compensation or (iii) receipt of notice that his principal workplace will be relocated by more than 30 miles. A condition shall not be considered "Good Reason" unless the Executive gives the Company written notice of such condition within 90 days after the initial existence of such condition and the Company fails to remedy such condition within 30 days after receiving the Executive's written notice.

"**Involuntary Termination**" shall mean a Separation resulting from either (i) the Executive's involuntary discharge by the Company for reasons other than Cause, Executive's death or Permanent Disability or (ii) the Executive's voluntary resignation for Good Reason.

"**Permanent Disability**" shall mean the Executive's inability to perform the essential functions of the Executive's position, with or without reasonable accommodation, for a period of at least 120 consecutive days because of a physical or mental impairment.

"**Separation**" shall mean a "separation from service," as defined in the regulations under Section 409A of the Code.

10. **Miscellaneous Provisions.**

(a) **Notice**. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by overnight courier, U.S. registered or certified mail, return receipt requested and postage prepaid. In the case of the Executive, mailed notices shall be addressed to him at the home address that he most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

(b) **Modifications and Waivers**. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by the Executive and by an authorized officer of the Company (other than the Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) **Whole Agreement**. No other agreements, representations or understandings (whether oral or written and whether express or implied) which are not expressly set forth in this Agreement have been made or entered into by either party with respect to the subject matter hereof. This Agreement and the Proprietary Information and Inventions Agreement contain the entire understanding of the parties with respect to the subject matter hereof.

(d) **Tax Matters**. All payments made under this Agreement shall be subject to reduction to reflect taxes or other charges required to be withheld by law. For purposes of Section 409A of the Code, each payment under Section 6(b) is hereby designated as a separate payment. If the Company determines that the Executive is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code and the regulations thereunder at the time of his Separation, then:

(i) Any salary continuation payments under Section 6(b)(i), to the extent not exempt from Section 409A of the Code, shall commence with the Company's first regularly scheduled payroll that occurs following the earlier of (x) expiration of the six-month period measured from Executive's Separation or (y) the date of Executive's death and, once such payments commence, any amounts accrued from the Separation date shall be paid in a lump sum on the first payment date; and

(ii) Any lump-sum payment under Section 6(b)(ii), to the extent not exempt from Section 409A of the Code, shall be made with the Company's first regularly scheduled payroll that occurs following the earlier of (x) expiration of the six-month period measured from Executive's Separation or (y) the date of Executive's death.

The Company shall not have a duty to design its compensation policies in a manner that minimizes the Executive's tax liabilities, and the Executive shall not make any claim against the Company or the Board related to tax liabilities arising from the Executive's compensation.

(e) **Choice of Law**. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the District of Columbia (except its provisions governing the choice of law).

(f) **Severability**. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(g) **No Assignment**. This Agreement and all rights and obligations of the Executive hereunder are personal to the Executive and may not be transferred or assigned by the Executive at any time. The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with any sale or transfer of all or a substantial portion of the Company's assets to such entity.

(h) **Counterparts**. This 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 LEFT BLANK INTENTIONALLY]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the date first written above.

/s/ Thomas E. Gibbs
Thomas E. Gibbs

VANDA PHARMACEUTICALS INC.

By /s/ Mihael H. Polymeropoulos
Title: Chief Executive Officer

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 quarterly report on Form 10-Q 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.

July 31, 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 quarterly report on Form 10-Q 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.

July 31, 2015

/s/ James P. Kelly

James P. Kelly
Senior Vice President, Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 (the Form 10-Q) 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-Q fairly presents, in all material respects, the consolidated financial condition and results of operations of the Company.

July 31, 2015

/s/ Mihael H. Polymeropoulos, M.D.

Mihael H. Polymeropoulos, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

July 31, 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-Q 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-Q), irrespective of any general incorporation language contained in such filing.