Table of Contents

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 September 30, 2016

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 October 24, 2016, there were 43,946,680 shares of the registrant's common stock issued and outstanding.

Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended September 30, 2016

Table of Contents

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:

- the ability of Vanda Pharmaceuticals Inc. (we, our or Vanda) 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 prepare, file, prosecute, defend and enforce any patent claims and other intellectual property rights;
- 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 ability to obtain and maintain regulatory approval of our products, and the labeling for any approved 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;
- 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 approval of any product;
- the scope, progress, expansion, and costs of developing and commercializing our products;
- our failure to identify or obtain rights to new products;
- a loss of any of our key scientists or management personnel;
- limitations on our ability to utilize some of all of our prior net operating losses and orphan drug and research and development credits;
- the cost and effects of 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. 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, 2015, other unknown or unpredictable factors also could affect our results. Therefore, the information in this quarterly report should be read together with other reports and documents that we file with the Securities and Exchange Commission 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.

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)	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,765	$ 50,843
Marketable securities	109,814	92,337
Accounts receivable, net	15,928	16,331
Inventory	865	1,294
Prepaid expenses and other current assets	11,036	5,742
Total current assets	170,408	166,547
Property and equipment, net	4,731	4,570
Intangible assets, net	29,924	38,752
Non-current inventory and other	3,380	3,181
Total assets	$ 208,443	$ 213,050
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 17,572	$ 15,767
Accrued government and other rebates	33,109	35,550
Total current liabilities	50,681	51,317
Milestone obligation under license agreement	25,000	25,000
Other non-current liabilities	3,597	3,706
Total liabilities	79,278	80,023
Commitments and contingencies (Notes 10 and 11)		
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; 43,930,529 and 42,815,291 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	44	43
Additional paid-in capital	474,234	460,794
Accumulated other comprehensive income	142	39
Accumulated deficit	(345,255)	(327,849)
Total stockholders' equity	129,165	133,027
Total liabilities and stockholders' equity	$ 208,443	$ 213,050

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		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Revenues:				
Net product sales	$ 38,482	$ 28,344	$ 107,773	$ 78,076
Total revenues	38,482	28,344	107,773	78,076
Operating expenses:				
Cost of goods sold	6,990	6,510	19,440	17,291
Research and development	7,294	9,974	21,542	20,398
Selling, general and administrative	21,908	18,458	75,880	55,650
Intangible asset amortization	2,943	2,943	8,828	10,029
Total operating expenses	39,135	37,885	125,690	103,368
Loss from operations	(653)	(9,541)	(17,917)	(25,292)
Other income	223	80	511	225
Net loss	$ (430)	$ (9,461)	$ (17,406)	$ (25,067)
Basic and diluted net loss per share	$ (0.01)	$ (0.22)	$ (0.40)	$ (0.60)
Weighted average shares outstanding, basic and diluted	43,515,404	42,435,405	43,275,074	42,059,839

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

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

(in thousands)	Three Months Ended		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Net loss	$ (430)	$ (9,461)	$ (17,406)	$ (25,067)
Other comprehensive income:				
Change in net unrealized gain on marketable securities	18	10	103	21
Tax provision on other comprehensive income	—	—	—	—
Other comprehensive income , net of tax	18	10	103	21
Comprehensive loss	$ (412)	$ (9,451)	$ (17,303)	$ (25,046)

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		Additional Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Par Value				
Balances at December 31, 2015	42,815,291	$ 43	$460,794	$ 39	$ (327,849)	$133,027
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	1,115,238	1	7,000	—	—	7,001
Stock-based compensation expense	—	—	6,440	—	—	6,440
Net loss	—	—	—	—	(17,406)	(17,406)
Other comprehensive income, net of tax	—	—	—	103	—	103
Balances at September 30, 2016	43,930,529	$ 44	$474,234	$ 142	$ (345,255)	$129,165

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)	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Cash flows from operating activities		
Net loss	$ (17,406)	(25,067)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation of property and equipment	654	420
Stock-based compensation	6,440	6,074
Amortization of discounts and premiums on marketable securities	76	612
Intangible asset amortization	8,828	10,029
Other non-cash adjustments	483	659
Changes in operating assets and liabilities:		
Accounts receivable	52	(12,135)
Prepaid expenses and other assets	(5,399)	(6,892)
Inventory	63	453
Accounts payable and accrued liabilities	1,730	7,737
Accrued government and other rebates	(2,441)	30,915
Net cash provided by (used in) operating activities	(6,920)	12,805
Cash flows from investing activities		
Purchases of property and equipment	(710)	(1,813)
Purchases of marketable securities	(130,858)	(127,609)
Proceeds from sales of marketable securities	—	999
Maturities of marketable securities	113,409	97,411
Net cash used in investing activities	(18,159)	(31,012)
Cash flows from financing activities		
Obligations paid in connection with settlement of equity awards	—	(282)
Proceeds from exercise of employee stock options	7,001	4,374
Net cash provided by financing activities	7,001	4,092
Net decrease in cash and cash equivalents	(18,078)	(14,115)
Cash and cash equivalents		
Beginning of period	50,843	60,901
End of period	$ 32,765	46,786

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. (the Company) is a specialty pharmaceutical company focused on the development and commercialization of novel therapies to address high unmet medical needs and improve the lives of patients. The Company commenced its operations in 2003 and operates in one reporting segment. The Company's portfolio includes the following products:

- HETLIOZ® (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24), 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 and included post-marketing commitments related to a pediatric investigation plan. 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® was commercially launched in Germany in August 2016. HETLIOZ® has potential utility in a number of other circadian rhythm disorders and is presently in clinical development for the treatment of Pediatric Non-24, Jet Lag Disorder and Smith-Magenis Syndrome (SMS).
- Fanapt® (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which was approved by the FDA in May 2009 and launched commercially in the U.S. by Novartis Pharma AG (Novartis) in January of 2010. Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt® franchise to the Company on December 31, 2014. Additionally, the Company's distribution partners launched Fanapt® in Israel and Mexico in 2014. Fanapt® has potential utility in a number of other disorders. An assessment of new Fanapt® clinical opportunities is ongoing.
- 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 and gastroparesis.
- 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, 2015 included in the Company's annual report on Form 10-K. The financial information as of September 30, 2016 and for the three and nine months ended September 30, 2016 and 2015 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, 2015 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, 2015.

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. The Company has estimated its annual fees for Fanapt® under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, however, the amount of the estimated liability could increase, but the range of this increase is not reasonably estimable at this time. Management continually re-evaluates its estimates, judgments and assumptions, and management's evaluation could change. 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. Inventory not expected to be consumed within 12 months following the balance sheet date are classified as non-current.

Revenue from Net Product Sales

The Company's revenues consist of net product sales of HETLIOZ® and net product sales of Fanapt®. Net sales by product for the three and nine months ended September 30, 2016 and 2015 were as follows:

	Three Months Ended		Nine Months Ended	
(in thousands)	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Revenues:				
HETLIOZ® product sales, net	$ 18,715	$ 11,682	$ 52,376	$ 29,159
Fanapt® product sales, net	19,767	16,662	55,397	48,917
Total revenues	$ 38,482	$ 28,344	$ 107,773	$ 78,076

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.

Major Customers

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. There were five major customers that each accounted for more than 10% of total revenues and, as a group, represented 86% of total revenues for the nine months ended September 30, 2016. There were four major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 80% of total accounts receivable at September 30, 2016.

Product Sales Discounts and Allowances

The Company's product sales are recorded net of applicable discounts, rebates, chargebacks, service fees, co-pay assistance 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 rebates, chargebacks 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:

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.

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.

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 recognizes the expense over the award's vesting period. The fair value of stock options granted and restricted stock units (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 employee and director stock options granted during the nine months ended September 30, 2016 and 2015 were as follows:

	Nine Months Ended	
	September 30, 2016	September 30, 2015
Expected dividend yield	0%	0%
Weighted average expected volatility	57%	60%
Weighted average expected term (years)	6.1	6.0
Weighted average risk-free rate	1.37%	1.67%
Weighted average fair value per share	$ 4.51	$ 6.45

Stock-based compensation expense recognized for the three and nine months ended September 30, 2016 and 2015 was comprised of the following:

	Three Months Ended		Nine Months Ended	
(in thousands)	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Research and development	$ 539	$ 516	$ 1,552	$ 1,743
Selling, general and administrative	1,561	1,545	4,888	4,331
	$ 2,100	$ 2,061	$ 6,440	$ 6,074

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 $0.1 million and $0.5 million for the three months ended September 30, 2016 and 2015, respectively, and $1.2 million and $2.4 million for the nine months ended September 30, 2016 and 2015, respectively.

Non-Cash Investing and Financing Activities

For the nine months ended September 30, 2015, the Company recorded an intangible asset of $25.0 million relating to HETLIOZ® and recorded the related non-current liability relating to its obligation to make a milestone payment to Bristol-Myers Squibb (BMS) of $25.0 million in the event that cumulative worldwide sales of HETLIOZ® reach $250.0 million. For each of the nine months ended September 30, 2016 and 2015, the Company recorded purchases of property, plant and equipment and the related current liability in the amount of $0.3 million.

Recent accounting pronouncements

In August 2016, the FASB issued Accounting Standards Update (ASU) 2016-15, *Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Payments*, to clarify guidance on the classification of certain cash receipts and cash payments in the statement of cash flow. The standard is effective for annual reporting periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2017. Early adoption is permitted. Adoption of this new standard is not expected to have a material impact on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses*, related to the measurement of credit losses on financial instruments. The standard will require the use of an "expected loss" model for instruments measured at amortized cost. The standard is effective for years beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2019. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. The ASU provides that all of the tax effects related to share-based payments are recorded as part of the provision for income taxes, allows entities to withhold an amount up to the employees' maximum individual tax rate in the relevant jurisdiction, allows entities to estimate the effect of forfeitures or recognized forfeitures when they occur, and other improvements to the accounting for share-based awards. The new standard is effective for annual periods beginning after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases*. The new standard requires that lessees will need to recognize a right-of-use asset and a lease liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability subject to certain adjustments. For income statement purposes, the FASB retained a dual model, requiring leases to be classified as either operating or finance. Operating leases will result in straight-line expense (similar to current operating leases) while finance leases will result in a front-loaded expense pattern (similar to current capital leases). The new standard is effective for annual periods ending after December 15, 2018, and interim periods within annual periods beginning after December 15, 2018. Early adoption is permitted. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*, dealing with changes to the subsequent measurement of inventory. Currently, an entity is required to measure its inventory at the lower of cost or market, whereby market can be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The changes require that inventory be measured at the lower of cost and net realizable value, thereby eliminating the use of the other two market methodologies. Net realizable value is defined as the estimated selling prices in the ordinary course of business less reasonably predictable costs of completion, disposal, and transportation. The new standard is effective for periods beginning after December 15, 2016. The Company adopted this new standard in the second quarter of 2016, and adoption did not 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*. This new standard 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. In July 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers*, which defers 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. In March 2016, the FASB issued ASU 2016-08 *Revenue from Contracts with Customers, Principal versus Agent Considerations (Reporting Revenue versus Net)*, in April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers, identifying Performance Obligations and Licensing*, and in May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers, Narrow-Scope Improvements and Practical Expedients*, which provide additional clarification on certain topics addressed in ASU 2014-09. ASU 2016-08, ASU 2016-10, and ASU 2016-12 follow the same implementation guidelines as ASU 2014-09 and ASU 2015-14. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

3. 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 nine months ended September 30, 2016 and 2015:

(in thousands, except for share and per share amounts)	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Numerator:				
Net loss	$ (430)	$ (9,461)	$ (17,406)	$ (25,067)
Denominator:				
Weighted average shares outstanding, basic and diluted	43,515,404	42,435,405	43,275,074	42,059,839
Net loss per share, basic and diluted	$ (0.01)	$ (0.22)	$ (0.40)	$ (0.60)
Antidilutive securities excluded from calculations of diluted net loss per share	3,845,456	5,181,975	5,298,256	5,534,752

The Company incurred net losses for the three and nine months ended September 30, 2016 and 2015 causing inclusion of any potentially dilutive securities to have an anti-dilutive effect, resulting in dilutive loss per share and basic loss per share attributable to common stockholders being equivalent.

4. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of September 30, 2016, which all have contract maturities of less than one year:

September 30, 2016 *(in thousands)*	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 54,662	$ 33	$ —	$ 54,695
Corporate debt	55,010	117	(8)	55,119
	$109,672	$ 150	$ (8)	$109,814

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2015, which all have contract maturities of less than one year:

December 31, 2015 *(in thousands)*	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 44,059	$ 6	$ (8)	$44,057
Corporate debt	48,239	46	(5)	48,280
	$ 92,298	$ 52	$ (13)	$92,337

5. 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 September 30, 2016 and December 31, 2015 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 nine months ended September 30, 2016 and 2015.

As of September 30, 2016, 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 September 30, 2016 Using		
(in thousands)	September 30, 2016	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:				
U.S. Treasury and government agencies	$ 54,695	$ 54,695	$ —	$ —
Corporate debt	55,119	—	55,119	
	$ 109,814	$ 54,695	$ 55,119	$ —

As of December 31, 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 December 31, 2015 Using		
(in thousands)	December 31, 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:				
U.S. Treasury and government agencies	$ 44,057	$ 44,057	$ —	$ —
Corporate debt	48,280	—	48,280	
	$ 92,337	$ 44,057	$ 48,280	$ —

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, and milestone obligations under license agreements, the carrying value of which materially approximate their fair values.

6. 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 levels are evaluated for the amount of inventory that would be sold within one year. At certain times, the level of inventory can exceed the forecasted level of cost of goods sold for the next twelve months. The Company classifies the estimate of such inventory as non-current. Inventory consisted of the following as of September 30, 2016 and December 31, 2015:

(in thousands)	September 30, 2016	December 31, 2015
Current assets		
Finished goods	$ 865	$ 1,294
	$ 865	$ 1,294
Non-Current assets		
Raw materials	$ 127	$ 127
Work-in-process	2,241	2,369
Finished goods	223	—
	$ 2,591	$ 2,496

7. Accounts Payable and Accrued Liabilities

The following is a summary of the Company's accounts payable and accrued liabilities as of September 30, 2016 and December 31, 2015:

(in thousands)	September 30, 2016	December 31, 2015
Research and development expenses	$ 2,575	$ 3,199
Consulting and other professional fees	4,162	5,088
Compensation and employee benefits	3,071	468
Royalties payable	6,413	5,328
Other	1,351	1,684
	$ 17,572	$ 15,767

8. Intangible Assets

The following is a summary of the Company's intangible assets as of September 30, 2016:

		September 30, 2016		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	January 2033	$33,000	$ 4,751	$28,249
Fanapt®	November 2016	27,941	26,266	1,675
		$60,941	$ 31,017	$29,924

The following is a summary of the Company's intangible assets as of December 31, 2015:

		December 31, 2015		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	January 2033	$33,000	$ 3,460	$29,540
Fanapt®	November 2016	27,941	18,729	9,212
		$60,941	$ 22,189	$38,752

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 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 2015. As a result, the future obligation of $25.0 million was recorded as a non-current liability along with a capitalized intangible assets relating to HETLIOZ®. The actual payment of the obligation will occur once the $250.0 million in cumulative worldwide sales of HETLIOZ® is realized. Intangible assets relating HETLIOZ® are 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.

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. Pursuant to the terms of a settlement agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company on December 31, 2014. As a result, the Company recognized an intangible asset of $15.9 million related to the reacquired rights to Fanapt®. Intangible assets relating to Fanapt® are being amortized on a straight-line basis over the remaining life of the U.S. composition of matter patent for Fanapt® through November 2016. The useful life estimation is based on the market participant methodology prescribed by ASC Subtopic 805, *Business Combinations*, 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 December 2031.

The intangible assets are being amortized over their estimated useful economic life using the straight-line method. Amortization expense was $2.9 million and $2.9 million for the three months ended September 30, 2016 and 2015, respectively, and $8.8 million and $10.0 million for the nine months ended September 30, 2016 and 2015, respectively. The following is a summary of the future intangible asset amortization schedule as of September 30, 2016:

(in thousands)	Total	Remainder of 2016	2017	2018	2019	2020	Thereafter
HETLIOZ®	$28,249	$ 430	$1,721	$1,721	$1,721	$1,721	$ 20,935
Fanapt®	1,675	1,675	—	—	—	—	—
	$29,924	$ 2,105	$1,721	$1,721	$1,721	$1,721	$ 20,935

9. 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 September 30, 2016 and December 31, 2015. As a result of the tax valuation allowance against deferred tax assets, there was no provision for income taxes for the three and nine months ended September 30, 2016 and 2015.

Certain tax attributes of the Company, including NOLs and credits, are subject to limitation as a result of any ownership change as defined under Internal Revenue Code of 1986, as amended (IRC), Section 382. A change in ownership could affect the Company's ability to use NOLs and credit carryforward (tax attributes). Ownership changes did occur as of December 31, 2014 and December 31, 2008. However, the Company believes that it had sufficient Built-In-Gain to offset the IRC Section 382 limitation generated by the ownership changes. Any future ownership changes may cause the Company's existing tax attributes to have additional limitations. Additionally, the Company maintains a valuation allowance on its tax attributes and therefore, any IRC Section 382 limitation would not have a material impact on the Company's provision for income taxes as of September 30, 2016.

10. Commitments and Contingencies

Operating leases

Commitments relating to operating leases represent the minimum annual future payments under operating leases for a total of 40,188 square feet of office space for the Company's headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. that expire in 2026 and the operating lease for 2,880 square feet of office space for the Company's European headquarters in London that has a noncancellable lease term ending in 2021. The following is a summary of the minimum annual future payments under operating leases for office space as of September 30, 2016:

	Cash payments due by year						
(in thousands)	Total	Remainder of 2016	2017	2018	2019	2020	Thereafter
Operating leases	$22,063	$ 445	$1,933	$2,230	$2,284	$2,341	$ 12,830

In 2011, the Company entered into an operating lease for its headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. A lease amendment in 2014 increased the office space under lease to 30,260 square feet, and a lease amendment in June 2016 extended the lease term from April 2023 to September 2026. Subject to the prior rights of other tenants, the Company has the right to renew the lease for five years following its expiration. 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 under certain circumstances.

In June 2016, the Company entered into a sublease under which the Company will lease 9,928 square feet of office space for its headquarters at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. The sublease term begins in January 2017 and ends in July 2026, but may be terminated earlier by either party under certain circumstances. The Company has the right to sublease or assign all or a portion of the premises, subject to standard conditions.

Rent expense under operating leases was $0.7 million and $0.5 million for the three months ended September 30, 2016 and 2015, respectively, and $1.7 million and $1.4 million for the nine months ended September 30, 2016 and 2015, 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®. 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 October 2009, subsequent to the FDA's approval of the NDA for Fanapt®, 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 had exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. Novartis began selling Fanapt® in the U.S. during the first quarter of 2010. Novartis was responsible for the further clinical development activities in the U.S. and Canada. The Company also received royalties equal to 10% of net sales of Fanapt® in the U.S. and Canada. The Company retained exclusive rights to Fanapt® outside the U.S. and Canada and was obligated to make royalty payments to Sanofi S.A. (Sanofi) on Fanapt® sales outside the U.S. and Canada.

Pursuant to the terms of the settlement agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to the Company on December 31, 2014. The Company is obligated to make royalty payments to Sanofi 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 rate in the mid-twenties on sales over $200.0 million through November 2016. In February 2016, the Company amended the agreement with Sanofi and Titan to remove Titan as the entity through which royalty payments from the Company are directed to Sanofi following the expiration of the new chemical entity (NCE) patent for Fanapt® in the U.S. on November 15, 2016. Under the amended agreement, the Company will pay directly to Sanofi a fixed royalty of 3% of net sales from November 16, 2016 through December 31, 2019 related to manufacturing know-how. The Company made a $2.0 million payment during the nine months ended September 30, 2016 that applied to this 3% manufacturing know-how royalty and will make additional royalty payments only to the extent that the Company's cumulative royalty obligations during this period exceed the amount of the pre-payment. No further royalties on manufacturing know-how are payable by the Company after December 31, 2019. This amended agreement does not alter Titan's obligation under the license agreement to make royalty payments to Sanofi prior to November 16, 2016 or the Company's obligations under the sublicense agreement to pay Sanofi a fixed royalty on Fanapt® net sales equal up to 6% on Sanofi know-how not related to manufacturing under certain conditions for a period of up to 10 years in markets where the NCE patent has expired or was not issued.

The Company has entered into distribution agreements with Probiomed S.A. de C.V. for the commercialization of Fanapt® in Mexico and Megapharm Ltd. for the commercialization of Fanapt® in Israel.

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. The Company 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 the Company terminates the license agreement, or if Lilly terminates due to the Company's breach or for certain other reasons set forth in the license agreement, all rights licensed and developed by the Company 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 with Novartis relating to Fanapt®, 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.

11. 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 Delaware District Court). 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 '610 Patent) by submitting to the FDA an Abbreviated New Drug Application (ANDA) for a generic version of Fanapt® prior to the expiration of the '610 Patent in November 2027. In addition, pursuant to the settlement agreement with Novartis, the Company assumed Novartis' patent infringement action against Roxane in the Delaware District Court. That suit alleges that Roxane has infringed one or more claims of U.S Patent RE39198 (the '198 Patent), which is licensed exclusively to the Company, by filing an ANDA for a generic version of Fanapt® prior to the expiration of the '198 Patent in November 2016. These two cases against Roxane were consolidated by agreement of the parties and were tried together in a five-day bench trial that concluded on March 4, 2016. On August 25, 2016, the Delaware District Court ruled in favor of the Company, finding that Roxane's ANDA product infringed the asserted claims of the '610 Patent and the '198 Patent. The Delaware District Court ruled that the Company is entitled to a permanent injunction against Roxane enjoining Roxane from infringing the '610 Patent, including the manufacture, use, sale, offer to sell, sale, distribution or importation of any generic iloperidone product described in the '610 Patent ANDA until the expiration of the '610 Patent in November 2027. If the Company obtains pediatric exclusivity, the injunction against Roxane would be extended until May 2028 under the Delaware District Court's order. On September 23, 2016, Roxane filed a notice of appeal with the Federal Circuit Court of Appeals.

In 2015, the Company filed six separate patent infringement lawsuits in the Delaware District Court against Roxane, Inventia Healthcare Pvt. Ltd., Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin), Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (Taro), and Apotex Inc. and Apotex Corp., (collectively, the Defendants). The lawsuits each seek an adjudication that the respective Defendants infringed one or more claims of the '610 Patent and/or the Company's U.S. Patent No. 9,138,432 (the '432 Patent) by submitting to the FDA an ANDA for a generic version of Fanapt® prior to the expiration of the '610 Patent in November 2027 or the '432 Patent in September 2025. The Defendants have denied infringement and counterclaimed for declaratory judgment of invalidity and noninfringement of the '610 Patent and the '432 Patent. The Delaware District Court has scheduled a five-day bench trial beginning on May 15, 2017 in which all of these lawsuits regarding infringement of the '610 Patent and the '432 Patent are expected to be tried together.

Lupin filed counter claims for declaratory judgment of invalidity and noninfringement of seven of the Company's method of treatment patents that are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) related to Fanapt® (such seven patents, the Method of Treatment Patents). The Company has not sued Lupin for infringing the Method of Treatment Patents. On October 13, 2016, the Company and Lupin filed a Stipulation of Dismissal in the Delaware District Court pursuant to which Lupin's counterclaims relating to the Method of Treatment Patents were dismissed without prejudice in recognition of an agreement reached between the parties.

On October 24, 2016, the Company entered into a License Agreement with Taro to resolve the Company's patent litigation against Taro regarding Taro's ANDA seeking approval of its generic version of Fanapt® (the Taro License Agreement). Under the Taro License Agreement, the Company granted Taro a non-exclusive license to manufacture and commercialize Taro's version of Fanapt® in the U.S. effective November 2, 2027, unless prior to that date the Company obtains pediatric exclusivity for Fanapt®, in which case, the license will be effective May 2, 2028. Taro may enter the market earlier under certain limited circumstances. The Taro License Agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, provides for a full settlement and release by the Company and Taro of all claims that are the subject of the litigation.

On February 26, 2016, Roxane filed suit against the Company in the U.S. District Court for the Southern District of Ohio. The suit seeks a declaratory judgment of invalidity and noninfringement of the Method of Treatment Patents. The Company has not sued Roxane for infringing the Method of Treatment Patents. The Company filed a motion to dismiss this lawsuit for lack of personal jurisdiction or to transfer the lawsuit to the Delaware District Court.

On February 26, 2016, Roxane filed a Petition for *Inter Partes* Review (IPR) of the '432 Patent with the Patent Trials and Appeals Board (PTAB) of the United States Patent and Trademark Office. The Company filed a Preliminary Response on June 7, 2016, and on August 30, 2016 the PTAB denied the request by Roxane to institute an IPR of the '432 Patent. On September 29, 2016, Roxane filed a Petition for Rehearing with the PTAB, and on October 13, 2016 the Company filed a Response to Roxane's Petition.

12. Stock-Based Compensation

As of September 30, 2016, there were 6,831,988 shares that were subject to outstanding options and RSUs under the 2006 Equity Incentive Plan (2006 Plan) and the 2016 Equity Incentive Plan (2016 Plan) (collectively, the Plans). The 2006 Plan expired by its terms on April 12, 2016. Outstanding options and RSUs under the 2006 Plan remain in effect and the terms of the 2006 Plan continue to apply, but no additional awards can be granted under the 2006 Plan. On June 16, 2016, the Company's stockholders approved the 2016 Plan. There are 2,000,000 shares of common stock reserved for issuance under the 2016 Plan, of which 1,835,000 shares remained available for future grant as of September 30, 2016.

The Company has granted option awards under the Plans 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 September 30, 2016, $10.2 million of unrecognized compensation costs related to unvested service option awards are expected to be recognized over a weighted average period of 1.3 years. No option awards are classified as a liability as of September 30, 2016.

A summary of option activity under the Plans for the nine months ended September 30, 2016 follows:

Stock Options *(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, 2015	6,252,448	$ 11.87	6.16	$ 7,498
Granted	861,511	8.39		
Forfeited	(377,448)	11.16		
Expired	(205,266)	14.47		
Exercised	(827,572)	8.46		3,870
Outstanding at September 30, 2016	5,703,673	11.79	5.78	36,336
Exercisable at September 30, 2016	3,908,977	12.41	4.47	25,210
Vested and expected to vest at September 30, 2016	5,569,895	11.84	5.70	35,434

Proceeds from the exercise of stock options amounted to $7.0 million for the nine months ended September 30, 2016 and $4.4 million for the nine months ended September 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 under the Plans with service conditions (service RSUs) that vest in four equal annual installments provided that the employee remains employed with the Company. As of September 30, 2016, $8.9 million of unrecognized compensation costs related to unvested service RSUs are expected to be recognized over a weighted average period of 1.8 years. No RSUs are classified as a liability as of September 30, 2016.

A summary of RSU activity under the Plans for the nine months ended September 30, 2016 follows:

RSUs	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Unvested at December 31, 2015	1,022,681	$ 10.90
Granted	632,242	8.39
Forfeited	(238,942)	10.27
Vested	(287,666)	9.65
Unvested at September 30, 2016	1,128,315	9.95

The grant date fair value for the 287,666 shares underlying RSUs that vested during the nine months ended September 30, 2016 was $2.8 million.

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

Overview

Vanda Pharmaceuticals Inc. (we, our or Vanda) is a specialty pharmaceutical company focused on the development and commercialization of novel therapies to address high unmet medical needs and improve the lives of patients. 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), 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 and included post-marketing commitments related to a pediatric investigation plan. 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® was commercially launched in Germany in August 2016. HETLIOZ® has potential utility in a number of other circadian rhythm disorders and is presently in clinical development for the treatment of Pediatric Non-24, Jet Lag Disorder and Smith-Magenis Syndrome (SMS).
- Fanapt® (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which was approved by the FDA in May 2009 and launched commercially in the U.S. by Novartis Pharma AG (Novartis) in January of 2010. Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt® franchise to us on December 31, 2014. Additionally, our distribution partners launched Fanapt® in Israel and Mexico in 2014. Fanapt® has potential utility in a number of other disorders. An assessment of new Fanapt® clinical opportunities is ongoing.
- 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 and gastroparesis.
- Trichostatin A, a small molecule histone deacetylase (HDAC) inhibitor.
- AQW051, a Phase II alpha-7 nicotinic acetylcholine receptor partial agonist.

Operational Highlights

- Total net product sales from HETLIOZ® and Fanapt® were $38.5 million during the third quarter of 2016, a 7% increase compared to $36.0 million in the second quarter of 2016 and a 36% increase compared to $28.3 million in the third quarter of 2015.
- Cash, cash equivalents and marketable securities were $142.6 million as of September 30, 2016, representing an increase of $6.6 million in the third quarter of 2016.

HETLIOZ® (tasimelteon)

- HETLIOZ® net product sales grew to $18.7 million in the third quarter of 2016, a 7% increase compared to $17.5 million in the second quarter of 2016 and a 60% increase compared to $11.7 million in the third quarter of 2015.
- In August 2016, HETLIOZ® was made available in Germany, representing the first launch of HETLIOZ® outside of the U.S.
- The pharmacokinetic study of the HETLIOZ® pediatric formulation is enrolling.
- Enrollment in the SMS open label interventional study is ongoing. Enrollment in the SMS placebo controlled clinical study began in the fourth quarter of 2016.
- The screening of patients for a Jet Lag Disorder clinical study is ongoing. Results from the Jet Lag Disorder study are expected in 2017.

Fanapt® (iloperidone)

- Fanapt® net product sales grew to $19.8 million in the third quarter of 2016, a 6% increase compared to $18.6 million in the second quarter of 2016 and a 19% increase compared to $16.7 million in the third quarter of 2015.
- In August 2016, the Delaware District Court ruled that Roxane Laboratories, Inc.'s (Roxane) proposed generic version of Fanapt® infringed two of Vanda's patents and issued an injunction barring Roxane from marketing its product until November 2, 2027.
- In October 2016, Vanda settled its Fanapt® patent litigation against Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd.
- An expansion of the Fanapt® U.S. field sales team is now planned for the first quarter of 2017. An assessment of new Fanapt® clinical opportunities is ongoing.

Tradipitant

- Enrollment in a tradipitant clinical study for the treatment of chronic pruritus in patients with atopic dermatitis is ongoing. Results are expected in 2017.
- A tradipitant clinical study for the treatment of gastroparesis is expected to begin enrolling patients in the fourth quarter of 2016. Results are expected in 2017.

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® in the U.S. and Europe, on our ability, alone or with others, to complete the development of our products, and to obtain the regulatory approvals for and to manufacture, market and sell our products. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks which are detailed in *Risk Factors* reported in Item 1A of Part I of our annual report on Form 10-K for the year ended December 31, 2015.

As described in Part II, Item 1, *Legal Proceedings*, of this quarterly report on Form 10-Q, we have initiated lawsuits to enforce our patent rights against Roxane Laboratories, Inc., Inventia Healthcare Pvt. Ltd., Taro Pharmaceuticals, U.S.A., Inc./Taro Pharmaceuticals Industries, Ltd., Apotex Inc. and Lupin Limited and Lupin Pharmaceuticals, Inc.

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.

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, 2015. 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, 2015. 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 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.

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. We invoice and record revenue when our customers, specialty pharmacies and wholesalers, receive product from the third-party logistics warehouse. Revenues and accounts receivable are concentrated with these customers.

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.

Product Sales Discounts and Allowances. Product sales are recorded net of applicable discounts, rebates, chargebacks, service fees, co-pay assistance 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 rebates, chargebacks 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:

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, deduct the full amount of these discounts from total product sales when revenues are recognized.

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.

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 nine months ended September 30, 2016:

(in thousands)	Rebates & Chargebacks	Discounts, Returns and Other	Total
Balance at December 31, 2015	$ 33,423	$ 3,557	$ 36,980
Provision related to current period sales	41,561	14,470	56,031
Adjustments for prior period sales	(2,338)	811	(1,527)
Credits/payments made	(41,932)	(13,281)	(55,213)
Balance at September 30, 2016	$ 30,714	$ 5,557	$ 36,271

The provision of $41.6 million for rebates and chargebacks for the nine months ended September 30, 2016 primarily represents Medicaid rebates and contracted rebate programs applicable to sales of Fanapt®. The provision of $14.5 million for discounts, returns and other for the nine months ended September 30, 2016 primarily represents wholesaler distribution fees applicable to sales of Fanapt® and co-pay assistance costs and prompt pay discounts applicable to the sales of both HETLIOZ® and Fanapt®.

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.

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. Additionally, selling, general and administrative expenses include our estimate for the annual Patient Protection and Affordable Care fee.

Intangible Assets

The following is a summary of our intangible assets as of September 30, 2016:

(in thousands)	Estimated Useful Life (Years)	September 30, 2016 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	January 2033	$33,000	$ 4,751	$28,249
Fanapt®	November 2016	27,941	26,266	1,675
		$60,941	$ 31,017	$29,924

In January 2014, we announced that the FDA had approved the NDA for HETLIOZ®. As a result of this approval, we met a milestone under our license agreement with Bristol-Myers Squibb (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 2015. As a result, the future obligation of $25.0 million was recorded as a non-current liability along with a capitalized intangible assets relating to HETLIOZ®. The actual payment of the obligation will occur once the $250.0 million in cumulative worldwide sales of HETLIOZ® is realized. Intangible assets relating HETLIOZ® are 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.

In 2009, we announced that the FDA had approved the NDA for Fanapt®. As a result of this approval, we met a milestone under our original sublicense agreement with Novartis that required us to make a license payment of $12.0 million to Novartis. Pursuant to the terms of the settlement agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us on December 31, 2014. As a result, we recognized an intangible asset of $15.9 million related to the reacquired rights to Fanapt®. Intangible assets relating to Fanapt® are being amortized on a straight-line basis over the remaining life of the U.S. composition of matter patent for Fanapt® to November 2016. The useful life estimation is based on the market participant methodology prescribed by ASC Subtopic 805, *Business Combinations*, and therefore does not reflect the impact of additional Fanapt® patents solely owned by us with varying expiration dates, the latest of which is December 2031.

The following table summarizes our future intangible asset amortization schedule as of September 30, 2016:

(in thousands)	Total	Remainder of 2016	2017	2018	2019	2020	Thereafter
HETLIOZ®	$28,249	$ 430	$1,721	$1,721	$1,721	$1,721	$ 20,935
Fanapt®	1,675	1,675	—	—	—	—	—
	$29,924	$ 2,105	$1,721	$1,721	$1,721	$1,721	$ 20,935

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 $345.3 million as of September 30, 2016.

Three months ended September 30, 2016 compared to three months ended September 30, 2015

Revenues. Total revenues increased by $10.1 million, or 36%, to $38.5 million for the three months ended September 30, 2016 compared to $28.3 million for the three months ended September 30, 2015. Revenues were as follows:

	Three Months Ended			
(in thousands)	September 30, 2016	September 30, 2015	Net Change	Percent
Revenues:				
HETLIOZ® product sales, net	$ 18,715	$ 11,682	$ 7,033	60%
Fanapt® product sales, net	19,767	16,662	3,105	19%
Total revenues	$ 38,482	$ 28,344	$10,138	36%

HETLIOZ® product sales increased by $7.0 million, or 60%, to $18.7 million for the three months ended September 30, 2016 compared to $11.7 million for the three months ended September 30, 2015.

Fanapt® product sales increased by $3.1 million, or 19%, to $19.8 million for the three months ended September 30, 2016 compared to $16.7 million for the three months ended September 30, 2015. We began selling Fanapt® commercially in the U.S. in January 2015.

Cost of goods sold. Cost of goods sold increased by $0.5 million, or 8%, to $7.0 million for the three months ended September 30, 2016 compared to $6.5 million for the three months ended September 30, 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 are 10% of net U.S. sales of HETLIOZ® and 23% of net U.S. sales of Fanapt®.

HETLIOZ® cost of goods sold as a percentage of HETLIOZ® revenue depends upon our cost to manufacture inventory at normalized production levels with our third party manufacturers. 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 were 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 U.S. Fanapt® manufacturing costs included in cost of goods sold will be less than 4% of our net U.S. Fanapt® product sales.

Research and development expenses. Research and development expenses decreased by $2.7 million, or 27%, to $7.3 million for the three months ended September 30, 2016 compared to $10.0 million for the three months ended September 30, 2015. The decrease resulted from the close out Fanapt® clinical trial expenses transitioned to us as part of the settlement agreement with Novartis and regulatory expenses related to our sNDA filing in the 2015 period. The decrease was partially offset by increased clinical trial expenses associated with the HETLIOZ® Jet Lag Disorder and SMS programs for the three months ended September 30, 2016. The following table summarizes the costs of our product development initiatives for the three months ended September 30, 2016 and 2015.

	Three Months Ended	
(in thousands)	September 30, 2016	September 30, 2015
Direct project costs (1)		
HETLIOZ®	$ 3,500	$ 2,895
Fanapt®	669	4,037
Tradipitant	1,583	1,705
Trichostatin A	402	323
	6,154	8,960
Indirect project costs (1)		
Stock-based compensation	539	516
Other indirect overhead	601	498
	1,140	1,014
Total research and development expense	$ 7,294	$ 9,974

(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 expand our product pipeline.

Selling, general and administrative expenses. Selling, general and administrative expenses increased by $3.4 million, or 18%, to $21.9 million for the three months ended September 30, 2016 compared to $18.5 million for the three months ended September 30, 2015. The increase was primarily the result of marketing and sales efforts around Fanapt® in the U.S. and HETLIOZ® in both Europe and the U.S.

Intangible asset amortization. Intangible asset amortization was $2.9 million for the three months ended September 30, 2016 and 2015. Intangible asset amortization relating to HETLIOZ® amounted to $0.4 million, and intangible asset amortization relating to Fanapt® amounted to $2.5 million for each of the three-month periods. Pursuant to the terms of the settlement agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us on December 31, 2014 resulting in an increase in capitalized intangible assets of $15.9 million that is being amortized until November 2016.

Nine months ended September 30, 2016 compared to nine months ended September 30, 2015

Revenues. Total revenues increased by $29.7 million, or 38%, to $107.8 million for the nine months ended September 30, 2016 compared to $78.1 million for the nine months ended September 30, 2015. Revenues were as follows:

	Nine Months Ended			
(in thousands)	September 30, 2016	September 30, 2015	Net Change	Percent
Revenues:				
HETLIOZ® product sales, net	$ 52,376	$ 29,159	$23,217	80%
Fanapt® product sales, net	55,397	48,917	6,480	13%
Total revenues	$ 107,773	$ 78,076	$29,697	38%

HETLIOZ® product sales increased by $23.2 million, or 80%, to $52.4 million for the nine months ended September 30, 2016 compared to $29.2 million for the nine months ended September 30, 2015.

Fanapt® product sales increased by $6.5 million, or 13%, to $55.4 million for the nine months ended September 30, 2016 compared to $48.9 million for the nine months ended September 30, 2015. We began selling Fanapt® commercially in the U.S. in January 2015.

Cost of goods sold. Cost of goods sold increased by $2.1 million, or 12%, to $19.4 million for the nine months ended September 30, 2016 compared to $17.3 million for the nine months ended September 30, 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 are 10% of net U.S. sales of HETLIOZ® and 23% of net U.S. sales of Fanapt®.

HETLIOZ® cost of goods sold as a percentage of HETLIOZ® revenue depends upon our cost to manufacture inventory at normalized production levels with our third party manufacturers. 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 were 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 U.S. Fanapt® manufacturing costs included in cost of goods sold will be less than 4% of our net U.S. Fanapt® product sales.

Research and development expenses. Research and development expenses increased by $1.1 million, or 6%, to $21.5 million for the nine months ended September 30, 2016 compared to $20.4 million for the nine months ended September 30, 2015. The increase is primarily the result of increased clinical trial expenses associated with the HETLIOZ® Jet Lag Disorder and SMS programs and the tradipitant chronic pruritus in atopic dermatitis program, partially offset by the close out Fanapt® clinical trial expenses transitioned to us as part of the settlement agreement with Novartis and regulatory expenses related to our sNDA filing in the 2015 period. The following table summarizes the costs of our product development initiatives for the nine months ended September 30, 2016 and 2015.

	Nine Months Ended	
(in thousands)	**September 30, 2016**	**September 30, 2015**
Direct project costs (1)		
HETLIOZ®	$ 9,500	$ 6,362
Fanapt®	2,088	6,764
Tradipitant	4,587	2,783
Trichostatin A	1,813	1,122
	17,988	17,031
Indirect project costs (1)		
Stock-based compensation	1,552	1,743
Other indirect overhead	2,002	1,624
	3,554	3,367
Total research and development expense	$ 21,542	$ 20,398

(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 increased by $20.2 million, or 36%, to $75.9 million for the nine months ended September 30, 2016 compared to $55.7 million for the nine months ended September 30, 2015. The increase was primarily the result of marketing and sales efforts around Fanapt® in the U.S. and HETLIOZ® in both Europe and the U.S., an increase in the number of employees during 2015, including the hiring of new members of the executive management team, as well as increased legal fees associated with ongoing litigation.

Intangible asset amortization. Intangible asset amortization decreased by $1.2 million, or 12%, to $8.8 million for the nine months ended September 30, 2016 compared to $10.0 million for the nine months ended September 30, 2015. 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. As a result, intangible asset amortization relating to HETLIOZ® for the nine months ended September 30, 2015 had included additional amortization of $1.2 million for a catch-up adjustment to retroactively record cumulative amortization from February 1 to December 31, 2014 relating to the capitalized intangible asset of $25.0 million.

Intangible asset amortization relating to Fanapt® was $7.5 million for the nine months ended September 30, 2016 and 2015. Pursuant to the terms of a settlement agreement with Novartis, Novartis transferred all U.S. and Canadian rights in the Fanapt® franchise to us on December 31, 2014 resulting in an increase in capitalized intangible assets of $15.9 million that is being amortized until November 2016.

Liquidity and Capital Resources

As of September 30, 2016, our total cash and cash equivalents and marketable securities were $142.6 million compared to $143.2 million at December 31, 2015. 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 September 30, 2016 and December 31, 2015 are summarized as follows:

(in thousands)	September 30, 2016	December 31, 2015
Cash and cash equivalents	$ 32,765	$ 50,843
Marketable securities:		
U.S. Treasury and government agencies	54,695	44,057
Corporate debt	55,119	48,280
Total marketable securities	109,814	92,337
Total cash and cash equivalents	$ 142,579	$ 143,180

As of September 30, 2016, we maintained all of our cash and cash equivalents with 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 2016 and beyond in connection with our U.S. commercial activities for HETLIOZ® and Fanapt®, including Medicaid rebates, the European commercial launch activities for HETLIOZ® and a probable future milestone payment of $25.0 million to BMS in the event cumulative worldwide sales of HETLIOZ® reach $250.0 million. During this time, we will evaluate the commercial opportunity for Fanapt® in Europe, assuming EMA approval. 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 U.S. commercial activities for HETLIOZ® and Fanapt® are difficult to estimate and may vary significantly. Additionally, the outcome of the outstanding Fanapt® patent infringement lawsuits could have a material impact on future cash flows. Management believes that our existing funds will be sufficient to meet our operating plans for the foreseeable future. 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 net cash flows from operating, investing and financing activities for the nine months ended September 30, 2016 and 2015:

(in thousands)	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Net Change
Net cash provided by (used in):			
Operating activities:			
Net loss	$ (17,406)	$ (25,067)	$ 7,661
Non-cash charges	16,481	17,794	(1,313)
Net change in operating assets and liabilities	(5,995)	20,078	(26,073)
Operating activities	(6,920)	12,805	(19,725)
Investing activities:			
Net purchases of marketable securities	(17,449)	(29,199)	11,750
Other	(710)	(1,813)	1,103
Investing activities	(18,159)	(31,012)	12,853
Financing activities			
Proceeds from exercise of employee stock options	7,001	4,374	2,627
Other	—	(282)	282
Financing activities	7,001	4,092	2,909
Net decrease in cash and cash equivalents	$ (18,078)	$ (14,115)	$ (3,963)

The decrease of $19.7 million in net cash provided by operating activities reflects the net change of $26.1 million in operating assets and liabilities resulting primarily from the net impact of accruals for government and other rebates and accounts receivable relating to initial sales of Fanapt® that began in the 2015 period. The decrease was partially offset by the reduction of $7.7 million in the net loss compared with the 2015 period.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

The following is a summary of our non-cancellable long-term contractual cash obligations as of September 30, 2016:

(in thousands)	Cash payments due by year (1) (2) (3) Total	Remainder of 2016	2017	2018	2019	2020	Thereafter
Operating leases	$22,063	$ 445	$1,933	$2,230	$2,284	$2,341	$ 12,830

(1) This table does not include various agreements that we have entered into for services with third party vendors, including agreements to conduct clinical trials, to manufacture products, and for consulting and other contracted services due to the cancelable nature of the services. We accrued the costs of these agreements based on estimates of work completed to date. Additionally, this table does not include rebates, chargebacks or discounts recorded as liabilities at the time that product sales are recognized as revenue.

(2) This table does not include a probable future milestone obligation under our license agreement with BMS, where we will be obligated to make a future milestone payment of $25.0 million in the event cumulative worldwide sales of HETLIOZ® reach $250.0 million. This probable obligation has been accrued as a non-current liability in our condensed consolidated balance sheet as of September 30, 2016.

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

Operating leases

Commitments relating to operating leases represent the minimum annual future payments under operating leases for a total of 40,188 square feet of office space for our headquarters office at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. that expire in 2026 and the operating lease for 2,880 square feet of office space for our European headquarters in London that has a noncancellable lease term ending in 2021.

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. There were five major customers that each accounted for more than 10% of total revenues and, as a group, represented 86% of total revenues for the nine months ended September 30, 2016. There were four major customers that each accounted for more than 10% of accounts receivable and, as a group, represented 80% of total accounts receivable at September 30, 2016. We mitigate our credit risk relating to accounts receivable from customers by performing ongoing credit evaluations.

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 September 30, 2016. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of September 30, 2016, 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

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the third quarter of 2016 that has materially affected, or is 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 Delaware District Court). The suit seeks an adjudication that Roxane has infringed one or more claims of our U.S. Patent No. 8,586,610 (the '610 Patent) by submitting to the U.S. Food and Drug Administration (the FDA) an Abbreviated New Drug Application (ANDA) for a generic version of Fanapt® prior to the expiration of the '610 Patent in November 2027. In addition, pursuant to the settlement agreement with Novartis Pharma AG (Novartis), we assumed Novartis' patent infringement action against Roxane in the Delaware District Court. That suit alleges that Roxane has infringed one or more claims of U.S Patent RE39198 (the '198 Patent), which is licensed exclusively to us, by filing an ANDA for a generic version of Fanapt® prior to the expiration of the '198 Patent in November 2016. These two cases against Roxane were consolidated by agreement of the parties and were tried together in a five-day bench trial that concluded on March 4, 2016. On August 25, 2016, the Delaware District Court ruled in our favor, finding that Roxane's ANDA product infringed the asserted claims of the '610 Patent and the '198 Patent. The Delaware District Court ruled that we are entitled to a permanent injunction against Roxane enjoining Roxane from infringing the '610 Patent, including the manufacture, use, sale, offer to sell, sale, distribution or importation of any generic iloperidone product described in the '610 Patent ANDA until the expiration of the '610 Patent in November 2027. If we obtain pediatric exclusivity, the injunction against Roxane would be extended until May 2028 under the Delaware District Court's order. On September 23, 2016, Roxane filed a notice of appeal with the Federal Circuit Court of Appeals.

In 2015, we filed six separate patent infringement lawsuits in the Delaware District Court against Roxane, Inventia Healthcare Pvt. Ltd., Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin), Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (Taro), and Apotex Inc. and Apotex Corp., (collectively, the Defendants). The lawsuits each seek an adjudication that the respective Defendants infringed one or more claims of the '610 Patent and/or our U.S. Patent No. 9,138,432 (the '432 Patent) by submitting to the FDA an ANDA for a generic version of Fanapt® prior to the expiration of the '610 Patent in November 2027 or the '432 Patent in September 2025. The Defendants have denied infringement and counterclaimed for declaratory judgment of invalidity and noninfringement of the '610 Patent and the '432 Patent. The Delaware District Court has scheduled a five-day bench trial beginning on May 15, 2017 in which all of these lawsuits regarding infringement of the '610 Patent and the '432 Patent are expected to be tried together.

Lupin filed counter claims for declaratory judgment of invalidity and noninfringement of seven of our method of treatment patents that are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) related to Fanapt® (such seven patents, the Method of Treatment Patents). We have not sued Lupin for infringing the Method of Treatment Patents. On October 13, 2016, we, along with Lupin filed a Stipulation of Dismissal in the Delaware District Court pursuant to which Lupin's counterclaims relating to the Method of Treatment Patents were dismissed without prejudice in recognition of an agreement reached between Lupin and us.

On October 24, 2016, we entered into a License Agreement with Taro to resolve our patent litigation against Taro regarding Taro's ANDA seeking approval of its generic version of Fanapt® (the Taro License Agreement). Under the Taro License Agreement, we granted Taro a non-exclusive license to manufacture and commercialize Taro's version of Fanapt® in the U.S. effective November 2, 2027, unless prior to that date we obtain pediatric exclusivity for Fanapt®, in which case, the license will be effective May 2, 2028. Taro may enter the market earlier under certain limited circumstances. The Taro License Agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, provides for a full settlement and release by us and Taro of all claims that are the subject of the litigation.

On February 26, 2016, Roxane filed suit against us in the U.S. District Court for the Southern District of Ohio. The suit seeks a declaratory judgment of invalidity and noninfringement of the Method of Treatment Patents. We have not sued Roxane for infringing the Method of Treatment Patents. We filed a motion to dismiss this lawsuit for lack of personal jurisdiction or to transfer the lawsuit to the Delaware District Court.

On February 26, 2016, Roxane filed a Petition for *Inter Partes* Review (IPR) of the '432 Patent with the Patent Trials and Appeals Board (PTAB) of the United States Patent and Trademark Office. We filed a Preliminary Response on June 7, 2016, and on August 30, 2016, the PTAB denied the request by Roxane to institute an IPR of the '432 Patent. On September 29, 2016, Roxane filed a Petition for Rehearing with the PTAB, and on October 13, 2016, we filed a Response to Roxane's Petition.

ITEM 1A Risk Factors

We previously disclosed in Part I, Item 1A of our annual report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on February 12, 2016, important factors which could affect our business, financial condition, results of operations and future operations under the heading *Risk Factors*. Our business, financial condition and operating results can be affected by a number of factors, whether current known or unknown, including but not limited to those described as risk factors, any one or more of which could, directly or indirectly, cause our actual operating results and financial condition to vary materially

from past, or anticipated future, operating results and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and the price of our common stock. There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015.

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
3.1	Form of Amended and Restated Certificate of Incorporation of the registrant (filed as Exhibit 3.8 to Amendment No. 2 to the registrant's registration statement on Form S-1 (File No. 333-130759) on March 17, 2006 and incorporated herein by reference).
3.2	Form of Certificate of Designation of Series A Junior Participating Preferred Stock (filed as Exhibit 3.10 to the registrant's current report on Form 8-K (File No. 001-34186) on September 25, 2008 and incorporated herein by reference).
3.3	Fourth Amended and Restated Bylaws of the registrant, as amended and restated on December 17, 2015 (filed as Exhibit 3.1 to the registrant's current report on Form 8-K (File No. 001-34186) on December 21, 2015 and incorporated herein by reference).
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 September 30, 2016 formatted in XBRL (eXtensible Business Reporting Language) and filed electronically herewith: (i) Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015; (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2016 and 2015; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three and nine months ended September 30, 2016 and 2015; (iv) Condensed Consolidated Statement of Changes in Stockholders' Equity for the nine months ended September 30, 2016; (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015; 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.

November 3, 2016 /s/ Mihael H. Polymeropoulos, M.D.

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

November 3, 2016 /s/ James P. Kelly

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

November 3, 2016

/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.

November 3, 2016

/s/ James P. Kelly

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

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Vanda Pharmaceuticals Inc., (the Company), does hereby certify, to the best of such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 (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.

November 3, 2016

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

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

November 3, 2016

/s/ James P. Kelly

James P. Kelly
Senior Vice President, Chief Financial Officer 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.