Vanda Pharmaceuticals Inc.
Form 10-Q
August 08, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2014

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 x 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 x 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 x
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 x

As of July 31, 2014, there were 33,877,841 shares of the registrant s common stock issued and outstanding.

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Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended June 30, 2014

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Part I FINANCIAL INFORMATION

ITEM 1 Financial Statements (Unaudited)

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except for share and per share amounts)	June 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,994	$ 64,764
Marketable securities	46,591	65,586
Accounts receivable, net	2,376	2,031
Inventory	1,093	
Prepaid expenses and other current assets	4,166	2,703
Restricted cash		530
Total current assets	71,220	135,614
Property and equipment, net	2,312	2,198
Intangible asset, net	11,855	5,037
Restricted cash, non-current	785	500
Total assets	$ 86,172	$ 143,349
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 248	$ 661
Accrued liabilities	6,753	5,180
Deferred rent	234	221
Deferred revenues	31,059	26,789
Total current liabilities	38,294	32,851
Deferred rent, non-current	2,853	2,888
Deferred revenues, non-current	44,000	63,486
Other liabilities	140	
Total liabilities	85,287	99,225
Commitments and contingencies (Note 13)		
Stockholders equity:		
Preferred stock, $0.001 par value; 20,000,000 shares authorized, and no shares		

issued or outstanding		
Common stock, $0.001 par value; 150,000,000 shares authorized; 33,877,841 and 33,338,543 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	34	33
Additional paid-in capital	357,119	352,240
Accumulated other comprehensive income	10	21
Accumulated deficit	(356,278)	(308,170)
Total stockholders equity	885	44,124
Total liabilities and stockholders equity	$ 86,172	$ 143,349

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(in thousands, except for share and per share amounts)	Three Months Ended June 30, 2014	Three Months Ended June 30, 2013	Six Months Ended June 30, 2014	Six Months Ended June 30, 2013
Revenues:				
Product revenue	$ 1,559	$	$ 1,559	$
Royalty revenue	1,539	1,641	3,230	3,103
Licensing agreement	7,764	6,678	15,216	13,284
Total revenues	10,862	8,319	20,005	16,387
Operating expenses:				
Cost of goods sold	198		198	
Research and development	3,514	6,100	10,777	14,211
Selling, general and administrative	28,139	5,260	56,032	9,413
Intangible asset amortization	617	372	1,182	741
Total operating expenses	32,468	11,732	68,189	24,365
Loss from operations	(21,606)	(3,413)	(48,184)	(7,978)
Other income	31	30	76	76
Loss before tax benefit	(21,575)	(3,383)	(48,108)	(7,902)
Tax benefit				
Net loss	$ (21,575)	$ (3,383)	$ (48,108)	$ (7,902)
Basic and diluted net loss per share	$ (0.64)	$ (0.12)	$ (1.42)	$ (0.28)
Weighted average shares outstanding, basic and diluted	33,874,625	28,377,254	33,777,207	28,361,340

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)

	Three Months Ended		Six Months Ended	
(in thousands)	**June 30, 2014**	**June 30, 2013**	**June 30, 2014**	**June 30, 2013**
Net loss	$ (21,575)	$ (3,383)	$ (48,108)	$ (7,902)
Other comprehensive income (loss):				
Change in net unrealized income (loss) on marketable securities	2		(11)	(10)
Tax provision on other comprehensive income (loss)				
Other comprehensive income (loss), net of tax:	2		(11)	(10)
Comprehensive loss	$ (21,573)	$ (3,383)	$ (48,119)	$ (7,912)

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY
(Unaudited)

(in thousands, except for share amounts)	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balances at December 31, 2013	33,338,543	33	355,432	21	(311,362)	44,124
Adjustment for change in accounting method			(3,192)		3,192	
Adjusted balances at December 31, 2013	33,338,543	33	352,240	21	(308,170)	44,124
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	571,684	1	2,479			2,480
Shares withheld upon settlement of restricted stock units	(32,386)		(436)			(436)
Employee and non-employee stock based compensation expense			2,836			2,836
Net loss					(48,108)	(48,108)
Other comprehensive loss, net of tax				(11)		(11)
Balances at June 30, 2014	33,877,841	34	357,119	10	(356,278)	885

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(in thousands)	Six Months Ended June 30, 2014	June 30, 2013
Cash flows from operating activities		
Net loss	$ (48,108)	$ (7,902)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	264	212
Employee and non-employee stock-based compensation	2,836	2,432
Amortization of discounts and premiums on marketable securities	96	121
Intangible asset amortization	1,182	741
Changes in assets and liabilities:		
Accounts receivable	(345)	(473)
Prepaid expenses and other current assets	(1,463)	1,316
Inventory	(1,093)	
Accounts payable	(413)	880
Accrued liabilities	1,573	(1,417)
Other liabilities	118	206
Deferred revenue	(15,216)	(13,284)
Net cash used in operating activities	(60,569)	(17,168)
Cash flows from investing activities		
Acquisition of intangible assets	(8,000)	
Purchases of property and equipment	(378)	(72)
Purchases of marketable securities	(20,544)	
Proceeds from sale of marketable securities	8,198	
Maturities of marketable securities	31,235	31,500
Change in restricted cash	245	
Net cash provided by investing activities	10,756	31,428
Cash flows from financing activities		
Tax obligations paid in connection with settlement of restricted stock units	(436)	(196)
Proceeds from exercise of employee stock options	2,479	797
Net cash provided by financing activities	2,043	601
Net (decrease) increase in cash and cash equivalents	(47,770)	14,861
Cash and cash equivalents		
Beginning of period	64,764	88,772

End of period	$ 16,994	$ 103,633
Non-cash investing activities		
Purchases of property and equipment in accrued liabilities	$ 20	$

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

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VANDA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Business Organization and Presentation

Business organization

Vanda Pharmaceuticals Inc. (Vanda or the Company) is a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders. Vanda commenced its operations in 2003. Vanda s product portfolio includes HETLIOZ® (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) and for which a New Drug Application (NDA) was approved by the U.S. Food and Drug Administration (FDA) in January 2014 and launched commercially in the U.S. in April 2014, Fanapt®(iloperidone), a product for the treatment of schizophrenia, the oral formulation of which is currently being marketed and sold in the U.S. by Novartis Pharma AG (Novartis), and VLY-686, a small molecule neurokinin-1 receptor (NK-1R) antagonist.

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, 2013 included in the Company s annual report on Form 10-K. The financial information as of June 30, 2014 and for the three and six months ended June 30, 2014 and 2013 is unaudited, but in the opinion of management, all adjustments with the exception of stock-based compensation expense, see Note 3, *Change in Method of Accounting for Stock-based Compensation*, consist only of normal recurring accruals, considered necessary for a fair statement of the results of these interim periods have been included. The condensed consolidated balance sheet data as of December 31, 2013 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, 2013.

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 revenues and expenses during the reporting period. Actual results could differ from those estimates.

Inventory

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

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Net Product Revenues

The Company s 2014 net product revenues consist solely of sales of HETLIOZ® for the treatment of Non-24. 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. The Company invoices and records revenue when the specialty pharmacies receive HETLIOZ® from the Company s third-party logistics warehouse.

In the U.S., HETLIOZ® is only available for distribution through specialty pharmacies, and is not available in retail pharmacies. In April 2014, the Company launched HETLIOZ*Solutions* to support and facilitate the treatment of blind individuals in the U.S. living with Non-24. HETLIOZ*Solutions* provides patients with a host of resources including information about Non-24 and HETLIOZ®, insurance support, overview of financial assistance programs and pharmacy access.

Product Sales Discounts and Allowances

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

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

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

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

adjustment.

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

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

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

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

Stock-based Compensation

In January 2014, the Company elected to change its method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions to the straight-line method. Previously, attribution was based on the accelerated attribution method, which treated each vesting tranche as an individual award and amortized them concurrently. Comparative financial statements for prior periods have been adjusted to apply the straight-line method retrospectively. See Note 3, *Change in Method of Accounting for Stock-based Compensation,* for further information. Beginning in 2014, the Company started using a mid-point scenario to calculate the weighted average expected term of stock options granted, which combines the Company s historical exercise data with hypothetical exercise data for unexercised stock options. Prior to 2014, the expected term assumption was determined using the simplified method.

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 $3.3 million and $4.3 million for the three and six months ended June 30, 2014, respectively. The Company did not incur any advertising expense during the six months ended June 30, 2013.

Recent accounting pronouncements

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

In July 2013, the FASB issued ASU 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists.* This new standard requires the netting of unrecognized tax benefits against a deferred tax asset for a loss or other carryforward that would apply in settlement of the uncertain tax positions. Under the new standard, unrecognized tax benefits will be netted against all available same-jurisdiction loss or other tax carryforwards that would be utilized, rather than only against carryforwards that are created by the unrecognized tax benefits. The new standard is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2013.

Adoption of this new standard did not have a material impact on the Company s condensed consolidated financial statements.

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

In January 2014, the Company elected to change its method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions to the straight-line method. Previously, attribution was based on the accelerated attribution method, which treated each vesting tranche as an individual award and amortized them concurrently. The straight-line method of accounting was adopted to better align the Company s recognition of stock option compensation cost with

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its peers and to expense stock options and restricted stock units (RSUs) in a consistent manner. Comparative financial statements for prior periods have been adjusted to apply the straight-line method retrospectively. As a result of the change in method of accounting for stock-based compensation, the expense for stock-based compensation related to option awards was $0.5 million and $1.2 million lower than it would have been under the accelerated attribution method for the three and six months ended June 30, 2014, respectively. This resulted in a reduction to the net loss of $0.5 million and $1.2 million, or $0.02 per share and $0.04 per share, respectively, for the three and six months ended June 30, 2014.

There was no adjustment as a result of the change in method of accounting for stock-based compensation to amounts previously reported as assets, liabilities and total stockholders equity in the consolidated balance sheets for prior periods. However, amounts previously reported as additional paid-in capital and accumulated deficit for prior periods have been adjusted to reflect the change in method of accounting for stock-based compensation. The cumulative effect of the change on accumulated deficit as of January 1, 2013, the beginning of the earliest period presented in the financial statements was a reduction of $3.2 million. The adjustments as of December 31, 2013 were as follows:

Balance Sheet *(in thousands, except for share and per share amounts)*	**December 31, 2013**		
	As Previously Reported	**Retrospective Adjustment**	**As Adjusted**
Stockholders equity:			
Preferred stock, $0.001 par value; 20,000,000 shares authorized, and no shares issued or outstanding			
Common stock, $0.001 par value; 150,000,000 shares authorized; 33,338,543 shares issued and outstanding at December 31, 2013	$ 33	$	$ 33
Additional paid-in capital	355,432	(3,192)	352,240
Accumulated other comprehensive income	21		21
Accumulated deficit	(311,362)	3,192	(308,170)
Total stockholders equity	$ 44,124	$	$ 44,124

The amounts previously reported in the consolidated statement of operations for research and development expense, selling, general and administrative expense and net loss for prior periods have been adjusted as a result of the change in method of accounting for stock-based compensation. The adjustments for the three and six months ended June 30, 2013 were as follows:

Statement of Operations *(in thousands, except for share and per share amounts)*	**Three Months Ended June 30, 2013**			**Six Months Ended June 30, 2013**		
	As previously Reported	**Retrospective Adjustment**	**As Adjusted**	**As previously Reported**	**Retrospective Adjustment**	**As Adjusted**
Revenues:						

Licensing agreement	$ 6,678	$	$ 6,678	$ 13,284	$	$ 13,284
Royalty revenue	1,641		1,641	3,103		3,103
Total revenues	8,319		8,319	16,387		16,387
Operating expenses:						
Research and development	5,982	118	6,100	13,942	269	14,211
Selling, general and administrative	5,074	186	5,260	9,032	381	9,413
Intangible asset amortization	372		372	741		741
Total operating expenses	11,428	304	11,732	23,715	650	24,365
Loss from operations	(3,109)	(304)	(3,413)	(7,328)	(650)	(7,978)
Other income	30		30	76		76
Loss before tax benefit	(3,079)	(304)	(3,383)	(7,252)	(650)	(7,902)
Tax benefit						
Net loss	$ (3,079)	$ (304)	$ (3,383)	$ (7,252)	$ (650)	$ (7,902)
Basic and diluted net loss per share	$ (0.11)	$ (0.01)	$ (0.12)	$ (0.26)	$ (0.02)	$ (0.28)
Weighted average shares outstanding, basic and diluted	28,377,254		28,377,254	28,361,340		28,361,340

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The amounts previously reported for net loss in the consolidated statement of comprehensive loss for prior periods have been adjusted as a result of the change in method of accounting for stock-based compensation. The adjustment for the three and six months ended June 30, 2013 was as follows:

Statement of Comprehensive Loss	Three Months Ended June 30, 2013			Six Months Ended June 30, 2013		
(in thousands)	As Previously Reported	Retrospective Adjustment	As Adjusted	As Previously Reported	Retrospective Adjustment	As Adjusted
Net loss	$ (3,079)	$ (304)	$ (3,383)	$ (7,252)	$ (650)	$ (7,902)
Other comprehensive loss:						
Change in net unrealized loss on marketable securities				(10)		(10)
Tax provision on other comprehensive income (loss)						
Other comprehensive loss, net of tax:				(10)		(10)
Comprehensive loss	$ (3,079)	$ (304)	$ (3,383)	$ (7,262)	$ (650)	$ (7,912)

There was no adjustment to the amounts previously reported for net cash used in operating activities in the consolidated statements of cash flows for prior periods as a result of the change in method of accounting for stock-based compensation. However, the amounts previously reported as net loss and employee and non-employee stock-based compensation expense in cash flows from operating activities have been adjusted to reflect the change in method of accounting for stock-based compensation. The adjustments for the six months ended June 30, 2013 were as follows:

Statement of Cash Flows	Six Months Ended June 30, 2013		
(in thousands)	As Previously Reported	Retrospective Adjustment	As Adjusted
Cash flows from operating activities			
Net loss	$ (7,252)	$ (650)	$ (7,902)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property and equipment	212		212
Employee and non-employee stock-based compensation	1,782	650	2,432
Amortization of discounts and premiums on marketable securities	121		121
Intangible asset amortization	741		741
Changes in assets and liabilities, net	(12,772)		(12,772)

Net cash used in operating activities	$ (17,168)	$	$ (17,168)

4. Earnings per Share

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

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The following table presents the calculation of basic and diluted net loss per share of common stock for the three and six months ended June 30, 2014 and 2013:

(in thousands, except for share and per share amounts)	Three Months Ended June 30, 2014	Three Months Ended June 30, 2013	Six Months Ended June 30, 2014	Six Months Ended June 30, 2013
Numerator:				
Net loss	$ (21,575)	$ (3,383)	$ (48,108)	$ (7,902)
Denominator:				
Weighted average shares outstanding, basic and diluted	33,874,625	28,377,254	33,777,207	28,361,340
Net loss per share, basic and diluted:				
Net loss per share	$ (0.64)	$ (0.12)	$ (1.42)	$ (0.28)
Antidilutive securities excluded from calculations of diluted net loss per share	3,739,874	4,234,017	3,805,191	4,997,542

The Company incurred net losses for the three and six months ended June 30, 2014 and 2013 causing inclusion of any potentially dilutive securities to have an anti-dilutive effect, resulting in dilutive loss per share and basic loss per share attributable to common stockholders being equivalent.

5. Marketable Securities

The following is a summary of the Company s available-for-sale marketable securities as of June 30, 2014, which all have contract maturities of less than one year:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 24,521	$ 2	$	$ 24,523
Corporate debt	$ 22,060	$ 10	$ (2)	$ 22,068
	$ 46,581	$ 12	$ (2)	$ 46,591

The following is a summary of the Company s available-for-sale marketable securities as of December 31, 2013:

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

6. Fair Value Measurements

Authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

Level 1 defined as observable inputs such as quoted prices in active markets

Level 2 defined as inputs other than quoted prices in active markets that are either directly or indirectly observable

Level 3 defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions

Marketable securities classified in Level 1 and Level 2 as of June 30, 2014 and December 31, 2013 consist of available-for-sale marketable securities. The valuation of Level 1 instruments is determined using a market approach, and is based upon unadjusted quoted prices for identical assets in active markets. The valuation of investments classified in Level 2 also is determined using a market approach based upon quoted prices for similar assets in active markets, or other inputs that are observable for substantially the full term of the financial instrument. Level 2 securities include certificates of deposit, commercial paper and corporate notes that use as their basis readily observable market parameters. The Company did not transfer any assets between Level 2 and Level 1 during the six months ended June 30, 2014.

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As of June 30, 2014, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

		Fair Value Measurement as of June 30, 2014 Using		
(in thousands)	June 30, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale securities	$ 46,591	$ 24,523	$ 22,068	$

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

		Fair Value Measurement as of December 31, 2013 Using		
(in thousands)	December 31, 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-sale securities	$ 65,586	$ 31,566	$ 34,020	$

The Company also has financial assets and liabilities, not required to be measured at fair value on a recurring basis, which primarily consist of cash and cash equivalents, accounts receivable, restricted cash, accounts payable and accrued liabilities, the carrying value of which materially approximate their fair values.

7. Inventory

The Company evaluates expiry risk by evaluating current and future product demand relative to product shelf life. The Company builds demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage. Inventory consisted of the following as of June 30, 2014 and December 31, 2013:

(in thousands)	June 30, 2014	December 31, 2013
Raw materials	$ 145	$
Work-in-process	7	
Finished goods	941	
Total	$ 1,093	$

8. Prepaid Expenses and Other Current Assets

The following is a summary of the Company s prepaid expenses and other current assets as of June 30, 2014 and December 31, 2013:

(in thousands)	**June 30, 2014**	**December 31, 2013**
Prepaid insurance	$ 708	$ 167
Prepaid manufacturing cost	608	
Other prepaid expenses and vendor advances	2,616	2,408
Other current assets	234	128
Total prepaid expenses and other current assets	$ 4,166	$ 2,703

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9. Intangible Assets

The following is a summary of the Company s intangible asset as of June 30, 2014:

		June 30, 2014		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
HETLIOZ®	19	$ 8,000	$ 333	$ 7,667
Fanapt®	7.5	$ 12,000	$ 7,812	$ 4,188

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

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

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

In 2009, the Company announced that the FDA had approved the NDA for Fanapt®. As a result of this approval, the Company met a milestone under its original sublicense agreement with Novartis that required the Company to make a license payment of $12.0 million to Novartis. The $12.0 million is being amortized on a straight-line basis over the remaining life of the U.S. patent for Fanapt®, which as of December 31, 2013 the Company expected to last until May 2017. In 2014, the Company became aware of events that led it to believe that Novartis would not complete the ongoing pediatric efficacy studies in a time that would enable it to receive the incremental six-month pediatric term extension. This resulted in a six-month reduction to the estimated patent life from May 2017 to November 2016.

The intangible assets are being amortized over their estimated useful economic life using the straight-line method. Amortization expense was $0.6 million and $0.4 million for the three months ended June 30, 2014 and 2013, respectively. Amortization expense was $1.2 million and $0.7 million for the six months ended June 30, 2014 and 2013, respectively. The following is a summary of future intangible asset amortization as of June 30, 2014:

(in thousands)	Total	Remainder of 2014	2015	2016	2017	2018	Thereafter
HETLIOZ®	$ 7,667	$ 205	$ 411	$ 411	$ 411	$ 411	$ 5,818

Fanapt®	4,188	866	1,733	1,589			
	$ 11,855	$ 1,071	$ 2,144	$ 2,000	$ 411	$ 411	$ 5,818

10. Accrued Liabilities

The following is a summary of the Company s accrued liabilities as of June 30, 2014 and December 31, 2013:

(in thousands)	**June 30, 2014**	**December 31, 2013**
Accrued research and development expenses	$ 1,845	$ 2,324
Accrued consulting and other professional fees	2,708	2,015
Employee benefits	1,255	176
Other accrued liabilities	945	665
	$ 6,753	$ 5,180

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11. Deferred Revenue

The following is a summary of changes in total deferred revenue for the six months ended June 30, 2014 and 2013:

	Six Months Ended	
(in thousands)	**June 30, 2014**	**June 30, 2013**
Balance beginning of period	$ 90,275	$ 117,064
Licensing revenue recognized	15,216	13,284
Balance end of period	$ 75,059	$ 103,780

The Company entered into an amended and restated sublicense agreement with Novartis in 2009, pursuant to which Novartis has the right to commercialize and develop Fanapt® in the U.S. and Canada. Under the amended and restated sublicense agreement, the Company received an upfront payment of $200.0 million. The Company and Novartis established a Joint Steering Committee (JSC) following the effective date of the amended and restated sublicense agreement. The Company concluded that the JSC constitutes a deliverable under the amended and restated sublicense agreement and that revenue related to the upfront payment will be recognized ratably over the term of the JSC; however, the delivery or performance has no term as the exact length of the JSC is undefined. As a result, the Company deems the performance period of the JSC to be the life of the U.S. patent of Fanapt®. Revenue related to the upfront payment will be recognized ratably from the date the amended and restated sublicense agreement became effective (November 2009) through the expected life of the U.S. patent for Fanapt® (November 2016). See Note 9 *Intangible Assets,* for a discussion of the Fanapt® patent life.

12. Income Taxes

Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The fact that the Company has historically generated net operating losses (NOLs) serves as strong evidence that it is more likely than not that deferred tax assets will not be realized in the future. Therefore, the Company has a full valuation allowance against all deferred tax assets as of June 30, 2014 and December 31, 2013. Changes in ownership may limit the amount of NOL carryforwards that can be utilized in the future to offset taxable income.

13. Commitments and Contingencies

Operating leases

In 2011, the Company entered into an office lease with Square 54 Office Owner LLC (the Landlord) for its current headquarters, consisting of 21,400 square feet at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. (the Lease). Subject to the prior rights of other tenants in the building, the Company has the right to renew the Lease for five years following the expiration of its original term. The Company has the right to sublease or assign all or a portion of the premises, subject to standard conditions. The Lease may be terminated early by the Company or the Landlord upon certain conditions.

In March 2014, the Company and the Landlord entered into a lease amendment (the Lease Amendment). Under the Lease Amendment, the Company has the right to occupy an additional 8,860 square feet in the building. The Lease

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

The following is a summary of the minimum annual future payments under operating leases as of June 30, 2014:

(in thousands)	**Total**	**Remainder of 2014**	**2015**	**2016**	**2017**	**2018**	**Thereafter**
Operating leases	$ 15,238	$ 587	$ 1,337	$ 1,500	$ 1,538	$ 1,576	$ 8,700

Rent expense under operating leases, was $0.4 million and $0.3 million for the three months ended June 30, 2014 and 2013, respectively. Rent expense under operating leases, was $0.8 million and $0.5 million for the six months ended June 30, 2014 and 2013, respectively.

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Consulting fees

The Company engaged a regulatory consultant to assist the Company s efforts to prepare, file and obtain FDA approval of an NDA for HETLIOZ®. As a result of the FDA approval of the NDA for HETLIOZ®, the Company made a milestone payment of $2.0 million, which is included in research and development expenses in the consolidated statement of operations for the six months ended June 30, 2014. In March 2014, the Company terminated the engagement.

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 the Company received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize HETLIOZ®. As a result of the FDA approval of the NDA for HETLIOZ® in January 2014, the Company made a milestone payment of $8.0 million in the first quarter of 2014. The Company will be obligated to make a future milestone payment to BMS of up to $25.0 million in the event that cumulative sales of HETLIOZ® reach $250.0 million. Additionally, the Company will be obligated to make royalty payments equal to 10% of net sales of HETLIOZ®. The Company is also obligated under the license agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that the Company receives from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. Under the license agreement with BMS for HETLIOZ®, the Company is obligated to use commercially reasonable efforts to develop and commercialize HETLIOZ® and to meet certain milestones in initiating and completing certain clinical work.

Either party may terminate the HETLIOZ® license agreement under certain circumstances, including a material breach of the agreement by the other. In the event the Company terminates the license, or if BMS terminates the license due to the Company s breach, all rights licensed and developed by the Company under the license agreement will revert or otherwise be licensed back to BMS on an exclusive basis.

Fanapt®. The Company acquired exclusive worldwide rights to patents and patent applications for Fanapt® in 2004 through a sublicense agreement with Novartis. As a result of the FDA s approval of the NDA for Fanapt® in May 2009, the Company met a milestone under the sublicense agreement, which required the Company to make a payment of $12.0 million to Novartis.

In 2009, the Company entered into an amended and restated sublicense agreement with Novartis, which amended and restated the 2004 sublicense agreement. Pursuant to the amended and restated sublicense agreement, the Company received an upfront payment of $200.0 million and is eligible for additional payments totaling up to $265.0 million upon Novartis achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. Based on the current sales performance of Fanapt® in the U.S., the Company expects that some or all of these commercial and development milestones will not be achieved by Novartis. The Company also receives royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada.

The Company retains exclusive rights to Fanapt® outside the U.S. and Canada, and the Company has exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. Novartis has chosen not to co-commercialize Fanapt® with the Company in Europe and certain other countries and will instead receive a royalty on net sales in those countries. These include, but are not limited to, the countries in the

European Union as well as Switzerland, Norway, Liechtenstein and Iceland. The Company has entered into agreements with the following partners for the commercialization of Fanapt® in the countries set forth below:

Country	Partner
Mexico	Probiomed S.A. de C.V.
Israel	Megapharm Ltd.

In 2012, the Israeli Ministry of Health and Argentina granted market approval for Fanapt® for the treatment of schizophrenia. In October 2013, the Mexican Federal Commission for Protection Against Sanitary Risks (COFEPRIS) granted market approval for Fanapt® for the treatment of schizophrenia.

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

Pursuant to the license agreement, the Company will be responsible for all development costs, and Lilly is eligible to receive 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 VLY-686.

Either party may terminate the license agreement under certain circumstances, including a material breach of the license agreement by the other. In the event 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 VLY-686.

Future milestone payments. No amounts were recorded as liabilities nor were any future contractual obligations relating to the license agreements included in the consolidated financial statements as of June 30, 2014 because the criteria for recording the future milestone payments have not yet been met. These criteria include the successful outcome of future clinical trials, regulatory filings, favorable FDA regulatory approvals, growth in product sales and other factors.

14. Legal Matters

In May 2014, the Company commenced arbitration proceedings with Novartis relating to the license of Fanapt®. The Company has requested an award of approximately $539.0 million in such proceedings. The Company is vigorously prosecuting its claims in the arbitration as well as defending counterclaims brought by Novartis for approximately $75.0 million, against which the Company believes it has meritorious defenses. The Company does not anticipate that this proceeding will have a material, adverse effect on its business, results of operations or financial condition. While it is not possible to accurately predict or determine the eventual outcome of this matter, these proceedings are subject to inherent uncertainties and the Company may not prevail. The Company currently anticipates that the arbitration proceeding will be completed within 12 to 18 months.

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

15. Employee Stock-Based Compensation

Compensation costs for all stock-based awards to employees and directors are measured based on the grant date fair value of those awards and recognized over the period during which the employee or director is required to perform

service in exchange for the award. The Company generally recognizes the expense over the award s vesting period.

In January 2014, the Company elected to change its method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions from the accelerated attribution method to the straight-line method. See Note 3, *Change in Method of Accounting for Stock-based Compensation* for additional discussion. The fair value of stock options granted and RSUs awarded are amortized using the straight-line method. As stock-based compensation expense recognized in the consolidated statements of operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model that uses the assumptions noted in the following table. Expected volatility rates are based on the historical volatility of the Company s

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publicly traded common stock and other factors. Beginning in 2014, the Company started using a mid-point scenario to calculate the weighted average expected term of stock options granted, which combines the Company s historical exercise data with hypothetical exercise data for unexercised stock options. Prior to 2014, the expected term assumption was determined using the simplified method. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception (other than a dividend of preferred share purchase rights, which was declared in September 2008) and does not plan to pay dividends in the foreseeable future.

Assumptions used in the Black-Scholes-Merton option pricing model for employee and director stock options granted during the six months ended June 30, 2014 and 2013 were as follows:

	Six Months Ended	
	June 30, 2014	June 30, 2013
Expected dividend yield	0%	0%
Weighted average expected volatility	64%	62%
Weighted average expected term (years)	5.83	6.03
Weighted average risk-free rate	1.77%	1.16%
Weighted average fair value per share	$ 7.14	$ 3.46

Total employee stock-based compensation expense related to stock-based awards for the three and six months ended June 30, 2014 and 2013 was comprised of the following:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2014	June 30, 2013	June 30, 2014	June 30, 2013
Research and development	$ 418	$ 461	$ 860	$ 1,058
Selling, general and administrative	989	646	1,901	1,353
	$ 1,407	$ 1,107	$ 2,761	$ 2,411

As of June 30, 2014, the Company had two equity incentive plans, the Second Amended and Restated Management Equity Plan (the 2004 Plan) and the 2006 Equity Incentive Plan (the 2006 Plan). There were 652,810 shares subject to outstanding options granted under the 2004 Plan as of June 30, 2014, and no additional options will be granted under this plan. As of June 30, 2014, there were 10,329,472 shares of common stock reserved for issuance under the 2006 Plan, of which 5,849,373 shares were subject to outstanding options and RSUs granted to employees and non-employees and 2,409,512 shares remained available for future grant.

The Company has granted option awards with service conditions 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 2007, 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 2006 vest and become exercisable monthly in

equal installments over four years. The initial service option awards granted to directors upon their election vest and become exercisable in equal monthly installments over a period of four years, while the subsequent annual service option awards granted to directors vest and become exercisable in equal monthly installments over a period of one year. Certain service option awards to executives and directors provide for accelerated vesting if there is a change in control of the Company. Certain service option awards to employees and executives provide for accelerated vesting if the respective employee s or executive s service is terminated by the Company for any reason other than cause or permanent disability. As of June 30, 2014, there was $8.6 million of unrecognized compensation costs related to unvested service option awards expected to be recognized over a weighted average period of 1.5 years. No service option awards are classified as a liability as of June 30, 2014.

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A summary of option activity for the 2004 Plan for the six months ended June 30, 2014 follows:

(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, 2013	670,744	$ 1.79	1.78	$ 7,124
Expired				
Exercised	(17,934)			
Outstanding at June 30, 2014	652,810	1.74	1.28	9,426
Exercisable at June 30, 2014	652,810	1.74	1.28	9,426

There are no options expected to vest as of June 30, 2014 under the 2004 Plan, given that the Company stopped issuing options from this plan in 2006.

A summary of option activity for the 2006 Plan for the six months ended June 30, 2014 follows:

(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, 2013	5,533,618	$ 10.98	6.93	$ 21,264
Granted	220,000	12.17		
Forfeited	(212,653)	8.30		
Expired				
Exercised	(344,188)	7.02		2,672
Outstanding at June 30, 2014	5,196,777	11.40	6.56	34,791
Exercisable at June 30, 2014	3,480,512	12.72	5.41	22,006
Expected to vest at June 30, 2014	1,639,031	8.67	8.87	12,316

Proceeds from the exercise of stock options amounted to $2.5 million for the six months ended June 30, 2014.

An RSU is a stock award that entitles the holder to receive shares of the Company s common stock as the award vests. The fair value of each RSU is based on the closing price of the Company s stock on the date of grant. The Company has granted RSUs with service conditions that vest in four equal annual installments provided that the employee remains employed with the Company. As of June 30, 2014, there was $4.8 million of unrecognized compensation costs related to unvested RSUs expected to be recognized over a weighted average period of 2.0 years. No RSUs are classified as a liability as of June 30, 2014.

A summary of RSU activity for the 2006 Plan for the six months ended June 30, 2014 follows:

	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Unvested at December 31, 2013	883,690	$ 7.70
Granted	52,000	13.36
Forfeited	(73,532)	6.50
Vested	(209,562)	6.67
Unvested at June 30, 2014	652,596	8.52

The grant date fair value for the 209,562 shares underlying RSUs that vested during the six months ended June 30, 2014 was $1.4 million. In order for certain employees to satisfy the minimum statutory employee tax withholding requirements related to the issuance of common stock underlying certain of the RSUs that vested and settled during the six months ended June 30, 2014, the Company withheld 32,386 shares of common stock and paid employee payroll withholding taxes of $0.4 million relating to the vesting and settlement of the RSUs.

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our ability to successfully commercialize HETLIOZ® (tasimelteon) for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in the U.S.;
- uncertainty as to the market awareness of Non-24 and the market acceptance of HETLIOZ®;
- our dependence on third-party manufacturers to manufacture HETLIOZ® in sufficient quantities and quality;
- our limited sales and marketing infrastructure;
- the regulatory status of HETLIOZ® in Europe;
- our ability to obtain the capital necessary to fund our research and development or commercial activities;
- a loss of rights to develop and commercialize our products under our license and sublicense agreements;
- the failure to obtain, or any delay in obtaining, regulatory approval for our products, particularly HETLIOZ® outside the U.S., or to comply with ongoing regulatory requirements;
- the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives;
- our inability to successfully commercialize Fanapt® outside of the U.S. and Canada;

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

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

our failure to identify or obtain rights to new products;

a loss of any of our key scientists or management personnel;

limitations on our ability to utilize some of all of our prior net operating losses and orphan drug and research and development credits;

the cost and effects of potential litigation; and

losses incurred from product liability claims made against us.

All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely too heavily on the forward-looking statements we make or that are made on our behalf. We undertake no obligation, and specifically decline any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

We encourage you to read Management s Discussion and Analysis of our Financial Condition and Results of Operations and our unaudited condensed consolidated financial statements contained in this quarterly report on Form 10-Q. We also encourage you to read Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2013, which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described below and in Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2013, other unknown or unpredictable factors also could affect our results. Therefore, the information in this report should be read together with other reports and documents that we file with the Securities and Exchange Commission (SEC) from time to time, including on Form 10-Q and Form 8-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that

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the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

Overview

Vanda Pharmaceuticals Inc. (we, our, or Vanda) is a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders. Vanda commenced its operations in 2003 and our product portfolio includes:

HETLIOZ® (tasimelteon), a product for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24), which was approved by the U.S. Food and Drug Administration (FDA) in January 2014;

Fanapt® (iloperidone), a product for the treatment of schizophrenia, the oral formulation of which is currently being marketed and sold in the U.S. by Novartis Pharma AG (Novartis); and

VLY-686 (tradipitant), a small molecule neurokinin-1 receptor (NK-1R) antagonist.

Since we began operations in March 2003, we have devoted substantially all of our resources to the in-licensing and clinical development of our products. Our products target prescription markets with significant unmet medical needs. Our ability to generate revenue and achieve profitability largely depends on our ability, alone or with others, to complete the development of our products, and to obtain the regulatory approvals for and manufacture, market and sell our products, including HETLIOZ® for the treatment of Non-24. The results of our operations will vary significantly and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks, which are detailed in Item 1A of Part II, entitled Risk Factors, of this quarterly report on Form 10-Q.

Our activities will necessitate significant uses of working capital throughout 2014 and beyond. We are currently concentrating our efforts on the commercialization of HETLIOZ® in the U.S. Additionally, we and our partners continue to pursue market approval of Fanapt® in a number of foreign jurisdictions, with Mexico, Israel and Argentina having already approved Fanapt® for the treatment of schizophrenia.

Second Quarter 2014 Operational Highlights

As of August 6, 2014, over 420 new prescriptions for HETLIOZ® have been written in the U.S. HETLIOZ® was launched in the U.S. in April 2014 for the treatment of Non-24, a disorder which affects the majority of totally blind individuals. It is estimated that approximately 80,000 Americans have the disorder.

In July 2014, a new method of use patent was issued by the U.S. Patent and Trademark Office for HETLIOZ® in the treatment of Non-24 (patent number 8,785,492). The 492 patent is expected to expire in 2033, potentially further extending the exclusivity protection of HETLIOZ®. In the U.S., HETLIOZ® is also covered by a composition of matter patent (patent number 5,856,529), which including a Hatch-Waxman 5-year extension, is currently expected to expire in 2022. Both patents, 529 and 492, are now listed in the FDA s Orange Book.

In June 2014, the European Medicines Agency accepted for evaluation our Marketing Authorization Application for oral HETLIOZ® capsules for the treatment of Non-24. HETLIOZ® was previously granted orphan drug designation by the European Commission for the treatment of Non-24.

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.

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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. We evaluate expiry risk by evaluating current and future product demand relative to product shelf life. We build demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage.

Net Product Revenues

Our 2014 net product revenues consist solely of sales of HETLIOZ® in the U.S. for the treatment of Non-24. We apply the revenue recognition guidance in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Subtopic 605-15, *Revenue Recognition Products*. We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collectability is reasonably assured and we have no further performance obligations. We invoice and record revenue when the specialty pharmacies receive HETLIOZ® from our third-party logistics warehouse.

In the U.S., HETLIOZ® is only available for distribution through three specialty pharmacies, and is not available in retail pharmacies. In April 2014, we launched HETLIOZ*Solutions* to support and facilitate the treatment of blind individuals in the U.S. living with Non-24. HETLIOZ*Solutions* provides patients with a host of resources including information about Non-24 and HETLIOZ®, insurance support, overview of financial assistance programs and pharmacy access.

Product Sales Discounts and Allowances

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

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

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from specialty pharmacies. Contracted customers, which currently consist primarily of Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty pharmacy, in turn, charges back the difference between the price initially paid by

the specialty pharmacy and the discounted price paid to the specialty pharmacy by the contracted customer. The allowance for chargebacks is based on actual and pending prescriptions for which we have validated the insurance benefits.

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

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

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

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

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

The following table summarizes HETLIOZ® sales discounts and allowance activity as of June 30, 2014. Due to the commercial launch of HETLIOZ® in the U.S. in April 2014, the balance as of December 31, 2013 was zero.

(in thousands)	**Rebates & Chargebacks**	**Discounts, Returns & Other**	**Total**
Balance as of December 31, 2013	$	$	$
Provision related to current period sales	156	110	266
Adjustments for prior period sales			
Credits/payments made		(32)	(32)
Balance as of June 30, 2014	$ 156	$ 78	$ 234

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 employee stock-based compensation, related to executive, finance, accounting, information technology, marketing, medical affairs and human resource functions. Other costs include facility costs not otherwise included in research and development expenses and fees for marketing, medical affairs, legal, accounting and other professional services. Selling, general and administrative expenses also include third party expenses incurred to support sales, business development, marketing and other business activities. We incurred selling, general and administrative expenses of $28.1 million and $56.0 million for the three and six months ended June 30, 2014, respectively.

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Stock-based Compensation

In January 2014, we elected to change our method of accounting for the attribution of compensation cost for stock options with graded-vesting and only service conditions to the straight-line method. Previously, attribution was based on the accelerated attribution method, which treated each vesting tranche as an individual award and amortized them concurrently. The straight-line method of accounting was adopted to better align our recognition of stock option compensation cost with our peers and to expense stock options and restricted stock units in a consistent manner. Comparative financial statements for prior periods have been adjusted to apply the straight-line method retrospectively. See *Change in Method of Accounting for Stock-based Compensation* footnote to the condensed consolidated financial statements included in Part I of this quarterly report on Form 10-Q for further information. Beginning in 2014, we started using a mid-point scenario to calculate the weighted average expected term of stock options granted, which combines our historical exercise data with hypothetical exercise data for unexercised stock options. Prior to 2014, the expected term assumption was determined using the simplified method.

Total employee stock-based compensation expense related to stock-based awards for the three and six months ended June 30, 2014 and 2013 was comprised of the following:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2014	June 30, 2013	June 30, 2014	June 30, 2013
Research and development	$ 418	$ 461	$ 860	$ 1,058
Selling, general and administrative	989	646	1,901	1,353
	$ 1,407	$ 1,107	$ 2,761	$ 2,411

With the exception of accounting for net product revenues and stock-based compensation, there have been no significant changes in our critical accounting policies including estimates, assumptions and judgments as described in 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, 2013.

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 $356.3 million as of June 30, 2014. Our total stockholders equity was $0.9 million as of June 30, 2014.

Three months ended June 30, 2014 compared to three months ended June 30, 2013

Revenues. Total revenues increased by $2.6 million, or 31%, to $10.9 million for the three months ended June 30, 2014 compared to $8.3 million for the three months ended June 30, 2013. Product sales related to U.S. sales of HETLIOZ® during the three months ended June 30, 2014 were $1.6 million compared to zero for the three months ended June 30, 2013. HETLIOZ® was commercially launched in the U.S. in April 2014. License revenues for the three months ended June 30, 2014 and 2013 include $7.8 million and $6.7 million, respectively, representing amortization of deferred revenue from the $200.0 million up-front license fee received from Novartis. Royalty revenues for the three months ended June 30, 2014 included $1.5 million from Novartis based on quarterly sales of Fanapt® by Novartis compared to $1.6 million for the three months ended June 30, 2013.

Cost of goods sold. HETLIOZ® cost of goods sold for the three months ended June 30, 2014 were $0.2 million compared to zero for the three months ended June 30, 2013. Cost of goods sold includes third party manufacturing costs of product sold, third party royalty costs and distribution and other costs. We began capitalizing HETLIOZ® manufacturing costs as inventory following the

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receipt of marketing approval from the FDA on January 31, 2014. The cost of product manufactured prior to FDA approval was expensed as research and development expense as incurred and was combined with other research and development expenses. While we tracked the quantities of individual HETLIOZ® product lots, we did not track pre-FDA approval manufacturing costs and therefore the manufacturing cost of HETLIOZ® produced prior to FDA approval is not reasonably determinable. Most of the product produced prior to FDA approval is expected to be available for us to use commercially. We expect that our cost of goods sold as a percentage of sales will increase in future periods as product manufactured prior to FDA approval, and therefore fully expensed, is consumed. The time period over which this reduced-cost inventory is consumed will depend on a number of factors, including the amount of future HETLIOZ® sales, the ultimate use of this inventory in either commercial sales, clinical development or other research activities and the ability to utilize inventory prior to its expiration date. We expect as this reduced-cost inventory is used, the percentage of total costs of goods sold for sales of HETLIOZ® will increase.

Research and development expenses. Research and development expenses decreased by $2.6 million, or 43%, to $3.5 million for the three months ended June 30, 2014 compared to $6.1 million for the three months ended June 30, 2013. The following table summarizes the costs of our product development initiatives for the three months ended June 30, 2014 and 2013. Included in this table are the research and development expenses recognized in connection with the clinical development of HETLIOZ®, VLY-686 and Fanapt®:

	Three Months Ended	
(in thousands)	**June 30, 2014**	**June 30, 2013**
Direct project costs [1]		
HETLIOZ®	$ 2,112	$ 4,700
VLY-686	427	474
Fanapt®	(6)	131
Other direct project costs	62	
	2,595	5,305
Indirect project costs [1]		
Employee stock-based compensation	418	461
Other indirect overhead	501	334
	919	795
Total research & development expense	$ 3,514	$ 6,100

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

Lower direct project costs were primarily driven by lower HETLIOZ® research and development activity. HETLIOZ® project costs decreased $2.6 million, or 55%, to $2.1 million for the three months ended June 30, 2014 compared to

$4.7 million for the three months ended June 30, 2013. Lower research and development expenses were primarily due to the completion of Non-24 and Major Depressive Disorder efficacy studies in 2013, partially offset by third-party manufacturing costs incurred in anticipation of HETLIOZ® FDA approval.

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*, g*eneral and administrative expenses increased by $22.8 million, or 430%, to $28.1 million for the three months ended June 30, 2014 compared to $5.3 million for the three months ended June 30, 2013. The increase is primarily due our Non-24 Disease Awareness campaign, which included radio and television advertisements broadcast nationwide. In addition, we added a field based sales force, a national accounts team, and a medical affairs team, which was deployed in 2014 to support HETLIOZ® and Non-24 medical education.

Intangible asset amortization. Intangible asset amortization was $0.6 million for the three months ended June 30, 2014 compared to $0.4 million for the three months ended June 30, 2013. The increase is due to amortization related to the $8.0 million milestone payment made to Bristol-Myers Squibb (BMS) as a result of receiving FDA approval for HETLIOZ® that was capitalized in the first quarter of 2014.

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Six months ended June 30, 2014 compared to six months ended June 30, 2013

Revenues. Total revenues increased by $3.6 million, or 22%, to $20.0 million for the three months ended June 30, 2014 compared to $16.4 million for the three months ended June 30, 2013. Product sales related to U.S. sales of HETLIOZ® during the six months ended June 30, 2014 were $1.6 million compared to zero for the six months ended June 30, 2013. HETLIOZ® was commercially launched in the U.S. in April 2014. License revenues for the six months ended June 30, 2014 and 2013 include $15.2 million and $13.3 million, respectively, representing amortization of deferred revenue from the $200.0 million up-front license fee received from Novartis. Royalty revenues for the six months ended June 30, 2014 included $3.2 million from Novartis based on year-to-date sales of Fanapt® by Novartis compared to $3.1 million for the six months ended June 30, 2013.

Cost of goods sold. HETLIOZ® cost of goods sold for the six months ended June 30, 2014 were $0.2 million compared to zero for the six months ended June 30, 2013. Cost of goods sold includes third party manufacturing costs of product sold, third party royalty costs and distribution and other costs. We began capitalizing HETLIOZ® manufacturing costs as inventory following the receipt of marketing approval from the FDA on January 31, 2014. The cost of product manufactured prior to FDA approval was expensed as research and development expense as incurred and was combined with other research and development expenses. While we tracked the quantities of individual HETLIOZ® product lots, we did not track pre-FDA approval manufacturing costs and therefore the manufacturing cost of HETLIOZ® produced prior to FDA approval is not reasonably determinable. Most of the product produced prior to FDA approval is expected to be available for us to use commercially. We expect that our cost of goods sold as a percentage of sales will increase in future periods as product manufactured prior to FDA approval, and therefore fully expensed, is consumed. The time period over which this reduced-cost inventory is consumed will depend on a number of factors, including the amount of future HETLIOZ® sales, the ultimate use of this inventory in either commercial sales, clinical development or other research activities and the ability to utilize inventory prior to its expiration date. We expect as this reduced-cost inventory is used, the percentage of total costs of goods sold for sales of HETLIOZ® will increase.

Research and development expenses. Research and development expenses decreased by $3.4 million, or 24%, to $10.8 million for the six months ended June 30, 2014 compared to $14.2 million for the six months ended June 30, 2013. The following table summarizes the costs of our product development initiatives for the six months ended June 30, 2014 and 2013. Included in this table are the research and development expenses recognized in connection with the clinical development of HETLIOZ®, VLY-686 and Fanapt®:

	Six Months Ended	
(in thousands)	**June 30, 2014**	**June 30, 2013**
Direct project costs [1]		
HETLIOZ®	$ 7,802	$ 11,554
VLY-686	1,014	704
Fanapt®	71	287
Other direct project costs	70	
	8,957	12,545
Indirect project costs [1]		
Employee stock-based compensation	860	1,058

Other indirect overhead	960	608
	1,820	1,666
Total research & development expense	$ 10,777	$ 14,211

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

Direct HETLIOZ® project costs decreased $3.8 million, or 33%, to $7.8 million for the six months ended June 30, 2014 compared to $11.6 million for the six months ended June 30, 2013. Lower research and development expenses were primarily due to 2013 costs incurred for the HETLIOZ® New Drug Application (NDA) submission to the FDA, the completion of Non-24 and Major Depressive Disorder efficacy studies in 2013, partially offset by a $2.0 million milestone payment related to our regulatory consulting agreement as a result of the FDA approval of our NDA for HETLIOZ® and third-party manufacturing costs incurred in anticipation of HETLIOZ® approval.

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Direct VLY-686 project costs increased $0.3 million, or 43%, to $1.0 million for the six months ended June 30, 2014 compared to $0.7 million for the six months ended June 30, 2013 due to increased activity related to the Phase 2 clinical study, which commenced in 2014.

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 $46.6 million, or 496%, to $56.0 million for the six months ended June 30, 2014 compared to $9.4 million for the six months ended June 30, 2013. The increase is primarily due our Non-24 Disease Awareness campaign, which included radio and television advertisements broadcast nationwide. In addition, we added a field based sales force, a national accounts team, and a medical affairs team, which was deployed in 2014 to support HETLIOZ® and Non-24 medical education.

Intangible asset amortization. Intangible asset amortization was $1.2 million for the six months ended June 30, 2014 compared to $0.7 million for the six months ended June 30, 2013. The increase is due to amortization related to the $8.0 million milestone payment made to BMS as a result of receiving FDA approval for HETLIOZ® that was capitalized in the first quarter of 2014.

Liquidity and Capital Resources

As of June 30, 2014, our total cash and cash equivalents and marketable securities were $63.6 million, compared to $130.4 million as of December 31, 2013. Our cash and cash equivalents are deposits in operating accounts and highly liquid investments with an original maturity of 90 days or less at date of purchase and consist of time deposits, investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers. Our marketable securities consist of investments in government sponsored enterprises and commercial paper.

Our liquidity resources as of June 30, 2014 and December 31, 2013 are summarized as follows:

(in thousands)	**June 30, 2014**	**December 31, 2013**
Cash and cash equivalents	$ 16,994	$ 64,764
Marketable securities:		
U.S. Treasury and government agencies	24,523	31,566
Corporate debt	22,068	34,020
Total marketable securities	46,591	65,586
Total cash and cash equivalents	$ 63,585	$ 130,350

As of June 30, 2014 we maintained all of our cash and cash equivalents in two financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits, but we do not anticipate any losses with respect to such deposits.

We expect to incur substantial costs and expenses as a result of the FDA approval of our NDA for HETLIOZ® and the U.S. commercial launch of HETLIOZ®. In the first quarter of 2014, we made milestone payments of $8.0 million under the license agreement with BMS and $2.0 million under a regulatory consulting agreement as a result of HETLIOZ® being approved by the FDA.

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

We may need or desire to obtain additional capital to finance our operations through debt, equity or alternative financing arrangements. We may also seek capital through collaborations or partnerships with other companies. The issuance of debt could require us to grant liens on certain of our assets that may limit our flexibility. If we raise additional capital by issuing equity securities, the terms and prices for these financings may be much more favorable to the new investors than the terms obtained by our existing stockholders. These financings also may significantly dilute the ownership of our existing stockholders. If we are

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unable to obtain additional financing, we may be required to reduce the scope of our future activities which could harm our business, financial condition and operating results. There can be no assurance that any additional financing required in the future will be available on acceptable terms, if at all.

Cash Flow

The following table summarizes our cash flows for the six months ended June 30, 2014 and 2013:

	Six Months Ended June 30,	
	2014	2013
Net cash provided by (used in):		
Operating activities	$ (60,569)	$ (17,168)
Investing activities	10,756	31,428
Financing activities	2,043	601
Net increase (decrease) in cash and cash equivalents	$ (47,770)	$ 14,861

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

Net cash used in operating activities was $60.6 million for the six months ended June 30, 2014, an increase of $43.4 million from net cash used in operating activities of $17.2 million for the six months ended June 30, 2013. The increase in net cash used for operating activities resulted from an increase in net loss of $40.2 million and a $4.1 million net use of working capital, which was partially offset by an increase of $0.9 million in non-cash charges.

Net cash provided by investing activities of $10.8 million for the six months ended June 30, 2014, a decrease of $20.6 million, from net cash provided by investing activities of $31.4 million for the six months ended June 30, 2013. The decrease primarily resulted from $12.6 million in lower net proceeds from sales, maturities and purchases of marketable securities and an $8.0 million milestone payment to BMS as a result of the FDA approval of HETLIOZ® in January 2014.

Net cash provided by financing activities of $2.0 million for the six months ended June 30, 2014, an increase of $1.4 million, from net cash used in financing activities of $0.6 million for the six months ended June 30, 2013. The increase is primarily due to an increase of $1.7 million in cash proceeds from the exercise of employee stock options, partially offset by a $0.2 million increase in cash used to pay tax obligations in connection with the settlement of employee RSUs.

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

Other than as set forth below, there have been no material changes to our contractual obligations from the information provided in Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations , included in our annual report on Form 10-K for the fiscal year ended December 31, 2013.

Operating leases

In March 2014, we entered into a lease amendment (Lease Amendment) with Square 54 Office Owner LLC (the Landlord) to occupy an additional 8,860 square feet in our headquarters building located in Washington, D.C. The Lease Amendment has a 12 year and one month term beginning on September 1, 2014, but may be terminated early by either the Landlord or us upon certain conditions. We will pay approximately $0.4 million in annual rent over the term of the Lease Amendment, however rent will be abated for the first nine months. Subject to the prior rights of other tenants in the building, we will have the right to renew the Lease Amendment for five years following the expiration of its original term. We will also have the right to sublease or assign all or a portion of the premises, subject to standard conditions.

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ITEM 3 Quantitative and Qualitative Disclosures about Market Risk

Interest rates

Our exposure to market risk is currently confined to our cash and cash equivalents, marketable securities and restricted cash. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments.

Marketable securities

We deposit our cash with financial institutions that we consider to be of high credit quality and purchase marketable securities which are generally investment grade, liquid, short-term fixed income securities and money-market instruments denominated in U.S. dollars. Our marketable securities consist of certificates of deposit, commercial paper, corporate notes and U.S. government agency notes.

Effects of inflation

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

ITEM 4 Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act)) as of June 30, 2014. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of June 30, 2014, the end of the period covered by this quarterly report, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

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

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PART II OTHER INFORMATION

ITEM 1 Legal Proceedings

In May 2014, we commenced arbitration proceedings with Novartis Pharma AG (Novartis) relating to the license of Fanapt®. We have requested an award of approximately $539.0 million in such proceedings. We are vigorously prosecuting our claims in the arbitration as well as defending counterclaims brought by Novartis for approximately $75.0 million, against which we believe we have meritorious defenses. We do not anticipate that this proceeding will have a material adverse effect on its business, results of operations or financial condition. While it is not possible to accurately predict or determine the eventual outcome of this matter, these proceedings are subject to inherent uncertainties and we may not prevail. We currently anticipate that the arbitration proceeding will be completed within 12 to 18 months.

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

ITEM 1A Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this quarterly report and our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, including the consolidated financial statements and the related notes appearing herein and therein, with respect to any investment in shares of our common stock. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment.

Risks related to our business and industry

HETLIOZ® may not be commercially successful.

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

- cost of treatment;
- pricing and availability of alternative products;
- the cost and success of our Non-24-Hour Sleep-Wake Disorder (Non-24) awareness campaign;

our ability to obtain third-party coverage or reimbursement for HETLIOZ®;

perceived efficacy relative to other available therapies;

shifts in the medical community to new treatment paradigms or standards of care;

relative convenience and ease of administration; and

prevalence and severity of adverse side effects associated with treatment.

Because we only recently initiated the U.S. commercialization of HETLIOZ®, we have limited information with regard to the market acceptance of HETLIOZ® in the U.S. or elsewhere. As a result, we may have to revise our estimates regarding the acceptance of HETLIOZ® under our current pricing structure and reevaluate or change the pricing for HETLIOZ®.

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

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

Our future success is currently dependent upon the commercial success of HETLIOZ® for the treatment of Non-24 in the U.S. In January 2014, the U.S. Food and Drug Administration (FDA) approved our New Drug Application (NDA) for HETLIOZ® for the treatment of Non-24 and in April 2014, we commenced the U.S. commercial launch of HETLIOZ®. Our future success is also dependent upon successfully obtaining regulatory approval from foreign regulatory bodies to market HETLIOZ® for the treatment of Non-24 in other jurisdictions, and if approved, successfully commercializing HETLIOZ® in such jurisdictions. In June 2014, the European Medicines Agency (EMA) accepted for evaluation our Marketing Authorization Application (MAA) for oral HETLIOZ® capsules for the treatment of Non-24.

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

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

As a company, we have minimal experience selling, marketing or distributing products, other than providing assistance to Novartis relating to the U.S. commercialization of Fanapt®, which may make commercializing our products difficult.

At present, we as a company have minimal marketing experience, other than providing assistance to Novartis relating to the U.S. commercialization of Fanapt® (iloperidone). Therefore, in order for us to successfully commercialize HETLIOZ®, Fanapt® (outside the U.S. and Canada) or our other products, we must either acquire or continue to internally develop sales, marketing and distribution capabilities, or enter into collaborations with partners to perform these services for us. We may, in some instances, rely significantly on sales, marketing and distribution arrangements with our collaborative partners and other third parties. For example, we rely completely on Novartis to market, sell and distribute Fanapt® in the U.S. and, if regulatory approval is obtained, Canada.

For the commercialization of HETLIOZ®, Fanapt® (outside the U.S. and Canada) or our other products, we may not be able to establish additional sales, marketing and distribution capabilities or partnerships on acceptable terms or at all. In regard to our current foreign partners and any additional distribution arrangements or other agreements we may enter into, our success will be materially dependent upon the performance of our partners. Factors that may inhibit our efforts to commercialize our products without partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;

the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage with respect to companies with broader product lines; and

unforeseen costs associated with growing our own sales and marketing team or with entering into a partnering agreement with an independent sales and marketing organization.

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

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

Even after obtaining regulatory approvals for the sale of our products, the commercial success of these products will depend, among other things, on their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. The degree of market acceptance of any product will depend on a number of factors, including the demonstration of its safety and efficacy, its cost-effectiveness, its potential advantages over other therapies, the reimbursement policies of government and third-party payors with respect to such

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product, our ability to attract and maintain corporate partners, including pharmaceutical companies, to assist in commercializing our products, receipt of regulatory clearance of marketing claims for the uses that we or our partners are developing and the effectiveness of our and our partners marketing and distribution capabilities. If our approved products fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. If our approved products do not become widely accepted by physicians, patients, third-party payors and other members of the medical community, it is unlikely that we will ever become profitable on a sustained basis or achieve significant revenues.

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

As of June 30, 2014, we had 56 full-time employees and, as a result, we rely, and expect to continue to rely, on outsourcing arrangements for a significant portion of our activities, including sales, distribution, medical affairs, clinical research, data collection and analysis, manufacturing, financial reporting and accounting and human resources, as well as for certain functions as a public company. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner.

Disruptions to our HETLIOZ® supply chain could materially affect our ability to commercialize HETLIOZ®, reduce our future earnings and prospects.

A loss or disruption with any one of our manufacturers or suppliers could disrupt supply of HETLIOZ®, possibly for a significant time period, and we may not have sufficient inventories to maintain supply before the manufacturer or supplier could be replaced or the disruption is resolved. In addition, marketed drugs and their contract manufacturing organizations are subject to continual review, including review and approval of their manufacturing facilities and the manufacturing processes, which can result in delays in the regulatory approval process and/or commercialization. Introducing a replacement or backup manufacturer or supplier for HETLIOZ® requires a lengthy regulatory and commercial process and there can be no guarantee that we could obtain necessary regulatory approvals in a timely fashion or at all. In addition, it is difficult to identify and select qualified suppliers and manufacturers with the necessary technical capabilities, and establishing new supply and manufacturing sources involves a lengthy and technical engineering process.

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

Following marketing approval of a product, we and our partners will continue to face heavy governmental regulation. The marketing, distribution and manufacture of approved products remain subject to extensive ongoing regulatory requirements. Failure to comply with applicable regulatory requirements could result in, among other things:

warning letters;

fines;

civil penalties;

injunctions;

recall or seizure of products;

total or partial suspension of production;

refusal of the government to grant future approvals;

withdrawal of approvals; and

criminal prosecution.

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

Failure to comply with government regulations regarding the sale and marketing of our products could harm our business.

Our and our partners activities, including the sale and marketing of our products, are subject to extensive government regulation and oversight, including regulation under the federal Food, Drug and Cosmetic Act and other federal and state statutes. We are also subject to the provisions of the Federal Anti-Kickback Statute and several similar state laws, which prohibit payments intended to induce physicians or others either to purchase or arrange for or recommend the purchase of healthcare products or

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services. While the federal law applies only to products or services for which payment may be made by a federal healthcare program, state laws may apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of drugs and biologicals, such as us, by limiting the kinds of financial arrangements, including sales programs, with hospitals, physicians, and other potential purchasers of drugs and biologicals. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance that can be substantial, including the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid).

Pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting antitrust violations, violations of the Federal False Claim Act, the Anti-Kickback Statute, the Prescription Drug Marketing Act and other violations in connection with off-label promotion of products and Medicare and/or Medicaid reimbursement or related to environmental matters and claims under state laws, including state anti-kickback and fraud laws.

While we continually strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing practices are ever evolving. If any such actions are instituted against us or our partners and we or they are not successful in defending such actions or asserting our rights, those actions could have a significant and material adverse impact on our business, including the imposition of significant fines or other sanctions. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition.

FDA regulatory approval of our products is uncertain.

The research, testing, manufacturing and marketing of products such as those that we have developed or that we or our partners are developing are subject to extensive regulation by federal, state and local government authorities, including the FDA. To obtain regulatory approval of such products, we or our partners must demonstrate to the satisfaction of the applicable regulatory agency that, among other things, the product is safe and effective for its intended use. In addition, we or our partners must show that the manufacturing facilities used to produce such products are in compliance with current Good Manufacturing Practices regulations (cGMP).

The process of obtaining FDA and other required regulatory approvals and clearances can take many years and will require us and our partners, as applicable, to expend substantial time and capital. Despite the time and expense expended, regulatory approval is never guaranteed. The number of pre-clinical and clinical trials that will be required for FDA approval varies depending on the product, the disease or condition that the product is in development for, and the requirements applicable to that particular product. The FDA can delay, limit or deny approval of a product for many reasons, including that:

- a product may not be shown to be safe or effective;
- the FDA may interpret data from pre-clinical and clinical trials in different ways than we or our partners do;
- the FDA may not approve our or our partners manufacturing processes or facilities;

a product may not be approved for all the indications we or our partners request;

the FDA may change its approval policies or adopt new regulations;

the FDA may not meet, or may extend, the Prescription Drug User Fee Act (PDUFA-V) date with respect to a particular NDA; and

the FDA may not agree with our or our partners regulatory approval strategies or components of the regulatory filings, such as clinical trial designs.

For example, if certain of our or our partners methods for analyzing trial data are not accepted by the FDA, we or our partners may fail to obtain regulatory approval for our products.

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

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Even following regulatory approval of our products, the FDA may impose limitations on the indicated uses for which such products may be marketed, subsequently withdraw approval or take other actions against us, our partners or such products that are adverse to our business. The FDA generally approves drugs for particular indications. An approval for a more limited indication reduces the size of the potential market for the product. Product approvals, once granted, may be withdrawn or modified if problems occur after initial marketing.

We and our partners also are subject to numerous federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the environment and the use and disposal of hazardous substances used in connection with discovery, research and development work. In addition, we cannot predict the extent to which new governmental regulations might significantly impede the discovery, development, production and marketing of our products. We or our partners may be required to incur significant costs to comply with current or future laws or regulations, and we may be adversely affected by the cost of such compliance or the inability to comply with such laws or regulations.

We intend to seek regulatory approvals for our products in foreign jurisdictions, but we may not obtain any such approvals.

We intend to market our products in foreign jurisdictions. In order to market our products in foreign jurisdictions, we or our partners may be required to obtain separate regulatory approvals and to comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional trials, and the time required to obtain approval may differ from that required to obtain FDA approval. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we or our partners may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We or our partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could harm our business materially.

If we fail to obtain the capital necessary to fund our research and development activities and commercialization efforts, we may be unable to continue operations or we may be forced to share our rights to commercialize our products with third parties on terms that may not be attractive to us.

Our activities will necessitate significant uses of working capital throughout 2014 and beyond. It is uncertain whether our existing funds will be sufficient to meet our operating needs. As of June 30, 2014, our total cash and cash equivalents and marketable securities were $63.6 million. Our long term capital requirements are expected to depend on many factors, including, among others:

- our ability to commercialize HETLIOZ® globally;
- costs of developing and maintaining sales, marketing and distribution channels and our ability to sell our products;
- costs involved in establishing manufacturing capabilities for commercial quantities of our products;

the amount of royalty and milestone payments received from our commercial partners;

our ability to commercialize Fanapt® outside the U.S. and Canada;

the number of potential formulations and products in development;

progress with pre-clinical studies and clinical trials;

time and costs involved in obtaining regulatory (including FDA) approval;

costs involved in preparing, filing, prosecuting, maintaining and enforcing patent, trademark and other intellectual property claims;

competing technological and market developments;

market acceptance of our products;

costs for recruiting and retaining employees and consultants;

costs for training physicians; and

legal, accounting, insurance and other professional and business related costs.

As a result, we may need to raise additional capital to fund our anticipated operating expenses and execute on our business plans. In our capital-raising efforts, we may seek to sell debt securities or additional equity securities or obtain a bank credit facility, or enter into partnerships or other collaboration agreements. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders and may also result in a lower price for our common stock. The incurrence of indebtedness

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

We face substantial competition which may result in others developing or commercializing products before or more successfully than we do.

Our future success will depend on our or our partners ability to demonstrate and maintain a competitive advantage with respect to our products and our ability to identify and develop additional products through the application of our pharmacogenetics and pharmacogenomics expertise. Large, fully integrated pharmaceutical companies, either alone or together with collaborative partners, have substantially greater financial resources and have significantly greater experience than we do in:

developing products;

undertaking pre-clinical testing and clinical trials;

obtaining FDA and other regulatory approvals of products; and

manufacturing, marketing and selling products.

These companies may invest heavily and quickly to discover and develop novel products that could make our products obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or foreign regulatory approval or commercializing superior products or other competing products before we do. Technological developments or the FDA or foreign regulatory approval of new therapeutic indications for existing products may make our products obsolete or may make them more difficult to market successfully, any of which could have a material adverse effect on our business, results of operations and financial condition.

Our products, if successfully developed and approved for commercial sale, will compete with a number of drugs and therapies currently manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products may also compete with new products currently under development by others or with products which may cost less than our products. Physicians, patients, third party payors and the medical community may not accept or utilize any of our products that may be approved. If HETLIOZ®, Fanapt® and our other products, if and when approved, do not achieve significant market acceptance, our business, results of operations and financial condition would be materially adversely affected. We believe the primary competitors for HETLIOZ® and Fanapt® are as follows:

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

For Fanapt® in the treatment of schizophrenia, the atypical antipsychotics competitors are Risperdal® (risperidone), including the depot formulation Risperdal® Consta® and Invega® (paliperidone), including the depot formulation Invega® Sustenna®, each by Ortho-McNeil-Janssen Pharmaceuticals, Inc., Zyprexa® (olanzapine), including the depot formulation Zyprexa® Relprevv , each by Eli Lilly and Company, Seroquel® (quetiapine) by AstraZeneca PLC, Abilify® (aripiprazole) by BMS/Otsuka Pharmaceutical Co., Ltd., Abilify® Maintena® (the depot formulation of Abilify®) by Lundbeck/Otsuka Pharmaceutical Co., Ltd., Geodon® (ziprasidone) by Pfizer Inc., Saphris® (asenapine) by Actavis plc, Latuda® (lurasidone) by Sunovion Pharmaceuticals Inc., and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are generic).

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

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

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

- the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives;
- the amount of resources and efforts utilized by Novartis in relation to the commercialization of Fanapt®;
- the ability of patients to be able to afford Fanapt® or obtain health care coverage that covers Fanapt®;
- acceptance of, and ongoing satisfaction, with Fanapt® by the medical community, patients receiving therapy and third party payors;
- a satisfactory efficacy and safety profile as demonstrated in a broad patient population;
- the size of the market for Fanapt®;
- successfully expanding and sustaining manufacturing capacity to meet demand;
- cost and availability of raw materials;
- safety concerns in the marketplace for schizophrenia therapies;

regulatory developments relating to the manufacture or continued use of Fanapt®;

decisions as to the timing of product launches, pricing and discounts;

the competitive landscape for approved and developing therapies that will compete with Fanapt®;

our or our partners ability to obtain regulatory approval for Fanapt® in countries outside the U.S. and Canada;

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

the unfavorable outcome or other negative effects of any potential litigation relating to Fanapt®.

We entered into an amended and restated sublicense agreement with Novartis to commercialize Fanapt® in the U.S. and Canada. As such, we are not directly involved in the marketing or sales efforts for Fanapt® in the U.S. and Canada. Our ability to generate meaningful product revenue from Fanapt® depends on royalties and milestone payments we may receive from Novartis. Pursuant to the amended and restated sublicense agreement with Novartis, we received an upfront payment of $200.0 million and are eligible for additional payments totaling up to $265.0 million upon Novartis achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. Based on the current sales performance of Fanapt® in the U.S., we expect that some or all of these commercial and development milestones will not be achieved by Novartis. In May 2014, we commenced arbitration proceedings with Novartis relating to the license of Fanapt®. See Item 1, *Legal Proceedings* for further information.

We also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. Such royalties may not be significant and will depend on numerous factors, many of which we cannot control. We cannot control the amount and timing of resources that Novartis may devote to Fanapt®. If Novartis fails to successfully commercialize Fanapt® in the U.S, if Novartis efforts are not effective, or if Novartis focuses its efforts on other schizophrenia therapies or schizophrenia drug candidates, our business will be negatively affected. If Novartis does not successfully commercialize Fanapt® in the U.S, we will receive limited revenues from them. Over time, Novartis has reduced the size of the Fanapt® sales organization and this could have a negative impact on the success of the product in the United States. We do not expect Novartis to commercialize Fanapt® in Canada. For reasons outside of our control, including those mentioned above, sales of Fanapt® may not meet our or financial or industry analysts expectations. Any significant negative developments relating to Fanapt®, such as safety or efficacy issues, the introduction or greater acceptance of competing products or adverse regulatory or legislative developments, will have an adverse effect on our financial condition and results of operations.

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If our products are determined to be unsafe or ineffective in humans, whether commercially or in clinical trials, our business will be materially harmed.

Despite the FDA s approval of the NDA for HETLIOZ® in January 2014 and the NDA for Fanapt® in May 2009, and the positive results of our completed trials for HETLIOZ® and Fanapt®, we are uncertain whether either of these products will ultimately prove to be effective and safe in humans. Frequently, products that have shown promising results in clinical trials have suffered significant setbacks in later clinical trials or even after they are approved for commercial sale. Future uses of our products, whether in clinical trials or commercially, may reveal that the product is ineffective, unacceptably toxic, has other undesirable side effects, is difficult to manufacture on a large scale, is uneconomical, infringes on proprietary rights of another party or is otherwise not fit for further use. If our products are determined to be unsafe or ineffective in humans, our business will be materially harmed.

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

Pre-clinical studies and clinical trials required to demonstrate the safety and efficacy of our products are time-consuming and expensive and together take several years to complete. Before obtaining regulatory approvals for the commercial sale of any of our products, we or our partners must demonstrate through preclinical testing and clinical trials that such product is safe and effective for use in humans. We have incurred, and we will continue to incur, substantial expense for, and devote a significant amount of time to, preclinical testing and clinical trials.

Historically, the results from preclinical testing and early clinical trials often have not predicted results of later clinical trials. A number of new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Clinical trials conducted by us, by our partners or by third parties on our or our partners behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for our products. Regulatory authorities may not permit us or our partners to undertake any additional clinical trials for our products, may force us to stop any ongoing clinical trials and it may be difficult to design efficacy studies for our products in new indications.

Clinical development efforts performed by us or our partners may not be successfully completed. Completion of clinical trials may take several years or more. The length of time can vary substantially with the type, complexity, novelty and intended use of the products and the size of the prospective patient population. The commencement and rate of completion of clinical trials for our products may be delayed by many factors, including:

- the inability to manufacture or obtain from third parties materials sufficient for use in pre-clinical studies and clinical trials;
- delays in beginning a clinical trial;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;

poor effectiveness of our products during clinical trials;

unforeseen safety issues or side effects; and

governmental or regulatory delays and changes in regulatory requirements and guidelines.

If we or our partners fail to complete successfully one or more clinical trials for our products, we or they may not receive the regulatory approvals needed to market that product. Therefore, any failure or delay in commencing or completing these clinical trials would harm our business materially.

Our products may cause undesirable side effects or have other properties that could delay, prevent or result in the revocation of their regulatory approval or limit their marketability.

Undesirable side effects caused by our products could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us or our partners from commercializing or continuing the commercialization of such products and generating revenues from their sale. We and our partners, as applicable, will continue to assess the side effect profile of our products in ongoing clinical development programs. However, we cannot predict whether the commercial use of our approved products (or our products in development, if and when they are approved for commercial use) will produce undesirable or unintended side effects that have not been evident in the use of, or in clinical trials conducted for, such products to date. Additionally, incidents of product misuse may occur. These events, among others, could result in product recalls, product liability actions or withdrawals or additional regulatory controls, all of which could have a material adverse effect on our business, results of operations and financial condition.

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In addition, if after receiving marketing approval of a product, we, our partners or others later identify undesirable side effects caused by such product, we or our partners could face one or more of the following:

- regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;
- regulatory authorities may withdraw their approval of the product;
- we or our partners may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; and
- our, our partners or the products reputation may suffer.

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

We have a history of operating losses, anticipate future losses and may never become profitable on a sustained basis.

We have been engaged in identifying and developing products since March 2003, which has required, and will continue to require, significant research and development expenditures. The continued commercial launch for HETLIOZ® will require substantial additional expenditures.

As of June 30, 2014, we had an accumulated deficit of $356.3 million, and we cannot estimate with precision the extent of our future losses. In April 2014, we commercially launched HETLIOZ® in the U.S. for the treatment of Non-24. The continuing commercialization of HETLIOZ® and our continuing Non-24 awareness campaign will require substantial additional expenditures. In addition, we may not succeed in commercializing HETLIOZ® or any other products. Our ability to generate meaningful product revenue prior to successfully commercializing HETLIOZ® depends on Novartis and our ability to sell Fanapt®. Novartis launched Fanapt® in the U.S. in the first quarter of 2010 and sales to date have not met our expectations. We do not expect Novartis to commercialize Fanapt® in Canada. Fanapt® may continue to not be as commercially successful as we expected, Novartis may not succeed in gaining additional market acceptance of Fanapt® in the U.S. and we may not succeed in commercializing Fanapt® outside of the U.S. and Canada. We may not be profitable even if our products are successfully commercialized. We may be unable to fully develop, obtain regulatory approval for, commercialize, manufacture, market, sell and derive revenue from our products in the timeframes we project, if at all, and our inability to do so would materially and adversely impact the market price of our common stock and our ability to raise capital and continue operations.

There can be no assurance that we will achieve sustained profitability. Our ability to achieve sustained profitability in the future depends, in part, upon:

our and our partners ability to obtain and maintain regulatory approval for our products, particularly HETLIOZ® for the treatment of Non-24, both in the U.S. and in foreign countries;

our ability to successfully commercialize HETLIOZ® in the U.S. and other jurisdictions in which HETLIOZ® may receive regulatory approval, if any;

our ability to successfully raise awareness regarding Non-24 in the medical and patient communities;

Novartis ability to successfully market and sell Fanapt® in the U.S.;

our and our partners ability to successfully commercialize Fanapt® outside the U.S. and Canada;

our ability to enter into and maintain agreements to develop and commercialize our products;

our and our partners ability to develop, have manufactured and market our products;

our and our partners ability to obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third party payors; and

our ability to obtain additional research and development funding from collaborative partners or funding for our products.

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

the costs of our marketing or awareness campaigns;

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- the progress of our research and development programs for our products, including clinical trials;
- the time and expense that will be required to pursue FDA and/or foreign regulatory approvals for our products and whether such approvals are obtained on a timely basis, if at all;
- the time and expense required to prosecute, enforce and/or challenge patent and other intellectual property rights;
- the cost of operating and maintaining development and research facilities;
- the cost of third party manufacturers;
- the number of additional products we pursue;
- how competing technological and market developments affect our products;
- the cost of possible acquisitions of technologies, products, product rights or companies;
- the cost of obtaining licenses to use technology owned by others for proprietary products and otherwise;
- the costs and effects of potential litigation; and
- the costs associated with recruiting and compensating a highly skilled workforce in an environment where competition for such employees may be intense.

We may not achieve all or any of these goals and, thus, we cannot provide assurances that we will ever be profitable on a sustained basis or achieve significant revenues. Even if we do achieve some or all of these goals, we may not achieve significant or sustained commercial success.

Our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income may be limited as a result of transactions involving our common stock.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (Code), a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses (NOLs) and certain other tax assets to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders lowest percentage ownership during the testing period (generally three years). Transactions involving our common stock, even those outside our control, such as purchases or sales by investors, within the testing period could result in an ownership change. A limitation on our ability to utilize some or all of our NOLs or credits could have a material

adverse effect on our results of operations and cash flows.

If our contract research organizations do not successfully carry out their duties or if we lose our relationships with contract research organizations, our drug development efforts could be delayed.

Our arrangements with contract research organizations are critical to our success in bringing our products to the market and promoting such marketed products profitably. We are dependent on contract research organizations, third-party vendors and investigators for pre-clinical testing and clinical trials related to our drug discovery and development efforts and we will likely continue to depend on them to assist in our future discovery and development efforts. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. As such, they may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The parties with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. If they fail to devote sufficient time and resources to our drug development programs or if their performance is substandard, it will delay the development, approval and commercialization of our products. Moreover, these parties may also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors, it could harm our competitive position.

Our contract research organizations could merge with or be acquired by other companies or experience financial or other setbacks unrelated to our collaboration that could, nevertheless, materially adversely affect our business, results of operations and financial condition.

If we lose our relationship with any one or more of these parties, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to current Good Laboratory Practices (cGLP), and similar foreign standards and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our products could be delayed.

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We rely on a limited number of third party manufacturers to formulate and manufacture our products and our business will be seriously harmed if these manufacturers are not able to satisfy our demand and alternative sources are not available.

Our expertise is primarily in the research and development and pre-clinical and clinical trial phases of product development. We do not have an in-house manufacturing capability and depend completely on a small number of third-party manufacturers and active pharmaceutical ingredient formulators for the manufacture of our products. Therefore, we are dependent on third parties for our formulation development and manufacturing of our products. This may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process and provide ample commercial supplies to successfully launch and maintain the marketing of our products. Furthermore, these third party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or other unforeseeable events that may delay or limit production. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes would have a material adverse effect on our ability to develop and commercialize our products.

In January 2014, we entered into a manufacturing agreement with Patheon Pharmaceuticals Inc. (Patheon) for the manufacture of commercial supplies of HETLIOZ® 20 mg capsules. This agreement has an initial term of five years. If Patheon is unable to perform its duties under the manufacturing agreement, it could adversely affect sales of our HETLIOZ® products, delay clinical trials and prevent us from developing our HETLIOZ® products in a cost-effective manner or on a timely basis. We do not have exclusive long-term agreements with any other third party manufacturers. If any of our third party manufacturers, including Patheon, are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers or formulators or enter into favorable agreements with them. Any inability to acquire sufficient quantities of our products in a timely manner from these third parties could adversely affect sales of our products, delay clinical trials and prevent us from developing our products in a cost-effective manner or on a timely basis. In addition, manufacturers of our products are subject to cGMP and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers. If one of our contract manufacturers fails to maintain compliance, the production of our products could be interrupted, resulting in delays and additional costs. In addition, if the facilities of such manufacturers do not pass a pre-approval or post-approval plant inspection, the FDA will not grant approval and may institute restrictions on the marketing or sale of our products.

Our manufacturing strategy presents the following additional risks:

- because most of our third-party manufacturers and formulators are located outside of the U.S., there may be difficulties in importing our products or their components into the U.S. as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging; and

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

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

We and our partners rely on manufacturers to purchase from third-party suppliers the materials necessary to produce our products for clinical trials and commercialization. Suppliers may not sell these materials to such manufacturers at

the times we or our partners need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by these manufacturers. Moreover, we currently do not have any agreements for the commercial production of these materials. If the manufacturers are unable to obtain these materials for our or our partners clinical trials, product testing, potential regulatory approval of our products and commercial scale manufacturing could be delayed, significantly affecting our and our partners ability to further develop and commercialize our products. If we, our manufacturers or our partners, as applicable, are unable to purchase these materials for our products, there would be a shortage in supply or the commercial launch of such products would be delayed, which would materially and adversely affect our or our partners ability to generate revenues from the sale of such products.

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

A component of our business strategy is acquiring rights to develop and commercialize products discovered or developed by other pharmaceutical and biotechnology companies for which we may find effective uses and markets through our unique pharmacogenetics and pharmacogenomics expertise for the treatment of central nervous system disorders. Competition for the

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

We may not be successful in the development of products for our own account.

In addition to our business strategy of acquiring rights to develop and commercialize products, we may develop products for our own account by applying our technologies to off-patent drugs as well as developing our own proprietary molecules. Because we will be funding the development of such programs, there is a risk that we may not be able to continue to fund all such programs to completion or to provide the support necessary to perform the clinical trials, obtain regulatory approvals or market any approved products. We expect the development of products for our own account to consume substantial resources. If we are able to develop commercial products on our own, the risks associated with these programs may be greater than those associated with our programs with collaborative partners.

If we lose key scientists or management personnel, or if we fail to recruit additional highly skilled personnel, it will impair our ability to identify, develop and commercialize products.

We are highly dependent on principal members of our management team and scientific staff, including our Chief Executive Officer, Mihael H. Polymeropoulos, M.D. These executives each have significant pharmaceutical industry experience. The loss of any such executives, including Dr. Polymeropoulos, or any other principal member of our management team or scientific staff, would impair our ability to identify, develop and market new products. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of these or other key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to development or approval, loss of sales and diversion of management resources. In addition, we depend on our ability to attract and retain other highly skilled personnel, including research scientists. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all, which would negatively impact our development and commercialization programs.

Additionally, we do not currently maintain key person life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.

The risk that we may be sued on product liability claims is inherent in the development and sale of pharmaceutical products. For example, we face a risk of product liability exposure related to the testing of our products in clinical trials and will face even greater risks upon commercialization by us or our partners of our products. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because our products are intended to treat central nervous system disorders, and it is possible that we may be held liable for the behavior and actions of patients who use our products. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and we or our partners may be forced to limit or forego further commercialization of one or more of our products. Although we maintain product liability insurance, our aggregate coverage limit under this insurance is $20.0 million, and while we believe this amount of insurance is sufficient to cover our product liability exposure,

these limits may not be high enough to fully cover potential liabilities. As our development activities and commercialization efforts progress and we and our partners sell our products, this coverage may be inadequate, we may be unable to obtain adequate coverage at an acceptable cost or we may be unable to get adequate coverage at all or our insurer may disclaim coverage as to a future claim. This could prevent the commercialization or limit the commercial potential of our products. Even if we are able to maintain insurance that we believe is adequate, our results of operations and financial condition may be materially adversely affected by a product liability claim. Uncertainties resulting from the initiation and continuation of products liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability litigation and other related proceedings may also require significant management time.

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Legislative or regulatory reform of the healthcare system in the U.S. and foreign jurisdictions may affect our or our partners ability to sell our products profitably.

The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our or our partners ability to set prices for our products which we or our partners believe are fair, and our ability to generate revenues and achieve and maintain profitability.

Specifically, in both the U.S. and some foreign jurisdictions there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our or our partners ability to sell our products profitably. In the U.S., the Medicare Prescription Drug Improvement and Modernization Act of 2003 reformed the way Medicare covered and provided reimbursement for pharmaceutical products. This legislation could decrease the coverage and price that we or our partners may receive for our products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time-consuming and expensive for us or our partners to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow the sale of such products on a competitive and profitable basis. Further federal and state proposals and healthcare reforms are likely which could limit the prices that can be charged for the drugs we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the Medicare prescription drug coverage legislation, by the possible effect of this legislation on amounts that private insurers will pay and by other healthcare reforms that may be enacted or adopted in the future.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, (PPACA), is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program, and the establishment of health care exchanges. Several provisions of the new law, which have varying effective dates, may affect us, and will likely increase certain of our costs. For example, an increase in the Medicaid rebate rate from 15.1% to 23.1% was effective as of January 1, 2010, and the volume of rebated drugs was expanded to include beneficiaries in Medicaid managed care organizations effective as of March 23, 2010. The PPACA also imposes an annual fee on pharmaceutical manufacturers which began in 2011, based on the manufacturer s sale of branded pharmaceuticals and biologics (excluding orphan drugs); expands the 340B drug discount program (excluding orphan drugs) including the creation of new penalties for non-compliance; and includes a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or doughnut hole . The law also revised the definition of average manufacturer price for reporting purposes (effective October 1, 2010), which could increase the amount of Medicaid drug rebates to states. Substantial new provisions affecting compliance also have been added, which may require us to modify our business practices with health care practitioners.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. We will continue to evaluate the PPACA, as amended, the implementation of regulations or guidance related to various provisions of the PPACA by federal agencies, as well as trends and changes that may be encouraged by the legislation and that may potentially impact on our business over time. These developments could, however, have a material adverse effect on our business, financial condition and results of operations.

In some foreign countries, including major markets in the European Union and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental

authorities can take nine to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. Our business could be materially harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Our business is subject to extensive governmental regulation and oversight and changes in laws could adversely affect our revenues and profitability.

Our business is subject to extensive government regulation and oversight. As a result, we may become subject to governmental actions which could materially and adversely affect our business, results of operations and financial condition, including:

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to patent protection and enforcement, health care availability, method of delivery and payment for health care products and services or our business operations generally;

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changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;

new laws, regulations and judicial decisions affecting pricing or marketing; and

changes in the tax laws relating to our operations.

In addition, the Food and Drug Administration Amendments Act of 2007 (FDAAA) included new authorization for the FDA to require post-market safety monitoring, along with a clinical trials registry, and expanded authority for the FDA to impose civil monetary penalties on companies that fail to meet certain commitments. The amendments, among other things, require some new drug applicants to submit risk evaluation and minimization strategies to monitor and address potential safety issues for products upon approval, grant the FDA the authority to impose risk management measures for marketed products and to mandate labeling changes in certain circumstances, and establish new requirements for disclosing the results of clinical trials. Companies that violate the law are subject to substantial civil monetary penalties. Additional measures have also been enacted to address the perceived shortcomings in the FDA s handling of drug safety issues, and to limit pharmaceutical company sales and promotional practices. While the FDAAA has had, and is expected to have, a substantial effect on the pharmaceutical industry, the full extent of that effect is not yet known. As the FDA issues further regulations, guidance and interpretations relating to this legislation, the impact on the industry as well as our business will become clearer. The requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute existing products. Our and our partners ability to commercialize approved products successfully may be hindered, and our business may be harmed as a result.

Future transactions may harm our business or the market price of our stock.

We regularly review potential transactions related to technologies, products or product rights and businesses complementary to our business. These transactions could include:

mergers;

acquisitions;

strategic alliances;

licensing agreements; and

co-promotion and similar agreements.

We may choose to enter into one or more of these transactions at any time, which may cause substantial fluctuations in the market price of our stock. Moreover, depending upon the nature of any transaction, we may experience a charge to earnings, which could also materially adversely affect our results of operations and could harm the market price of our stock.

We may undertake strategic acquisitions in the future, and difficulties integrating such acquisitions could damage our ability to achieve or sustain profitability.

Although we have no experience in acquiring businesses, we may acquire businesses or assets that complement or augment our existing business. If we acquire businesses with promising products or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to move one or more products through preclinical and/or clinical development to regulatory approval and commercialization. Integrating any newly acquired businesses or technologies could be expensive and time-consuming, resulting in the diversion of resources from our current business. We may not be able to integrate any acquired business successfully. We cannot assure you that, following an acquisition, we will achieve revenues, specific net income or loss levels that justify the acquisition or that the acquisition will result in increased earnings, or reduced losses, for the combined company in any future period. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, which would result in dilution for stockholders or the incurrence of indebtedness and may not be available on terms which would otherwise be acceptable to us. We may not be able to operate acquired businesses profitably or otherwise implement our growth strategy successfully.

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Our operating results may fluctuate significantly.

Our operating results will continue to be subject to fluctuations. The revenues we generate, if any, and our operating results will be affected by numerous factors, including:

- product sales;
- cost of product sales;
- marketing and other expenses;
- manufacturing or supply issues;
- the timing and amount of royalties or milestone payments;
- our addition or termination of development programs;
- variations in the level of expenses related to our products or future development programs;
- regulatory developments affecting our products or those of our competitors; our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- any intellectual property infringement or other lawsuit in which we may become involved; and
- the timing and recognition of stock-based compensation expense.

If our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Risks related to intellectual property and other legal matters

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

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

Fanapt® is based in part on patents and other intellectual property owned by Sanofi and Novartis. Titan Pharmaceuticals, Inc. (Titan) holds an exclusive license from Sanofi to the intellectual property owned by Sanofi, and Titan has sublicensed its rights under such license on an exclusive basis to Novartis. We acquired exclusive rights to this and other intellectual property through a further sublicense from Novartis. The sublicense with Novartis was amended and restated in October of 2009 to provide Novartis with exclusive rights to commercialize Fanapt® in the U.S. and Canada. We retained exclusive rights to Fanapt® outside the U.S. and Canada and we have exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. At Novartis option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt® outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt® outside of the U.S. and Canada. Novartis has chosen not to co-commercialize Fanapt® in Europe and certain other countries and will instead receive a royalty on net sales in those countries. These include, but are not limited to, the countries in the European Union, as well as Switzerland, Norway, Liechtenstein and Iceland. We may lose our rights to develop and commercialize Fanapt® outside the U.S. and Canada if we fail to comply with certain requirements in the amended and restated sublicense agreement regarding our financial condition, or if we fail to comply with certain diligence obligations regarding our development or commercialization activities or if we otherwise breach the amended and restated sublicense agreement and fail to cure such breach. Our rights to develop and commercialize Fanapt® outside the U.S. and Canada may be impaired if we do not cure breaches by Novartis of similar obligations contained in its sublicense agreement with Titan. Our loss of rights in Fanapt® to Novartis would have a material adverse effect on our business, financial condition and results of operations. In addition, if Novartis breaches the amended and restated sublicense agreement with respect to its commercialization activities in the U.S. or Canada, we may terminate Novartis commercialization rights in the applicable country. We would no longer receive royalty payments from Novartis in connection with such country in the event of such termination.

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

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

In addition to the rights we have licensed from BMS, Novartis and Lilly relating to our products, we rely upon intellectual property we own relating to these products, including patents, patent applications and trade secrets. As of June 30, 2014, excluding in-licensed patents and patent applications, we had 33 patent and patent application families, most of which have been filed in key markets including the U.S., relating to HETLIOZ® and Fanapt®. In addition, we had five other patent applications relating to products not presently in clinical studies. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around these patents. In addition, we generally rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug development processes that involve proprietary know-how, information and technology that is not covered by patent applications. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to protect or defend the intellectual property related to our technologies, we will not be able to establish or maintain a competitive advantage in our market.

If we do not obtain protection under the Hatch-Waxman Act and similar foreign legislation to extend our patents and to obtain market exclusivity for our products, our business will be harmed.

The Hatch-Waxman Act provides for an extension of patent term for drugs for a period of up to five years to compensate for time spent in development. Assuming we gain a five-year patent term restoration for HETLIOZ®, and that we continue to have rights under our license agreement with respect to this product, we would have exclusive rights to HETLIOZ® s U.S. new chemical entity patent (the primary patent covering the product as a new composition of matter) until 2022 and HETLIOZ® s U.S. method of use patent (the patent covering the method of treatment as described in the HETLIOZ® label approved by the FDA) until 2033.

In August 2011, the U.S. Patent and Trademark Office issued a certificate of extension under the Hatch-Waxman Act, extending by five years the term of Sanofi s new chemical entity patent relating to Fanapt® to November 2016. A directive in the European Union provides that companies that receive regulatory approval for a new product will have a 10-year period of market exclusivity for that product (with the possibility of a further one-year extension) in most countries in Europe, beginning on the date of such European regulatory approval, regardless of when the European new chemical entity patent covering such product expires. A generic version of the approved drug may not be marketed or sold in Europe during such market exclusivity period. This directive is of material importance with respect to Fanapt®, since the European new chemical entity patent for Fanapt® has expired. Assuming we gain a five-year patent term restoration for VLY-686, and that we continue to have rights under our license agreement with

respect to this product, we would have exclusive rights to VLY-686 s U.S. new chemical entity patent until 2029.

However, there is no assurance that we will receive the extensions of our patents or other exclusive rights available under the Hatch-Waxman Act or similar foreign legislation. If we fail to receive such extensions or exclusive rights, our or our partners ability to prevent competitors from manufacturing, marketing and selling generic versions of our products will be materially impaired.

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Litigation or third-party claims of intellectual property infringement could require us to divert resources and may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our not infringing the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to develop and commercialize one or more of our products. Defense of these claims, regardless of their merit, would divert substantial financial and employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain additional licenses from third parties to advance our research or allow commercialization of our products. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to develop and commercialize further one or more of our products.

In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties. Prosecution of these claims to enforce our rights against others could divert substantial financial and employee resources from our business. If we fail to enforce our proprietary rights against others, our business will be harmed.

Risks related to our common stock

Our stock price has been highly volatile and may be volatile in the future, and purchasers of our common stock could incur substantial losses.

The realization of any of the risks described in these risk factors or other unforeseen risks could have a dramatic and adverse effect on the market price of our common stock. Between January 1, 2014 and June 30, 2014, the high and low sales prices of our common stock as reported on The NASDAQ Global Market varied between $9.27 and $19.25 per share. Additionally, market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons that were unrelated to the operating performance of any one company.

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

- our or our partners ability to successfully commercialize our products;
- our ability to successfully execute our commercialization strategies;
- publicity regarding actual or potential testing or trial results relating to products under development by us or our competitors;

the outcome of regulatory review relating to products under development by us or our competitors;

regulatory developments in the U.S. and foreign countries;

developments concerning any collaboration or other strategic transaction we may undertake;

announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;

termination or delay of development or commercialization program(s) by our partners;

safety issues with our products or those of our competitors;

announcements of technological innovations or new therapeutic products or methods by us or others;

actual or anticipated variations in our quarterly operating results;

changes in estimates of our financial results or recommendations by securities analysts or failure to meet such financial expectations;

changes in government regulations or policies;

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

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

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

publicity regarding actual or potential transactions involving us; and

economic, political and other external factors beyond our control.

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

We have been the subject of litigation in the past and may be subject to litigation in the future. In the past, following periods of volatility in the market price of their stock, many companies, including us, have been the subjects of securities class action litigation. Any such litigation can result in substantial costs and diversion of management s attention and resources and could harm our stock price, business results of operations and financial condition. As a result of these factors, holders of our common stock might be unable to sell their shares at or above the price they paid for such shares.

If there are substantial sales of our common stock, our stock price could decline.

A small number of institutional investors and private equity funds hold a significant number of shares of our common stock. Sales by these stockholders of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

In addition to our outstanding common stock, as of June 30, 2014, there were a total of 5,849,373 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options and settlement of restricted stock unit awards granted under our Second Amended and Restated Management Equity Plan and 2006 Equity Incentive Plan. Upon the exercise of these options or settlement of the shares underlying these restricted stock units, as the case may be, in accordance with their respective terms, these shares may be resold freely, subject to restrictions imposed on our affiliates under Rule 144. If significant sales of these shares occur in short periods of time, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms, if at all.

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

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

If we fail to maintain the requirements for continued listing on The NASDAQ Global Market, our common stock could be delisted from trading, which would adversely affect the liquidity of our common stock and our ability to raise additional capital.

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

If securities or industry analysts do not publish research or reports or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have research coverage by securities and industry analysts. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases coverage of our Company or fails to regularly publish reports on us, interest in the purchase of our stock could decrease, which could cause our stock price or trading volume to decline.

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

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

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stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in previous offerings.

Our business could be negatively affected as a result of the actions of activist stockholders.

Proxy contests have been waged against many companies in the biopharmaceutical industry, including us, over the last few years. If faced with a proxy contest or other type of shareholder activism, we may not be able to respond successfully to the contest or dispute, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest or shareholder dispute involving us or our partners because:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees;
- perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to a board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

These actions could cause our stock price to experience periods of volatility.

Anti-takeover provisions in our charter and bylaws, and in Delaware law, and our rights plan could prevent or delay a change in control of our company.

We are a Delaware corporation and the anti-takeover provisions of Section 203 of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our amended and restated certificate of incorporation and bylaws:

- authorize the issuance of blank check preferred stock that could be issued by our board of directors to thwart a takeover attempt;
- do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of the stock to elect some directors;
- establish a classified board of directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting

following their election;

require that directors only be removed from office for cause;

provide that vacancies on the board of directors, including newly-created directorships, may be filled only by a majority vote of directors then in office;

limit who may call special meetings of stockholders;

prohibit stockholder action by written consent, requiring all actions to be taken at a meeting of the stockholders; and

establish advance notice requirements for nominating candidates for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

Moreover, in September 2008, our board of directors adopted a rights agreement, the provisions of which could result in significant dilution of the proportionate ownership of a potential acquirer and, accordingly, could discourage, delay or prevent a change in our management or control over us.

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

The global economic downturn and market instability has made the business climate more volatile and more costly. These economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control and may make any necessary debt or equity financing more difficult, more costly, and more dilutive. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, a lingering economic downturn or

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significant increase in our expenses could require additional financing on less than attractive rates or on terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our stock price and could require us to delay or abandon clinical development plans.

Sales of our products will be dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. As a result of negative trends in the general economy in the U.S. or other jurisdictions in which we may do business, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our or our partners product sales and revenue.

In addition, we rely on third parties for several important aspects of our business. For example, we depend upon Novartis for Fanapt® royalty revenue, we use third parties for sales, distribution, medical affairs and clinical research, and we rely upon several single source providers of raw materials and contract manufacturers for the manufacture of our products. During challenging and uncertain economic times and in tight credit markets, there may be a disruption or delay in the performance of our third party contractors, suppliers or partners. If such third parties are unable to satisfy their commitments to us, our business and results of operations would be adversely affected.

ITEM 2 Unregistered Sales of Equity Securities and Use of Proceeds

None

ITEM 3 Defaults Upon Senior Securities

None

ITEM 4 Mine Safety Disclosures

Not applicable

ITEM 5 Other Information

None

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ITEM 6 Exhibits.

Exhibit Number	Description
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2014 formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) Condensed Consolidated Balance Sheets as of June 30, 2014 and December 31, 2013; (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2014 and 2013; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three and six months ended June 30, 2014 and 2013; (iv) Condensed Consolidated Statement of Changes in Stockholders Equity for the six months ended June 30, 2014; (v) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2014 and 2013; 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.

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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.

August 8, 2014 /s/ Mihael H. Polymeropoulos, M.D.
Mihael H. Polymeropoulos, M.D.

President and Chief Executive Officer

(Principal Executive Officer)

August 8, 2014 /s/ James P. Kelly
James P. Kelly

Senior Vice President, Chief Financial Officer, Secretary and Treasurer

(Principal Financial Officer and Principal Accounting Officer)

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VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

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