Vanda Pharmaceuticals Inc.
Form 10-Q
November 08, 2013
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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 September 30, 2013

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 October 31, 2013, there were 33,190,106 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 September 30, 2013

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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)	September 30, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 142,172	$ 88,772
Marketable securities		31,631
Accounts receivable	1,956	1,168
Prepaid expenses and other current assets	2,412	3,967
Restricted cash, current	530	430
Total current assets	147,070	125,968
Property and equipment, net	2,106	2,348
Intangible asset, net	5,414	6,532
Restricted cash, non-current	500	600
Total assets	$ 155,090	$ 135,448
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 369	$ 287
Accrued liabilities	4,532	5,187
Deferred rent, current	215	
Deferred revenue, current	26,789	26,789
Total current liabilities	31,905	32,263
Deferred rent, non-current	2,945	3,005
Deferred revenue, non-current	70,238	90,275
Total liabilities	105,088	125,543
Commitments and contingencies (Notes 10 and 13)		
Stockholders equity:		
Preferred stock, $0.001 par value; 20,000,000 shares authorized and none issued and outstanding		
Common stock, $0.001 par value; 150,000,000 shares authorized; 33,190,106 and 28,241,743 shares issued and outstanding as of September 30, 2013 and	33	28

December 31, 2012, respectively		
Additional paid-in capital	353,708	300,974
Accumulated other comprehensive income		10
Accumulated deficit	(303,739)	(291,107)
Total stockholders equity	50,002	9,905
Total liabilities and stockholders equity	$ 155,090	$ 135,448

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 September 30, 2013	Three Months Ended September 30, 2012	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
Revenues:				
Licensing agreement	$ 6,753	$ 6,753	$ 20,037	$ 20,037
Royalty revenue	1,956	1,535	5,059	4,770
Total revenues	8,709	8,288	25,096	24,807
Operating expenses:				
Research and development	8,026	10,159	21,968	34,829
General and administrative	5,711	3,147	14,743	10,657
Intangible asset amortization	377	377	1,118	1,118
Total operating expenses	14,114	13,683	37,829	46,604
Loss from operations	(5,405)	(5,395)	(12,733)	(21,797)
Other income	25	69	101	502
Loss before tax benefit	(5,380)	(5,326)	(12,632)	(21,295)
Tax benefit				
Net loss	$ (5,380)	$ (5,326)	$ (12,632)	$ (21,295)
Net loss per share:				
Basic	$ (0.17)	$ (0.19)	$ (0.43)	$ (0.75)
Diluted	$ (0.17)	$ (0.19)	$ (0.43)	$ (0.75)
Shares used in calculations of net loss per share:				
Basic	31,332,993	28,226,743	29,363,162	28,226,743
Diluted	31,332,993	28,226,743	29,363,162	28,226,743

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)

(in thousands)	Three Months Ended September 30, 2013	Three Months Ended September 30, 2012	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
Net loss	$ (5,380)	$ (5,326)	$ (12,632)	$ (21,295)
Other comprehensive income (loss):				
Change in net unrealized gain (loss) on marketable securities	18		(10)	2
Tax provision on other comprehensive income (loss)				
Other comprehensive income (loss), net of tax	18		(10)	2
Comprehensive loss	$ (5,380)	$ (5,308)	$ (12,642)	$ (21,293)

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS EQUITY
(Unaudited)

(in thousands except for share amounts)	Common Stock Shares	Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balances at December 31, 2012	28,241,743	$ 28	$ 300,974	$ 10	$ (291,107)	$ 9,905
Net proceeds from public offering of common stock	4,680,000	5	48,547			48,552
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	317,883		1,062			1,062
Shares withheld upon settlement of restricted stock units	(49,520)		(196)			(196)
Employee and non-employee stock-based compensation expense			3,321			3,321
Net loss					(12,632)	(12,632)
Other comprehensive loss, net of tax				(10)		(10)
Balances at September 30, 2013	33,190,106	$ 33	$ 353,708	$	$ (303,739)	$ 50,002

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)	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
Cash flows from operating activities		
Net loss	$ (12,632)	$ (21,295)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	321	528
Employee and non-employee stock-based compensation expense	3,321	3,171
Amortization of discounts and premiums on marketable securities	121	416
Amortization of intangible asset	1,118	1,118
Landlord contributions for tenant improvements		1,826
Changes in assets and liabilities:		
Accounts receivable	(788)	83
Prepaid expenses and other assets	1,555	(401)
Accounts payable	82	94
Accrued liabilities	(655)	3,372
Other liabilities	155	57
Deferred revenue	(20,037)	(20,037)
Net cash used in operating activities	(27,439)	(31,068)
Cash flows from investing activities		
Purchases of property and equipment	(79)	(2,010)
Purchases of marketable securities		(49,967)
Proceeds from sales of marketable securities		2,497
Maturities of marketable securities	31,500	97,140
Net cash provided by investing activities	31,421	47,660
Cash flows from financing activities		
Net proceeds from public offering of common stock	48,552	
Tax obligations paid in connection with settlement of restricted stock units	(196)	
Proceeds from exercise of stock options	1,062	
Net cash provided by financing activities	49,418	
Net increase in cash and cash equivalents	53,400	16,592
Cash and cash equivalents		
Beginning of period	88,772	87,923
End of period	$ 142,172	$ 104,515

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 tasimelteon, a product for the treatment of circadian rhythm sleep disorders, which is currently in clinical development for Non-24-Hour Disorder (Non-24) and for which a New Drug Application (NDA) is under review by the U.S. Food and Drug Administration (FDA), Fanapt®, 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 year ended December 31, 2012 included in the Company s annual report on Form 10-K. The financial information as of September 30, 2013 and for the three and nine months ended September 30, 2013 and 2012 is unaudited, but in the opinion of management, all adjustments, consisting only of normal recurring accruals, considered necessary for a fair statement of the results of these interim periods have been included. The condensed consolidated balance sheet data as of December 31, 2012 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 year ended December 31, 2012.

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.

Recent accounting pronouncements

On January 1, 2013, Vanda adopted changes issued by the Financial Accounting Standards Board (FASB) for the reporting of amounts reclassified out of accumulated other comprehensive income. The changes require an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required to be reclassified in its entirety to net income. For other amounts that are not required to be reclassified in their entirety to net income in the same reporting period, an

entity is required to cross-reference other disclosures that provide additional detail about those amounts. Adoption of these changes did not have a material impact on the condensed consolidated financial statements.

In July 2013, the FASB issued Accounting Standard Update (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 Company does not expect that the new standard will have a material impact on the condensed consolidated financial statements.

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2. 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 Restricted Stock Units (RSUs), but only to the extent that their inclusion is dilutive.

The following table presents the calculation of basic and diluted net loss per share of common stock for the three and nine months ended September 30, 2013 and 2012:

(in thousands, except for share and per share amounts)	Three Months Ended September 30, 2013	Three Months Ended September 30, 2012	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
Numerator:				
Net loss	$ (5,380)	$ (5,326)	$ (12,632)	$ (21,295)
Denominator:				
Weighted average shares of common stock outstanding, basic	31,332,993	28,226,743	29,363,162	28,226,743
Stock options and restricted stock units related to the issuance of common stock				
Weighted average shares of common stock outstanding, diluted	31,332,993	28,226,743	29,363,162	28,226,743
Net loss per share:				
Basic	$ (0.17)	$ (0.19)	$ (0.43)	$ (0.75)
Diluted	$ (0.17)	$ (0.19)	$ (0.43)	$ (0.75)
Anti-dilutive securities excluded from calculations of diluted net loss per share:				
Stock options and restricted stock units	3,801,651	5,150,778	4,556,838	5,184,757

The Company incurred net losses for the three and nine months ended September 30, 2013 and 2012 causing inclusion of any potentially dilutive securities to have an anti-dilutive effect, resulting in dilutive loss per share and basic loss per share attributable to common stockholders being equivalent.

3. Marketable Securities

The Company did not hold any available-for-sale marketable securities as of September 30, 2013.

The following is a summary of the Company s available-for-sale marketable securities as of December 31, 2012:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. Treasury and government agencies	$ 14,439	$ 3	$	$ 14,442
Corporate debt	17,182	7		17,189
	$ 31,621	$ 10	$	$ 31,631

4. 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

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The Company did not hold any marketable securities as of September 30, 2013. Marketable securities classified in Level 1 and Level 2 at December 31, 2012 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.

As of September 30, 2013, the Company did not hold any assets that are required to be measured at fair value on a recurring basis.

As of December 31, 2012, the Company held certain assets that are required to be measured at fair value on a recurring basis, as follows:

		Fair Value Measurements at Reporting Date Using		
(in thousands)	December 31, 2012	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	$ 31,631	$ 14,442	$ 17,189	$

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.

5. Prepaid Expenses and Other Current Assets

The following is a summary of the Company s prepaid expenses and other current assets as of September 30, 2013 and December 31, 2012:

(in thousands)	September 30, 2013	December 31, 2012
Prepaid insurance	$ 303	$ 155
Other prepaid expenses and vendor advances	2,099	3,479
Inventory		57
Accrued interest income	10	276
Total prepaid expenses and other current assets	$ 2,412	$ 3,967

6. Intangible Asset

The following is a summary of the Company s intangible asset as of September 30, 2013:

		September 30, 2013		
(in thousands)	**Estimated Useful Life (Years)**	**Gross Carrying Amount**	**Accumulated Amortization**	**Net Carrying Amount**
Fanapt®	8	$ 12,000	$ 6,586	$ 5,414

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The following is a summary of the Company s intangible asset as of December 31, 2012:

		December 31, 2012		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	8	$ 12,000	$ 5,468	$ 6,532

In May 2009, the Company announced that the FDA had approved the New Drug Application (NDA) for Fanapt®. As a result of this approval, the Company met a milestone under its original sublicense agreement with Novartis which 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 the Company expects to last until May 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and the Company expects that Fanapt® will be eligible for six months of pediatric exclusivity. This term is the Company s best estimate of the life of the patent; if, however, the pediatric extension is not granted, the intangible asset will be amortized over a shorter period.

The intangible asset is being amortized over its estimated useful economic life using the straight-line method. Amortization expense was $0.4 million for the three months ended September 30, 2013 and 2012 and $1.1 million for the nine months ended September 30, 2013 and 2012. The Company capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanapt®.

The following is a summary of the future intangible asset amortization schedule as of September 30, 2013:

(in thousands)	Total	Remainder of 2013	2014	2015	2016	2017
Intangible asset	$ 5,414	$ 377	$ 1,495	$ 1,495	$ 1,495	$ 552

7. Accrued Liabilities

The following is a summary of the Company s accrued liabilities as of September 30, 2013 and December 31, 2012:

(in thousands)	September 30, 2013	December 31, 2012
Accrued research and development expenses	$ 2,082	$ 3,900
Accrued consulting and other professional fees	1,060	386
Compensation and employee benefits	1,304	127
Accrued lease exit liability (refer to note 10)	59	453
Other accrued expenses	27	321
Total accrued liabilities	$ 4,532	$ 5,187

8. Deferred Revenue

The following is a summary of changes in total deferred revenue for the nine months ended September 30, 2013:

(in thousands)	**Balance at Beginning of Period**	**Reduction from Licensing Revenue Recognized**	**Balance at End of Period**
Nine months ended September 30, 2013	$ 117,064	$ 20,037	$ 97,027

The following is a summary of changes in total deferred revenue for the nine months ended September 30, 2012:

(in thousands)	**Balance at Beginning of Period**	**Reduction from Licensing Revenue Recognized**	**Balance at End of Period**
Nine months ended September 30, 2012	$ 143,853	$ 20,037	$ 123,816

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The Company entered into an amended and restated sublicense agreement with Novartis in October 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 in December 2009. 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®, which the Company expects to last until May 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and the Company expects that Fanapt® will be eligible for six months of pediatric exclusivity. This term is the Company s best estimate of the life of the patent. 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® (May 2017).

9. Income Taxes

Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The fact that the Company has historically generated net operating losses (NOLs) serves as strong evidence that it is more likely than not that deferred tax assets will not be realized in the future. Therefore, the Company has a full valuation allowance against all deferred tax assets as of September 30, 2013 and December 31, 2012. Changes in ownership may limit the amount of NOL carryforwards that can be utilized in the future to offset taxable income.

10. Commitments and Contingencies

Operating leases

The following is a summary of the minimum annual future payments under operating leases as of September 30, 2013:

		Cash payments due by period					
(in thousands)	**Total**	**Remainder of 2013**	**2014**	**2015**	**2016**	**2017**	**After 2017**
Operating leases	$ 11,007	$ 316	$ 1,052	$ 1,079	$ 1,106	$ 1,133	$ 6,321

The minimum annual future payments for operating leases consists of the lease for office space for the Company s headquarters located in Washington, D.C., which expires in 2023.

In July 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). Under the Lease, rent payments were abated for the first 12 months, and the Landlord will provide the Company with an allowance of $1.9 million for leasehold improvements. As of September 30, 2013, the Company had received the full allowance. 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.

As a result of the Company s relocation from its former headquarters office space in Rockville, Maryland to Washington, D.C., the Company provided notice in the fourth quarter of 2011 to the landlord that it was terminating the Rockville lease effective June 30, 2013. As a result, the Company recognized an expense of $0.7 million in the year ended December 31, 2011 related to a lease termination penalty, of which $0.6 million was included as research and development expense in the consolidated statement of operations for the year ended December 31, 2011 and $0.1 million was included as general and administrative expense in the consolidated statement of operations for the year ended December 31, 2011. In the first quarter 2012, the Company ceased using the Rockville, Maryland location and, as a result, recognized additional rent expense of $0.8 million, of which $0.6 million was included as research and development expense in the consolidated statement of operations for the year ended December 31, 2012 and $0.2 million was included as general and administrative expense in the consolidated statement of operations for the year ended December 31, 2012. The rent expense of

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$0.8 million for the year ended December 31, 2012, consisted of a lease exit liability of $1.3 million for the remaining lease payments net of the reversal of the deferred rent liability of $0.5 million related to the Rockville lease.

The following is a summary of the Company s lease exit activity for the nine months ended September 30, 2013, the year ended December 31, 2012 and the year ended December 31, 2011:

(in thousands)	Balance at Beginning of Period	Costs Incurred and Charged to Expense	Costs Paid or Otherwise Settled	Balance at End of Period
Nine months ended September 30, 2013	$ 453	$ (10)	$ 384	$ 59
Year ended December 31, 2012	740	1,220	1,507	453
Year ended December 31, 2011		740		740

Rent expense under operating leases, including lease exit costs, was $0.3 million and $0.2 million for the three months ended September 30, 2013 and 2012, respectively. Rent expense under operating leases, including lease exit costs, was $0.8 million and $1.8 million for the nine months ended September 30, 2013 and 2012, respectively.

Consulting fees

The Company has engaged a regulatory consultant to assist the Company s efforts to prepare, file and obtain FDA approval of an NDA for tasimelteon. As a result of the FDA acceptance of the NDA filing for tasimelteon for the treatment of Non-24, the Company made a milestone payment of $0.5 million to the regulatory consultant during the three months ended September 30, 2013. The payment was included as research and development expense in the consolidated statement of operations for the three and nine months ended September 30, 2013. Pursuant to the agreement and subject to certain conditions, the Company would be obligated to make a milestone payment of $2.0 million in the event the tasimelteon NDA is approved by the FDA. In addition to consulting fees and milestone payments, the Company is obligated to reimburse the consultant for ordinary and necessary business expenses incurred in connection with the engagement. The Company may terminate the engagement at any time upon prior notice; however, subject to certain conditions, the Company would remain obligated to make the milestone payment if the milestone is achieved following such termination.

Guarantees and indemnifications

The Company has entered into a number of standard intellectual property indemnification agreements in the ordinary course of its business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company s business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company s products. The term of these indemnification agreements is generally perpetual from the date of execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain conditions.

License agreements

The Company s rights to develop and commercialize its products and product candidates are subject to the terms and conditions of licenses granted to the Company by other pharmaceutical companies.

Tasimelteon. In February 2004, the Company entered into a license agreement with Bristol-Myers Squibb (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 tasimelteon. In partial consideration for the license, the Company paid BMS an initial license fee of $0.5 million. Pursuant to the license agreement, the Company would be obligated to make future milestone payments to BMS of up to $37.0 million in the aggregate. The Company made a milestone payment to BMS of $1.0 million under the license agreement in 2006 relating to the initiation of its first Phase III clinical trial for tasimelteon. The Company made a milestone payment of $3.0 million during the three months ended September 30, 2013 relating to the FDA acceptance of the NDA filing for tasimelteon in the treatment of Non-24. The payment was included as research and development expense in the consolidated statement of operations for the three

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and nine months ended September 30, 2013. The Company will incur milestone obligations of $8.0 million in the event that the tasimelteon NDA is approved by the FDA and $25.0 million in the event that sales of tasimelteon reach a certain agreed upon sales threshold. Additionally, the Company would be obligated to make royalty payments based on net sales of tasimelteon which, as a percentage of net sales, are in the low teens. 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. The Company is obligated to use commercially reasonable efforts to develop and commercialize tasimelteon and to meet certain milestones in initiating and completing certain clinical work.

Under the license agreement, the Company was required to enter into a development and commercialization agreement with a third party for tasimelteon. If the Company had not entered into such an agreement with respect to certain major market countries by a certain deadline, then BMS would have had the option to develop and commercialize tasimelteon itself in those countries not covered by a development and commercialization agreement on certain pre-determined terms (the BMS Option). However, the license agreement was amended in April 2013 to add a process that would allow BMS, prior to such deadline, to waive such right to develop and commercialize tasimelteon in those countries not covered by a development and commercialization agreement. Subsequent to the execution of the April 2013 amendment, BMS provided the Company with formal written notice that it irrevocably waived the BMS Option to exercise the right to reacquire any or all rights to any product (as defined in the license agreement) containing tasimelteon, or to develop or commercialize any such product, in the countries not covered by a development and commercialization agreement.

Either party may terminate the tasimelteon license agreement under certain circumstances, including a material breach of the agreement by the other. In the event that BMS has not exercised its option to reacquire the rights to tasimelteon and 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® (iloperidone) in 2004 through a sublicense agreement with Novartis. A predecessor company of sanofi-aventis, Hoechst Marion Roussel, Inc. (HMRI), discovered Fanapt® and completed early clinical work on the product. In 1996, following a review of its product portfolio, HMRI licensed its rights to the Fanapt® patents and patent applications to Titan Pharmaceuticals, Inc. (Titan) on an exclusive basis. In 1997, soon after it had acquired its rights, Titan sublicensed its rights to Fanapt® on an exclusive basis to Novartis. In June 2004, the Company acquired exclusive worldwide rights to these patents and patent applications, as well as certain Novartis patents and patent applications to develop and commercialize Fanapt®, through a sublicense agreement with Novartis. In partial consideration for this sublicense, the Company paid Novartis an initial license fee of $0.5 million and was obligated to make future milestone payments to Novartis of less than $100.0 million in the aggregate (the majority of which were tied to sales milestones), as well as royalty payments to Novartis at a rate which, as a percentage of net sales, was in the mid-twenties. In November 2007, the Company met a milestone under the sublicense agreement relating to the acceptance of its filing of the NDA for Fanapt® for the treatment of schizophrenia and made a milestone payment of $5.0 million to Novartis. As a result of the FDA s approval of the NDA for Fanapt® in May 2009, the Company met an additional milestone under the sublicense agreement, which required the Company to make a payment of $12.0 million to Novartis.

In October 2009, Vanda entered into an amended and restated sublicense agreement with Novartis, which amended and restated the June 2004 sublicense agreement. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. Novartis

began selling Fanapt® in the U.S. during the first quarter of 2010. Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanapt®. In October 2012, Novartis informed Vanda that it had determined to cease the development of the long-acting injectable (or depot) formulation of Fanapt®. Pursuant to the amended and restated sublicense agreement, Vanda 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. and the decision by Novartis to cease development of the long-acting

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injectable (or depot) formulation of Fanapt®, Vanda expects that some or all of these commercial and development milestones will not be achieved by Novartis. Vanda 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. Vanda retains exclusive rights to Fanapt® outside the U.S. and Canada and Vanda has exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. At Novartis option, Vanda 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® with Vanda 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. Vanda 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 August 2012, the Israeli Ministry of Health granted market approval for Fanapt® for the treatment of schizophrenia. In November 2012, Vanda was notified that Fanapt® had been granted market approval in Argentina 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.

VLY-686. In April 2012, the Company entered into a license agreement with Eli Lilly and Company (Lilly) pursuant to which the Company acquired an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize an NK-1R antagonist, 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 paid Lilly an initial license fee of $1.0 million and will be responsible for all development costs. The initial license fee was recognized as research and development expense in the consolidated statement of operations for the nine months ended September 30, 2012. Lilly is also eligible to receive additional payments based upon achievement of specified development and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. These milestones include $4.0 million for pre-NDA approval milestones and up to $95.0 million for future regulatory approval and sales milestones. Vanda is obligated to use its commercially reasonable efforts to develop and commercialize 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 that Vanda terminates the license agreement, or if Lilly terminates due to Vanda s breach or for certain other reasons set forth in the license agreement, all rights licensed and developed by Vanda under the license agreement will revert or otherwise be licensed back to Lilly on an exclusive basis, subject to payment by Lilly to the Company of a royalty on net sales of products that contain 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 September 30, 2013 because the criteria for recording the future milestone payments have not yet been met. These criteria include the successful outcome of future clinical trials, regulatory filings, favorable FDA regulatory approvals, growth in product sales and other factors.

Research and development and marketing agreements

In the course of its business, the Company regularly enters into agreements with clinical organizations to provide services relating to clinical development and clinical manufacturing activities under fee service arrangements. The Company s current agreements for clinical services may be terminated on no more than 60 days notice without incurring additional charges, other than charges for work completed but not paid for through the effective date of termination and other costs incurred by the Company s contractors in closing out work in progress as of the effective date of termination.

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11. Common Stock

In August 2013, the Company completed a public offering of 4,680,000 shares of common stock at a price to the public of $11.14 per share. Net cash proceeds from the public offering were $48.6 million, after deducting the underwriting discounts and commissions and offering expenses.

12. 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.

The fair value of stock options granted is amortized using the accelerated attribution method. The fair value of RSUs awarded is 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.

Total employee stock-based compensation expense related to stock-based awards for the three and nine months ended September 30, 2013 and 2012 was comprised of the following:

	Three Months Ended		Nine Months Ended	
(in thousands)	September 30, 2013	September 30, 2012	September 30, 2013	September 30, 2012
Research and development	$ 404	$ (110)	$ 1,164	$ 1,003
General and administrative	1,091	686	2,063	2,152
Total employee stock-based compensation expense	$ 1,495	$ 576	$ 3,227	$ 3,155

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model that uses the assumptions noted in the following table. Expected volatility rates are based on the historical volatility of the Company s publicly traded common stock and other factors. The weighted average expected term of stock options granted is based on the simplified method as the options meet the plain vanilla criteria required by authoritative guidance. Significant changes in the market prices of the Company s common stock in recent years has made historical data less reliable for the purpose of estimating future vesting, exercise, and employment behavior. The simplified method provides a more reasonable approach for estimating the weighted average expected term for options granted in 2013 and 2012. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception (other than a dividend of preferred share purchase rights, which was declared in September 2008) and does not plan to pay dividends in the foreseeable future.

Assumptions used in the Black-Scholes-Merton option pricing model for employee and director stock options granted during the nine months ended September 30, 2013 and 2012 were as follows:

	Nine Months Ended	
	September 30, 2013	September 30, 2012
Expected dividend yield	%	%
Weighted average expected volatility	63%	68%
Weighted average expected term (years)	6.03	6.03
Weighted average risk-free rate	1.28%	1.04%
Weighted average fair value per share	$ 3.98	$ 2.71

As of September 30, 2013, 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 670,744 shares subject to outstanding options granted under the 2004 Plan as of September 30, 2013, and no

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additional options will be granted under this plan. As of September 30, 2013, there were 8,995,930 shares of common stock reserved for issuance under the 2006 Plan, of which 5,332,870 shares were subject to outstanding options and RSUs granted to employees and non-employees and 2,213,524 shares remained available for future grant.

The Company has granted two types of options, option awards with service conditions (service option awards) and options with service and performance conditions (performance option awards). Service option awards are subject to terms and conditions established by the compensation committee of the board of directors. Service option awards have 10-year contractual terms and all service option awards granted prior to December 31, 2006, service option awards granted to new employees, and certain service option awards granted to existing employees vest and become exercisable on the first anniversary of the grant date with respect to the 25% of the shares subject to service option awards. The remaining 75% of the shares subject to the service option awards vest and become exercisable monthly in equal installments thereafter over three years. Certain service option awards granted to existing employees after December 31, 2006 vest and become exercisable monthly in equal installments over four years. The initial service option awards granted to directors upon their election vest and become exercisable in equal monthly installments over a period of four years, while the subsequent annual service option awards granted to directors vest and become exercisable in equal monthly installments over a period of one year. Certain service option awards to executives and directors provide for accelerated vesting if there is a change in control of the Company. Certain service option awards to employees and executives provide for accelerated vesting if the respective employee s or executive s service is terminated by the Company for any reason other than cause or permanent disability. There were 151,250 performance option awards outstanding with unrecognized stock-based compensation costs of $0.3 million at June 30, 2013. In July 2013, the performance option awards vested upon the acceptance by the FDA of the Company s tasimelteon NDA (the Vesting Event). The Vesting Event for the performance option awards resulted in the recognition of additional stock-based compensation expense of $0.3 million for the three months and nine months ended September 30, 2013. As of September 30, 2013, there was $2.1 million of unrecognized compensation costs related to unvested service option awards expected to be recognized over a weighted average period of 1.6 years. None of the service option awards or performance option awards are classified as a liability as of September 30, 2013.

A summary of option activity for the 2004 Plan for the nine months ended September 30, 2013 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, 2012	672,145	$ 1.79	2.78	$ 1,512
Expired	(115)	4.73		
Exercised	(1,286)	3.67		7
Outstanding at September 30, 2013	670,744	1.79	2.03	6,144
Exercisable at September 30, 2013	670,744	1.79	2.03	6,144

A summary of option activity for the 2006 Plan for the nine months ended September 30, 2013 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, 2012	4,865,487	$ 10.83	7.15	$ 634
Granted	356,000	6.88		
Forfeited	(50,533)	6.35		
Expired	(258,238)	10.68		
Exercised	(164,161)	6.44		836
Outstanding at September 30, 2013	4,748,555	10.75	6.65	16,292
Exercisable at September 30, 2013	3,343,423	12.97	5.80	8,561

Proceeds from the exercise of stock options amounted to $1.1 million for the nine months ended September 30, 2013.

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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 two types of RSUs, RSUs with service conditions (service RSUs) and RSUs with service and performance conditions (performance RSUs). The service RSUs vest in four equal annual installments provided that the employee remains employed with the Company. There were 48,750 performance RSUs outstanding with unrecognized stock-based compensation costs of $0.2 million at June 30, 2013. In July 2013, the performance RSUs vested upon the Vesting Event. The Vesting Event for the performance RSUs resulted in the recognition of additional stock-based compensation expense of $0.2 million for the three months and nine months ended September 30, 2013. As of September 30, 2013, there was $2.4 million of unrecognized compensation costs related to unvested service RSUs expected to be recognized over a weighted average period of 1.7 years. None of the service RSUs or performance RSUs are classified as a liability as of September 30, 2013.

A summary of RSU activity for the 2006 Plan for the nine months ended September 30, 2013 follows:

	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2012	705,376	$ 5.91
Granted	99,500	6.69
Forfeited	(19,375)	6.66
Vested and unissued	(48,750)	3.11
Vested	(152,436)	7.86
Outstanding at September 30, 2013	584,315	5.74

The vesting date fair value for the 48,750 shares underlying performance RSUs that vested but are unissued during the nine months ended September 30, 2013 was $0.4 million. The vesting date fair value for the 152,436 shares underlying RSUs that vested during the nine months ended September 30, 2013 was $0.6 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 RSUs that vested and settled during the nine months ended September 30, 2013, the Company withheld 49,520 shares of common stock and paid employee payroll withholding taxes of $0.2 million relating to the vesting and settlement of the RSUs.

13. Legal Matters

On June 24, 2013, a securities class action complaint was filed in the United States District Court for the District of Columbia, naming the Company and certain of its officers as defendants. The complaint, filed on behalf of purported stockholders of the Company, seeks to assert violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with allegedly false and misleading statements and alleged omissions regarding the Company s Phase III trial results for tasimelteon and other disclosures between December 18, 2012 and June 18, 2013 (the Class Period). The plaintiff seeks to represent a class comprised of purchasers of the Company s common stock during the Class Period and seeks damages, costs and expenses and such other relief as determined by the Court. A similar complaint was filed on July 8, 2013.

The Company s management believes that Vanda has meritorious defenses and intends to defend these lawsuits vigorously. The Company does not anticipate that this litigation will have a material adverse effect on its business,

results of operations or financial condition. However, these lawsuits are subject to inherent uncertainties, the actual cost may be significant, and the Company may not prevail. The Company believes it is entitled to coverage under its relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

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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:

- the failure to obtain, or any delay in obtaining, regulatory approval for our products, particularly tasimelteon for the treatment of Non-24-Hour Disorder (Non-24), or to comply with ongoing regulatory requirements;
- our inability to successfully commercialize tasimelteon following the receipt of regulatory approval, if any;
- our inability to obtain the capital necessary to fund our research and development or commercial activities;
- our failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage our growth;
- a lack of acceptance of our products in the marketplace, or a failure to become or remain profitable;
- a loss of rights to develop and commercialize our products under our license and sublicense agreements;
- 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;
- delays in the completion of our or our partners clinical trials;

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 or all of our prior net operating losses and orphan drug and research and development credits;

the cost and effects of current or 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.

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We encourage you to read Management s Discussion and Analysis of Financial Condition and Results of Operations as well as our unaudited condensed consolidated financial statements contained in this quarterly report on Form 10-Q. In addition, you should refer to Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2012, and Item 1A of Part II of this quarterly report on Form 10-Q for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. 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 Forms 10-Q, 8-K and 10-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

Overview

We are a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders. We believe that each of our products will address a large market with significant unmet medical needs. Our product portfolio includes tasimelteon, a product for the treatment of circadian rhythm sleep disorders, which is currently in clinical development for Non-24-Hour Disorder (Non-24) and for which a New Drug Application (NDA) is under review by the U.S. Food and Drug Administration (FDA), Fanapt®, 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.

In December 2012 and January 2013, we announced positive results for two Phase III studies for tasimelteon in the treatment of Non-24. The SET Phase III study demonstrated that tasimelteon was able to entrain the master body clock as measured by melatonin and cortisol circadian rhythms. Tasimelteon was also shown to significantly improve clinical symptoms across a number of sleep and wake measures. These results provided robust evidence of direct and clinically meaningful benefits to patients with Non-24. The RESET Phase III study demonstrated the maintenance effect of 20 milligrams (mg) of tasimelteon to entrain melatonin and cortisol circadian rhythms in individuals with Non-24. Patients treated with tasimelteon maintained their clinical benefits while patients receiving placebo showed significant deterioration in measures of nighttime sleep, daytime naps and timing of sleep. In May 2013, we submitted an NDA to the FDA for tasimelteon for the treatment of Non-24. In July 2013, we announced that the FDA accepted the filing and granted a priority review classification to our NDA for tasimelteon for the treatment of Non-24 in the totally blind. The FDA determined the action target date under the Prescription Drug User Fee Act (PDUFA-V) to be January 31, 2014. The FDA scheduled a Peripheral and Central Nervous System Drugs Advisory Committee meeting on November 14, 2013 for the review of our NDA for tasimelteon, proposed trade name HETLIOZ™, for the treatment of Non-24 in the totally blind. As a result of the FDA accepting the NDA filing for tasimelteon, we incurred costs of $4.0 million in the three and nine months ended September 30, 2013, including a $3.0 million milestone obligation under our license agreement with Bristol-Meyers Squibb (BMS), a $0.5 million milestone obligation under a regulatory consulting agreement and non-cash stock-based compensation expense of $0.3 million for performance-based stock options and $0.2 million for performance-based restricted stock unit (RSU) awards**.** In January 2013, we reported top-line results of the Phase IIb/III clinical study (MAGELLAN) in Major Depressive Disorder (MDD), investigating the efficacy and safety of tasimelteon as a monotherapy in the treatment of patients with MDD. The clinical study did not meet the primary endpoint of change from baseline in the Hamilton Depression Scale (HAMD-17) after eight weeks of treatment as compared to placebo. As a result, all activities have been discontinued related to the MDD indication for tasimelteon. We incurred $19.1 million in research and development costs for the nine months ended September 30, 2013 directly attributable to our development of tasimelteon.

In December 2012, the European Medicines Agency s (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a negative opinion recommending against approval of Fanaptum (oral iloperidone tablets) for the treatment of schizophrenia in adult patients in the European Union. The CHMP was of the opinion that the benefits of Fanaptum did not outweigh its risks and recommended against marketing authorization. We initiated an appeal of this opinion and requested a re-examination of the decision by the CHMP, but withdrew our Marketing Authorization Application in the first quarter of 2013 because the additional clinical data requested by the CHMP would not have been available in the timeframe allowed by the EMA s Centralized Procedure. We

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intend to reassess our European regulatory strategy for Fanaptum once the results from the Relapse Prevention Study in Patients with Schizophrenia (REPRIEVE) being conducted by Novartis become available. We incurred $0.4 million in research and development costs for the nine months ended September 30, 2013 directly attributable to our development of Fanapt®.

In the second half of 2013, we plan to initiate a proof of concept study for VLY-686 in treatment resistant pruritus in atopic dermatitis. We incurred $1.5 million in research and development costs for the nine months ended September 30, 2013 directly attributable to our development of VLY-686.

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 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 to manufacture, market and sell our products, including tasimelteon for the treatment of Non-24 and Novartis ability to successfully commercialize Fanapt® in the U.S. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks which are detailed in Risk Factors reported in Item 1A of Part I of our annual report in Form 10-K for the year ended December 31, 2012 and Item 1A of Part II of this quarterly report on Form 10-Q.

Revenues

Our revenues are derived primarily from our amended and restated sublicense agreement with Novartis and include an upfront payment, product sales and future milestone and royalty payments. Revenues are considered both realizable and earned when the following four conditions are met: (i) persuasive evidence of an arrangement exists, (ii) the arrangement fee is fixed or determinable, (iii) delivery or performance has occurred, and (iv) collectability is reasonably assured. Revenue related to the $200.0 million upfront payment is being recognized ratably on a straight-line basis from the date the amended and restated sublicense agreement became effective (November 2009) through the expected life of the U.S. patent for Fanapt® which we expect to last until May 2017. This includes the Hatch-Waxman extension that extends patent protection for drug compounds for a period of five years to compensate for time spent in development and a six-month pediatric term extension. Fanapt® has qualified for the full five-year patent term Hatch-Waxman extension and we expect that Fanapt® will be eligible for six months of pediatric exclusivity. We recognize revenues from Fanapt® royalties and commercial and development milestones from Novartis when realizable.

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.

We incurred research and development expenses in the aggregate of $22.0 million for the nine months ended September 30, 2013 including employee stock-based compensation expense of $1.2 million. Milestone payments relating to research and development activities are accrued when it is deemed probable that the milestone event will be achieved. As a result of the FDA acceptance of our NDA for tasimelteon for the treatment of Non-24 in July 2013, we incurred milestone obligations of $3.5 million for the three and nine months ended September 30, 2013 including a $3.0 million milestone obligation under our license agreement with BMS and a $0.5 million milestone obligation under a regulatory consulting agreement.

We will be obligated to make a milestone payment of $8.0 million to BMS under the license agreement for tasimelteon in the event our NDA for tasimelteon for the treatment of Non-24 is approved by the FDA. Upon

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and subsequent to FDA approval, milestone payments made under license agreements are capitalized. In addition, we will be obligated to make a milestone payment of $2.0 million under a regulatory consulting agreement in the event our NDA for tasimelteon for the treatment of Non-24 is approved by the FDA. The FDA determined the action target date under the Prescription Drug User Fee Act (PDUFA-V) to be January 31, 2014. The FDA scheduled a Peripheral and Central Nervous System Drugs Advisory Committee meeting on November 14, 2013 for the review of the Company s NDA for tasimelteon, proposed trade name HETLIOZ™, for the treatment of Non-24 in the totally blind. We expect to incur significant research and development expenses as we continue to develop our products and product candidates. We expect to incur licensing costs in the future that could be substantial, as we continue our efforts to develop our products.

The following table summarizes the costs of our product development initiatives for the three and nine months ended September 30, 2013 and 2012. Included in this table are the research and development expenses recognized in connection with the clinical development of tasimelteon, Fanapt® and VLY-686:

	Three Months Ended		Nine Months Ended	
(in thousands)	September 30, 2013	September 30, 2012	September 30, 2013	September 30, 2012
Direct project costs: (1)				
Tasimelteon	$ 6,835	$ 9,437	$ 19,105	$ 30,856
Fanapt®	69	423	362	1,173
VLY-686	771	42	1,542	1,056
Total direct project costs	7,675	9,902	21,009	33,085
Indirect project costs: (1)				
Facility	189	114	502	1,216
Depreciation	54	57	168	295
Other indirect overhead	108	86	289	233
Total indirect project costs	351	257	959	1,744
Total research and development expenses	$ 8,026	$ 10,159	$ 21,968	$ 34,829

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

General and administrative expenses

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. General and administrative expenses also include third party expenses incurred to support business development,

marketing and other business activities. We incurred general and administrative expenses of $14.7 million for the nine months ended September 30, 2013, including employee stock-based compensation expense of $2.1 million.

Employee stock-based compensation expense

Total employee stock-based compensation expense related to stock-based awards for the three and nine months ended September 30, 2013 and 2012 was comprised of the following:

	Three Months Ended		Nine Months Ended	
(in thousands)	September 30, 2013	September 30, 2012	September 30, 2013	September 30, 2012
Research and development	$ 404	$ (110)	$ 1,164	$ 1,003
General and administrative	1,091	686	2,063	2,152
Total employee stock-based compensation expense	$ 1,495	$ 576	$ 3,227	$ 3,155

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Critical Accounting Policies

The preparation of our condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes in our critical accounting policies including estimates, assumptions and judgments 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 year ended December 31, 2012.

Recent Accounting Pronouncements

See Note 1 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 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 and our and our partners ability to successfully commercialize our products. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses resulting in an accumulated deficit of $303.7 million as of September 30, 2013. Our total stockholders equity was $50.0 million as of September 30, 2013, and reflects net proceeds of $48.6 million from the public offering of common stock completed in August 2013.

Three months ended September 30, 2013 compared to three months ended September 30, 2012

Revenues. Total revenues increased by $0.4 million, or 5%, to $8.7 million for the three months ended September 30, 2013 compared to $8.3 million for the three months ended September 30, 2012. Revenues for both quarterly periods include licensing revenue of $6.8 million representing amortization of deferred revenue from straight-line recognition of the up-front license fee of $200.0 million received from Novartis for Fanapt® in 2009. Revenues for the three months ended September 30, 2013 included royalty revenue of $2.0 million from Novartis based on quarterly sales of Fanapt® by Novartis compared to $1.5 million for the three months ended September 30, 2012.

Intangible asset amortization. Intangible asset amortization was $0.4 million for the three months ended September 30, 2013 and 2012. Intangible amortization relates to the capitalized intangible asset of $12.0 million resulting from the Fanapt® milestone payment to Novartis in 2009.

Research and development expenses. Research and development expenses decreased by $2.2 million, or 22%, to $8.0 million for the three months ended September 30, 2013 compared to $10.2 million for the three months ended September 30, 2012. Expenses were lower for the three months ended September 30, 2013 as a result of completion of the tasimelteon Non-24 and MDD efficacy studies, partially offset by milestone obligations of $3.5 million incurred in the three months ended September 30, 2013 as a result of the FDA acceptance of our NDA for tasimelteon for the

treatment of Non-24 in July 2013. The SET-3201 efficacy study in Non-24 was completed in the fourth quarter of 2012 and the RESET-3203 efficacy study in Non-24 and the MAGELLAN-2301 efficacy study in MDD were both completed in the first quarter of 2013.

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The following table discloses the components of research and development expenses reflecting all of our project expenses for the three months ended September 30, 2013 and 2012:

	Three Months Ended	
	September 30, 2013	September 30, 2012
(in thousands)		
Direct project costs:		
Clinical trials	$ 402	$ 6,794
Contract research and development, consulting, materials and other direct costs	5,727	1,759
Salaries, benefits and related costs	1,142	1,459
Employee stock-based compensation expense	404	(110)
Total direct costs	7,675	9,902
Indirect project costs	351	257
Total research and development expenses	$ 8,026	$ 10,159

Total direct costs decreased by $2.2 million, or 22%, to $7.7 million for the three months ended September 30, 2013 compared to $9.9 million for the three months ended September 30, 2012 reflecting lower costs as a result of the completion of the tasimelteon Non-24 and MDD efficacy studies, partially offset by milestone obligations of $3.5 million incurred in the three months ended September 30, 2013 as a result of the FDA acceptance of our NDA for tasimelteon for the treatment of Non-24 in July 2013.

Clinical trials costs decreased by $6.4 million, or 94%, to $0.4 million for the three months ended September 30, 2013 compared $6.8 million for the three months ended September 30, 2012 as a result of the completion of the tasimelteon Non-24 and MDD efficacy studies.

Contract research and development, consulting, materials and other direct costs increased by $3.9 million, or 217%, to $5.7 million for the three months ended September 30, 2013 compared to $1.8 million for the three months ended September 30, 2012 primarily as a result of milestone obligations of $3.5 million incurred in the three months ended September 30, 2013 as a result of the FDA acceptance of our NDA for tasimelteon for the treatment of Non-24 in July 2013.

Salaries, benefits and related costs decreased by $0.4 million, or 27%, to $1.1 million for the three months ended September 30, 2013 compared to $1.5 million for the three months ended September 30, 2012 as costs for three months ended September 30, 2012 included severance costs associated with the termination of our Chief Medical Officer.

Employee stock-based compensation expense increased by $0.5 million to $0.4 million for the three months ended September 30, 2013 compared to a credit of $0.1 million for the three months ended September 30, 2012. The credit for the three months ended September 30, 2012 resulted from the reversal of expense from the cancellation of equity awards due to the termination of our Chief Medical Officer.

General and administrative expenses. General and administrative expenses increased by $2.6 million, or 84%, to $5.7 million for the three months ended September 30, 2013 compared to $3.1 million for the three months ended September 30, 2012.

The following table discloses the components of our general and administrative expenses for the three months ended September 30, 2013 and 2012:

	Three Months Ended	
(in thousands)	September 30, 2013	September 30, 2012
Salaries, benefits and related costs	$ 1,263	$ 808
Employee stock-based compensation expense	1,091	686
Marketing, medical affairs, legal, accounting and other professional expenses	2,537	847
Other expenses	820	806
Total general and administrative expenses	$ 5,711	$ 3,147

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Salaries, benefits and related costs increased by $0.5 million, or 63%, to $1.3 million for the three months ended September 30, 2013 compared to $0.8 million for the three months ended September 30, 2012 primarily due to increases in our employee headcount.

Employee stock-based compensation expense increased by $0.4 million, or 57%, to $1.1 million for the three months ended September 30, 2013 compared to $0.7 million for the three months ended September 30, 2012 primarily as a result of stock-based compensation expense recorded in the three months ended September 30, 2013 related to performance-based stock options and RSUs which vested upon the FDA acceptance of our NDA for tasimelteon for the treatment of Non-24 in July 2013.

Marketing, medical affairs, legal, accounting and other professional expenses increased by $1.7 million, or 213%, to $2.5 million for the three months ended September 30, 2013 compared to $0.8 million for the three months ended September 30, 2012 primarily due to increased market development expenses associated with tasimelteon.

Nine months ended September 30, 2013 compared to nine months ended September 30, 2012

Revenues. Total revenues increased by $0.3 million, or 1%, to $25.1 million for the nine months ended September 30, 2013 compared to $24.8 million for the nine months ended September 30, 2012. Revenues for both periods includes licensing revenue of $20.0 million representing amortization of deferred revenue from straight-line recognition of the up-front license fee of $200.0 million received from Novartis for Fanapt® in 2009. Revenues for the nine months ended September 30, 2013 included royalty revenue of $5.1 million from Novartis based on year-to-date sales of Fanapt® by Novartis compared to $4.8 million for the nine months ended September 30, 2012.

Intangible asset amortization. Intangible asset amortization was $1.1 million for the nine months ended September 30, 2013 and 2012. Intangible amortization relates to the capitalized intangible asset of $12.0 million resulting from the Fanapt® milestone payment to Novartis in 2009.

Research and development expenses. Research and development expenses decreased by $12.8 million, or 37%, to $22.0 million for the nine months ended September 30, 2013 compared to $34.8 million for the nine months ended September 30, 2012. Expenses were lower for the nine months ended September 30, 2013 as a result of completion of the tasimelteon Non-24 and MDD efficacy studies partially offset by milestone obligations of $3.5 million incurred in the three months ended September 30, 2013 as a result of the FDA acceptance of our NDA for tasimelteon for the treatment of Non-24 in July 2013. The SET-3201 efficacy study in Non-24 was completed in the fourth quarter of 2012 and the RESET-3203 efficacy study in Non-24 and the MAGELLAN-2301 efficacy study in MDD were both completed in the first quarter of 2013.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the nine months ended September 30, 2013 and 2012:

	Nine Months Ended September 30, 2013	September 30, 2012
(in thousands)		
Direct project costs:		
Clinical trials	$ 6,443	$ 21,831
	9,971	6,511

Contract research and development, consulting, materials and other direct costs		
Salaries, benefits and related costs	3,431	3,740
Employee stock-based compensation expense	1,164	1,003
Total direct costs	21,009	33,085
Indirect project costs	959	1,744
Total research and development expenses	$ 21,968	$ 34,829

Total direct costs decreased by $12.1 million, or 37%, to $21.0 million for the nine months ended September 30, 2013 compared to $33.1 million for the nine months ended September 30, 2012 as a result of the completion of the tasimelteon Non-24 and MDD efficacy studies.

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Clinical trials costs decreased by $15.4 million, or 71%, to $6.4 million for the nine months ended September 30, 2013 compared $21.8 million for the nine months ended September 30, 2012 as a result of the completion of the tasimelteon Non-24 and MDD efficacy studies.

Contract research and development, consulting, materials and other direct costs increased by $3.5 million, or 54%, to $10.0 million for the nine months ended September 30, 2013 compared to $6.5 million for the nine months ended September 30, 2012 primarily as a result of milestone obligations of $3.5 million incurred in the three months ended September 30, 2013 as a result of the FDA acceptance of our NDA for tasimelteon for the treatment of Non-24 in July 2013.

Salaries, benefits and related costs decreased by $0.3 million, or 8%, to $3.4 million for the nine months ended September 30, 2013 compared to $3.7 million for the nine months ended September 30, 2012 as costs for nine months ended September 30, 2012 included severance costs associated with the termination of our Chief Medical Officer.

Employee stock-based compensation expense increased by $0.2 million, or 20%, to $1.2 million for the nine months ended September 30, 2013 compared to $1.0 million for the nine months ended September 30, 2012. Expense for the nine months ended September 30, 2012 reflects the reversal of expense from the cancellation of equity awards due to the termination of our Chief Medical Officer.

Indirect project costs decreased by $0.7 million, or 41%, to $1.0 million for the nine months ended September 30, 2013 compared to $1.7 million for the nine months ended September 30, 2012 primarily as a result of the lease exit liability and accelerated depreciation related to our former headquarters lease in Rockville, Maryland that was recognized in the nine months ended September 30, 2012.

General and administrative expenses. General and administrative expenses increased by $4.0 million, or 37%, to $14.7 million for the nine months ended September 30, 2013 compared to $10.7 million for the nine months ended September 30, 2012.

The following table discloses the components of our general and administrative expenses for the nine months ended September 30, 2013 and 2012:

	Nine Months Ended September 30,	
(in thousands)	**2013**	**September 30, 2012**
Salaries, benefits and related costs	$ 3,121	$ 2,314
Employee stock-based compensation expense	2,063	2,152
Marketing, medical affairs, legal, accounting and other professional expenses	7,271	3,589
Other expenses	2,288	2,602
Total general and administrative expenses	$ 14,743	$ 10,657

Salaries, benefits and related costs increased by $0.8 million, or 35%, to $3.1 million for the nine months ended September 30, 2013 compared to $2.3 million for the nine months ended September 30, 2012 primarily due to increases in our employee headcount.

Employee stock-based compensation expense decreased by $0.1 million, or 5%, to $2.1 million for the nine months ended September 30, 2013 compared to $2.2 million for the nine months ended September 30, 2012.

Marketing, medical affairs, legal, accounting and other professional expenses increased by $3.7 million, or 103%, to $7.3 million for the nine months ended September 30, 2013 compared to $3.6 million for the nine months ended September 30, 2012 primarily due to increased market development expenses associated with tasimelteon.

Other expenses decreased by $0.3 million, or 12%, to $2.3 million for the nine months ended September 30, 2013 compared to $2.6 million for the nine months ended September 30, 2012 primarily as a result of the lease exit liability and accelerated depreciation related to our former headquarters lease in Rockville, Maryland that was recognized in the first quarter of 2012.

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Other income. Other income decreased by $0.4 million, or 80%, to $0.1 million for the nine months ended September 30, 2013 compared to $0.5 million for the nine months ended September 30, 2012 primarily due to income from a legal settlement we recognized in the nine months ended September 30, 2012 related to a lawsuit filed against one of our stockholders. While we did not participate in the lawsuit proceedings, we received a portion of the settlement.

Liquidity and Capital Resources

In August 2013, we completed a public offering of 4,680,000 shares of common stock at a price to the public of $11.14 per share. Net cash proceeds from the public offering were $48.6 million, after deducting the underwriting discounts and commissions and offering expenses.

As of September 30, 2013, our total cash and cash equivalents and marketable securities was $142.2 million, including net proceeds from the public offering of common stock completed in August 3013, compared to $120.4 million at December 31, 2012. Our cash and cash equivalents are deposits in operating accounts and highly liquid investments with an original maturity of 90 days or less at date of purchase and consist of time deposits, investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers. Our marketable securities consist of investments in government sponsored enterprises and commercial paper.

Our liquidity resources as of September 30, 2013 and December 31, 2012 are summarized as follows:

(in thousands)	**September 30, 2013**	**December 31, 2012**
Cash and cash equivalents	$ 142,172	$ 88,772
Marketable securities:		
U.S. Treasury and government agencies		14,442
Corporate debt		17,189
Total marketable securities		31,631
Total cash and cash equivalents and marketable securities	$ 142,172	$ 120,403

As of September 30, 2013 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 continue to incur substantial expenses relating to our research and development and regulatory efforts as we pursue FDA approval of an NDA for tasimelteon in Non-24. Additionally, we expect to incur substantial expenses in preparation of a potential commercial launch of tasimelteon in Non-24. We must receive regulatory approval to launch any of our products commercially. If tasimelteon is approved by the FDA for the treatment of Non-24, we expect to incur substantial commercial expenses. In order to receive such approval, the appropriate regulatory agency must conclude that our clinical data establish safety and efficacy and that tasimelteon and the manufacturing facilities meet all applicable regulatory requirements. We cannot be certain that we will establish sufficient safety and efficacy data to receive regulatory approval for any of our products or that our products and the manufacturing facilities will

meet all applicable regulatory requirements.

Because of the uncertainties discussed above, the costs to advance our research and development projects are difficult to estimate and may vary significantly. We expect that our existing funds will be sufficient to fund our currently planned operations. Our future capital requirements and the adequacy of our available funds will depend on many factors, primarily including the scope and costs of our commercial, manufacturing and process development activities and the magnitude of our discovery, preclinical and clinical development programs.

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

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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 nine months ended September 30, 2013 and 2012:

	Nine Months Ended	
(in thousands)	**September 30, 2013**	**September 30, 2012**
Net cash provided by (used in):		
Operating activities	$ (27,439)	$ (31,068)
Investing activities	31,421	47,660
Financing activities	49,418	
Net increase in cash and cash equivalents	$ 53,400	$ 16,592

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 $27.4 million for the nine months ended September 30, 2013, a reduction of $3.7 million from net cash used in operating activities of $31.1 million for the nine months ended September 30, 2012. The decrease in net cash used for operating activities of $3.7 million resulted from a reduction in the net loss of $8.7 million which was partially offset by a reduction of $0.4 million in non-cash charges, a cash contribution of $1.8 million for tenant improvements that was received from the landlord for the nine months ended September 30, 2012, and a net reduction of $2.9 million in the working capital components that provided operating cash flow in the nine months ended September 30, 2013 and 2012.

Net cash provided by investing activities of $31.4 million for the nine months ended September 30, 2013 resulted from proceeds from maturities of marketable securities. Net cash provided by investing activities of $47.7 million for the nine months ended September 30, 2012 consisted of net purchases, sales and maturities of marketable securities of $49.7 million reduced by purchases of property and equipment.

Net cash provided by financing activities of $49.4 million for the nine months ended September 30, 2013 reflects the net proceeds of $48.6 million received from the public offering of 4,680,000 shares of common stock completed in August 2013.

Off-balance sheet arrangements

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

Contractual obligations and commitments

The following is a summary of our non-cancellable long-term contractual cash obligations as of September 30, 2013:

	Cash payments due by period						
(in thousands) (1)(2)(3)	**Total**	**Remainder of 2013**	**2014**	**2015**	**2016**	**2017**	**After 2017**
Operating leases	$ 11,007	$ 316	$ 1,052	$ 1,079	$ 1,106	$ 1,133	$ 6,321

(1) This table does not include various agreements that we have entered into for services with third party vendors, including agreements to conduct clinical trials, to manufacture product candidates, and for consulting and other contracted services due to the cancelable nature of the services. We accrued the costs of these agreements based on estimates of work completed to date.

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(2) This table does not include a milestone payment that could be due under our agreement with a regulatory consultant we have engaged to assist in our efforts to prepare, file and obtain FDA approval of the NDA for tasimelteon. We made a milestone payment of $0.5 million during the three months ended September 30, 2013 upon the acceptance of the tasimelteon NDA by the FDA in July 2013. As part of the engagement and subject to certain conditions, we could be obligated to make a milestone payment of $2.0 million in the event that the tasimelteon NDA is approved by the FDA.

(3) This table does not include milestone payments that could be due under our license agreements. Under our license agreement with Bristol-Meyers Squibb (BMS) for the exclusive rights to develop and commercialize tasimelteon, we would be obligated to make future milestone payments to BMS of up to $37.0 million in the aggregate. We made a milestone payment to BMS of $1.0 million under the license agreement in 2006 relating to the initiation of its first Phase III clinical trial for tasimelteon. We made a milestone payment of $3.0 million during the three months ended September 30, 2013 upon the acceptance of the tasimelteon NDA by the FDA in July 2013. We will incur milestone obligations of $8.0 million in the event that the tasimelteon NDA is approved by the FDA and $25.0 million in the event that sales of tasimelteon reach a certain agreed upon sales threshold. Under our license agreement with Eli Lilly and Company for the exclusive rights to develop and commercialize VLY-686, we could be obligated to make future milestone payments of up to $4.0 million for pre-NDA approval milestones and up to $95.0 million for future regulatory approval and sales milestones.

Operating leases

Our commitments related to operating leases represent the minimum annual payments for the operating lease for our headquarters located in Washington, D.C., which expires in 2023.

In July 2011, we entered into an office lease with Square 54 Office Owner LLC (the Landlord) for our current headquarters, consisting of 21,400 square feet at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. (the Lease). Under the Lease, rent payments were abated for the first 12 months. The Landlord will provide us with an allowance of $1.9 million for leasehold improvements. As of September 30, 2013, we had received the full allowance. Subject to the prior rights of other tenants in the building, we have the right to renew the Lease for five years following the expiration of its original term. We also have the right to sublease or assign all or a portion of the premises, subject to standard conditions. The Lease may be terminated early by us or the Landlord upon certain conditions.

As a result of our relocation from our former headquarters office space in Rockville, Maryland to Washington, D.C., we provided notice in the fourth quarter of 2011 to the landlord that we were terminating the Rockville lease effective June 30, 2013. As a result, we recognized an expense of $0.7 million in the year ended December 31, 2011 related to a lease termination penalty, of which $0.6 million was included as research and development expense in the consolidated statement of operations for the year ended December 31, 2011 and $0.1 million was included as general and administrative expense in the consolidated statement of operations for the year ended December 31, 2011. In the first quarter of 2012, we ceased using the Rockville, Maryland location and, as a result, recognized additional rent expense of $0.8 million, of which $0.6 million was included as research and development expense in the consolidated statement of operations for the year ended December 31, 2012 and $0.2 million was included as general and administrative expense in the consolidated statement of operations for the year ended December 31, 2012. The rent expense of $0.8 million for the year ended December 31, 2012, consisted of a lease exit liability of $1.3 million for the remaining lease payments net of the reversal of the deferred rent liability of $0.5 million related to the Rockville lease.

The following is a summary of lease exit activity for the nine months ended September 30, 2013, the year ended December 31, 2012 and the year ended December 31, 2011:

(in thousands)	Balance at Beginning of Period	Costs Incurred and Charged to Expense	Costs Paid or Otherwise Settled	Balance at End of Period
Nine months ended September 30, 2013	$ 453	$ (10)	$ 384	$ 59
Year ended December 31, 2012	740	1,220	1,507	453
Year ended December 31, 2011		740		740

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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 (Exchange Act)) as of September 30, 2013. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of September 30,2013, the end of the period covered by this quarterly report, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the third quarter of 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

On June 24, 2013, a securities class action complaint was filed in the United States District Court for the District of Columbia, naming the Company and certain of our officers as defendants. The complaint, filed on behalf of purported

stockholders of the Company, seeks to assert violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with allegedly false and misleading statements and alleged omissions regarding our Phase III trial results for tasimelteon and other disclosures between December 18, 2012 and June 18, 2013 (the Class Period). The plaintiff seeks to represent a class comprised of purchasers of our common stock during the Class Period and seeks damages, costs and expenses and such other relief as determined by the Court. A similar complaint was filed on July 8, 2013.

Our management believes that we have meritorious defenses and intends to defend this lawsuit vigorously. We do not anticipate that this litigation will have a material adverse effect on our business, results of operations or financial condition. However, this lawsuit is subject to inherent uncertainties, the actual cost may be significant, and we may not prevail. We believe we are entitled to coverage under our relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

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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 report and our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, 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

If the U.S. Food and Drug Administration (FDA) does not approve our New Drug Application (NDA) for tasimelteon for the treatment of Non-24-Hour Disorder (Non-24) or continued development of tasimelteon is significantly delayed or terminated, our business will be significantly harmed, and the market price of our stock could decline.

We commenced our Phase III program for tasimelteon for the treatment of Non-24 in the third quarter of 2010. In December 2012, we reported positive top-line results in a randomized, double-blind, multi-center, placebo-controlled Phase III trial (SET study) that enrolled 84 patients. In January 2013, we announced positive results for the second Phase III study of tasimelteon for the treatment of Non-24 (RESET study). In addition, we have two ongoing open-label safety studies for tasimelteon in treatment of Non-24. We met with the FDA in the first quarter of 2013 for a pre-NDA meeting regarding tasimelteon in the treatment of patients with Non-24 and submitted an NDA to the FDA in May 2013. In July 2013, we announced that the FDA accepted the filing and granted a priority review classification to our NDA for tasimelteon for the treatment of Non-24 in the totally blind. The FDA determined the action target date under the Prescription Drug User Fee Act (PDUFA-V) to be January 31, 2014. The FDA scheduled a Peripheral and Central Nervous System Drugs Advisory Committee meeting on November 14, 2013 for the review of our NDA for tasimelteon, proposed trade name HETLIOZ™, for the treatment of Non-24 in the totally blind. Any adverse developments or results or perceived adverse developments or results with respect to our regulatory submission, the advisory committee meeting or the tasimelteon Phase III program will significantly harm our business and could cause the market price of our stock to decline. Examples of such adverse developments include, but are not limited to:

- the FDA determining that additional clinical studies are required with respect to the Phase III program in Non-24;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in this program, or the manufacturing processes or facilities used for the program; and
- the FDA determining that the Phase III program in Non-24 raises safety concerns or does not demonstrate adequate efficacy.

We and our partners face heavy government regulation. FDA regulatory approval of our products is uncertain and 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.

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 or cGMP.

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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.

Moreover, 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.

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 Fanapt® in the U.S., Israel and Argentina, we have not received regulatory approval to market any of our products in any jurisdiction.

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

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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.

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 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.

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 2013 and beyond. As of September 30, 2013, our total cash and cash equivalents and marketable securities were $142.2 million. In August 2013, we completed a public offering of 4,680,000 shares of our common stock resulting in net proceeds to us of $48.6 million after deducting underwriting discounts and commissions and other estimated offering expenses. Our long term capital

requirements are expected to depend on many factors, including, among others:

our ability to commercialize tasimelteon globally;

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

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

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 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.

We expect to continue to receive royalty payments and hope to receive commercial and development milestone payments relating to Fanapt® in connection with our amended and restated sublicense agreement with Novartis. Based on the current sales performance of Fanapt® in the U.S. and the decision by Novartis to cease development of the long-acting injectable (or depot) formulation of Fanapt®, we expect that some or all of these commercial and development milestones will not be achieved by Novartis. 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 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.

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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 tasimelteon, 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 tasimelteon and Fanapt® are as follows:

- For tasimelteon 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-aventis (including Ambien CR®), Lunesta® (eszopiclone) by Dainippon Sumitomo Pharma, Sonata® (zaleplon) by Pfizer Inc., Silenor® (doxepin) by Somaxon Pharmaceuticals, Inc., 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 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 , by Eli Lilly and Company, Seroquel® (quetiapine) by AstraZeneca PLC, Abilify® (aripiprazole) by BMS/Otsuka Pharmaceutical Co., Ltd., Geodon® (ziprasidone) by Pfizer Inc., Saphris® (asenapine) by Schering-Plough, Latuda® (lurasidone) by Dainippon Sumitomo Pharma, and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are generic).

Additionally, we may also 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

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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, or ANDA, filed pursuant to the Hatch-Waxman Act, cheaper generic versions of our products, which may be favored by insurers and third-party payors, may be launched commercially, which would harm our business.

We have no 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 have no marketing experience, other than providing assistance to Novartis relating to the U.S. commercialization of Fanapt®. Therefore, in order for us to commercialize tasimelteon, Fanapt® (outside the U.S. and Canada) or our other products, we must either acquire or 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 Canada.

For the commercialization of tasimelteon, Fanapt® (outside the U.S. and Canada) or our other products, we may not be able to establish additional sales and distribution 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 partner. In the event that we attempt to acquire or develop our own in-house sales, marketing and distribution capabilities, 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 against companies with broader product lines; and
- unforeseen costs associated with creating our own sales and marketing team or with entering into a partnering agreement with an independent sales and marketing organization.

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

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 product revenue prior to the approval of any of our other products will depend on the success of this product in the marketplace.

Our ability to generate product revenue prior to the approval of any of our other products will depend on the success of Fanapt® and the sales of this product by Novartis in the U.S. and Canada. 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®;

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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 payers;

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®;

Novartis ability to obtain regulatory approval in Canada for Fanapt® and 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®, including a long-acting injectable (or depot) formulation of 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 product revenue prior to the approval of any of our other products 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. and the decision by Novartis to cease development of the long-acting injectable (or depot) formulation of Fanapt®, we expect that some or

all of these commercial and development milestones will not be achieved by Novartis. 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. or fails to develop and commercialize Fanapt® in Canada, 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. or Canada, we will receive limited revenues from them. Although we have developed and continue to develop additional products intended for commercial introduction, in the absence of any other approved product, our ability to generate product revenue will be dependent on sales from Fanapt® for the foreseeable future. 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 Fanapt® in May 2009 and the positive results of our completed trials for tasimelteon 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.

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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.

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. If the NDA for tasimelteon is approved, the commercial launch for tasimelteon will require substantial additional expenditures.

As of September 30, 2013, we had an accumulated deficit of $303.7 million, and we cannot estimate with precision the extent of our future losses. Our ability to generate product revenue prior to the approval of any of our other products 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. 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. or developing and commercializing Fanapt® in Canada, and we may not succeed in commercializing Fanapt® outside of

the U.S. and Canada. In addition, we may not succeed in commercializing any other products. Although the FDA is currently reviewing the NDA for tasimelteon, the product is not yet approved and may require significant resources prior to market approval. 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.

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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 tasimelteon for the treatment of Non-24, both in the U.S. and in foreign countries;
- our ability to successfully commercialize tasimelteon following the receipt of regulatory approval, if any;
- Novartis ability to successfully market and sell Fanapt® in the U.S. and Canada and achieve certain product development and sales milestones;
- 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 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.

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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, or 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 or cGLP, and similar foreign standards and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our products could be delayed.

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

Our expertise is primarily in the research and development and pre-clinical and clinical trial phases of product development. We do not have an in-house manufacturing capability and depend completely on a small number of third-party manufacturers and active pharmaceutical ingredient formulators for the manufacture of our products.

Therefore, we are dependent on third parties for our formulation development and manufacturing of our products. This may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process and provide ample commercial supplies to successfully launch and maintain the marketing of our products. Furthermore, these third party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or other unforeseeable events that may delay or limit production. Our inability to adequately establish,

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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.

We do not have long-term agreements with any of these third parties, and if they 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 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.

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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 $10.0 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.

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.

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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, or 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.

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

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

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to patent protection and enforcement, health care availability, method of delivery and payment for health care products and services or our business operations generally;
- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;
- new laws, regulations and judicial decisions affecting pricing or marketing; and
- changes in the tax laws relating to our operations.

In addition, the Food and Drug Administration Amendments Act of 2007 or the 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.

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

Our and our partners activities, including the sale and marketing of our products, are subject to extensive government regulation and oversight, including regulation under the federal Food, Drug and Cosmetic Act and other federal and state statutes. We are also subject to the provisions of the Federal Anti-Kickback Statute and several similar state laws, which prohibit payments intended to induce physicians or others either to purchase or arrange for or recommend the purchase of healthcare products or services. While the federal law applies only to products or services for which payment may be made by a federal healthcare program, state laws may apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of drugs and

biologicals, such as us, by limiting the kinds of financial arrangements, including sales programs, with hospitals, physicians, and other potential purchasers of drugs and biologicals. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance that can be substantial, including the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid).

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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.

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

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

mergers;

acquisitions;

strategic alliances;

licensing agreements; and

co-promotion and similar agreements.

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

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

Although we have no experience in acquiring businesses, we may acquire businesses or assets that complement or augment our existing business. If we acquire businesses with promising products or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to move one or more products through preclinical and/or clinical development to regulatory approval and commercialization. Integrating any newly acquired businesses or technologies could be expensive and time-consuming, resulting in the diversion of resources from our current business. We may not be able to integrate any acquired business successfully. We cannot assure you that, following an acquisition, we will achieve revenues, specific net income or loss levels that justify the acquisition or that the

acquisition will result in increased earnings, or reduced losses, for the combined company in any future period. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, which would result in dilution for stockholders or the incurrence of indebtedness and may not be available on terms which would otherwise be acceptable to us. We may not be able to operate acquired businesses profitably or otherwise implement our growth strategy successfully.

Our quarterly operating results may fluctuate significantly.

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

our addition or termination of development programs;

variations in the level of expenses related to our products or future development programs;

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our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;

the timing and amount of royalties or milestone payments;

regulatory developments affecting our products or those of our competitors;

product sales;

cost of product sales;

marketing and other expenses;

manufacturing or supply issues;

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 quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly 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. With respect to tasimelteon, these terms and conditions include an option in favor of the licensor to reacquire rights to commercialize and develop this product in certain circumstances.

Tasimelteon 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 tasimelteon in the license agreement. BMS may terminate our license if we fail to meet certain milestones or if we otherwise breach our royalty or other obligations in the agreement. In the event that we terminate our license, or if BMS terminates our license due to our breach, all of our rights to tasimelteon (including any intellectual property we develop with respect to tasimelteon) will revert back to BMS or otherwise be licensed back to BMS on an exclusive basis. Any termination or reversion of our rights to develop or commercialize tasimelteon, including any reacquisition by BMS of our rights, may have a material adverse effect on our business.

Fanapt® (iloperidone) is based in part on patents and other intellectual property owned by sanofi-aventis and Novartis. Titan Pharmaceuticals, Inc. (Titan) holds an exclusive license from sanofi-aventis to the intellectual property owned by sanofi-aventis, 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 and further develop and commercialize a long-acting injectable or depot formulation of Fanapt® in the U.S. and Canada. In October 2012, Novartis informed us that it had determined to cease development of the long-acting (or depot) formulation of Fanapt®. 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

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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.

VLY-686 is based in part on patents that we have licensed on an exclusive basis and other intellectual property licensed from 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 September 30, 2013, excluding in-licensed patents and patent applications, we had 25 patent and patent application families, most of which have been filed in key markets including the U.S., relating to tasimelteon and Fanapt®. In addition, we had eight 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 tasimelteon, and

that we continue to have rights under our license agreement with respect to this product, we would have exclusive rights to tasimelteon s U.S. new chemical entity patent (the primary patent covering the product as a new composition of matter) until 2022. 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-aventis new chemical entity patent relating to Fanapt® to November 2016. Fanapt® will also be

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eligible for 6 months of additional protection for successfully completing studies in the pediatric population potentially extending the term of the new chemical entity parent in the U.S. until May 2017. The patent for the microsphere long-acting injectable (or depot) formulation of Fanapt® expires in 2024 in the U.S. and 2022 in most of the major markets in Europe. The pending patent application for the aqueous microcrystals long acting injectable (or depot) formulation of Fanapt® will expire in 2023 in the U.S. The patent for the aqueous microcrystals long acting injectable (or depot) formulation of Fanapt® will expire in 2023 in most of the major markets in Europe. 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.

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, 2013 and September 30, 2013, the high

and low sale prices of our common stock as reported on The NASDAQ Global Market varied between $3.57 and $13.47. 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.

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

- publicity regarding actual or potential testing or trial results relating to products under development by us or our competitors;
- the outcome of regulatory review relating to products under development by us or our competitors;
- regulatory developments in the U.S. and foreign countries;
- developments concerning any collaboration or other strategic transaction we may undertake;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- termination or delay of development or commercialization program(s) by our partners;
- safety issues with our products or those of our competitors;
- our or our partners ability to successfully commercialize our products;
- our ability to successfully execute our commercialization strategies;
- announcements of technological innovations or new therapeutic products or methods by us or others;
- actual or anticipated variations in our quarterly operating results;
- changes in estimates of our financial results or recommendations by securities analysts or failure to meet such financial expectations;
- changes in government regulations or policies;
- changes in patent legislation or patent decisions or adverse changes to patent law;

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

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

publicity regarding actual or potential transactions involving us; and

economic, political and other external factors beyond our control.

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

We have been the subject of litigation in the past and may be subject to litigation in the future. In the past, following periods of volatility in the market price of their stock, many companies, including us, have been the subjects of securities class action litigation. Any such litigation can result in substantial costs and diversion of management s attention and resources and could harm our stock price, business results of operations and financial condition. As a result of these factors, holders of our common stock might be unable to sell their shares at or above the price they paid for such shares. On June 24, 2013, a securities class action complaint was filed in the United States District Court for the District of Columbia, naming the Company and certain of our officers as defendants seeking to assert violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with allegedly false and misleading

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statements and alleged omissions regarding our Phase III trial results for tasimelteon and other disclosures between December 18, 2012 and June 18, 2013. A similar complaint was filed on July 8, 2013. Our management believes that we have meritorious defenses and intends to defend these lawsuits vigorously. We do not anticipate that this litigation will have a material adverse effect on our business, results of operations or financial condition. However, the lawsuits are subject to inherent uncertainties, the actual cost may be significant, and we may not prevail. We believe we are entitled to coverage under our relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

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 September 30, 2013, there were a total of 5,381,620 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options and settlement of restricted stock unit awards granted under our Second Amended and Restated Management Equity Plan and 2006 Equity Incentive Plan. Upon the exercise of these options or settlement of the shares underlying these restricted stock units, as the case may be, in accordance with their respective terms, these shares may be resold freely, subject to restrictions imposed on our affiliates under Rule 144. If significant sales of these shares occur in short periods of time, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms, if at all.

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

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

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

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

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

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in recent 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 recent offerings, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in recent offerings.

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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 the net proceeds. They might not apply the net proceeds 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 net proceeds. You will not have the opportunity to influence our decisions on how to use the proceeds.

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;

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

limit who may call special meetings of stockholders;

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

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

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

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

The global economic downturn and market instability has made the business climate more volatile and more costly. These economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control and may make any necessary debt or equity financing more difficult, more costly, and more dilutive. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, a lingering economic downturn or significant increase in our expenses could require additional financing on less than attractive rates or on terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our stock price and could require us to delay or abandon clinical development plans.

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

In addition, we rely on third parties for several important aspects of our business. For example, we depend upon Novartis for Fanapt® royalty revenue, we use third party contract research organizations for many of our clinical trials, 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 September 30, 2013 formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) Condensed Consolidated Balance Sheets as of September 30, 2013 and December 31, 2012; (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2013 and 2012; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three and nine months ended September 30, 2013 and 2012; (iv) Condensed Consolidated Statement of Changes in Stockholders Equity for the nine months ended September 30, 2013; (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2013 and 2012; 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.

November 8, 2013 /s/ Mihael H. Polymeropoulos, M.D.
Mihael H. Polymeropoulos, M.D.

President and Chief Executive Officer

(Principal Executive Officer)

November 8, 2013 /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.

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