Vanda Pharmaceuticals Inc.
Form 10-Q
July 31, 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 June 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 July 26, 2013, there were 28,483,231 shares of the registrant s common stock issued and outstanding.

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Quarterly Report on Form 10-Q

For the Quarter Ended June 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)	June 30, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 103,633	$ 88,772
Marketable securities		31,631
Accounts receivable	1,641	1,168
Prepaid expenses and other current assets	2,651	3,967
Restricted cash, current	430	430
Total current assets	108,355	125,968
Property and equipment, net	2,208	2,348
Intangible asset, net	5,791	6,532
Restricted cash, non-current	600	600
Total assets	$ 116,954	$ 135,448
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,167	$ 287
Accrued liabilities	3,770	5,187
Deferred rent, current	209	
Deferred revenue, current	26,789	26,789
Total current liabilities	31,935	32,263
Deferred rent, non-current	3,002	3,005
Deferred revenue, non-current	76,991	90,275
Total liabilities	111,928	125,543
Commitments and contingencies (Notes 10 and 12)		
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; 28,483,231 and 28,241,743 shares issued and outstanding as of June 30, 2013 and December 31, 2012, respectively	28	28
Additional paid-in capital	303,357	300,974
Accumulated other comprehensive income		10
Accumulated deficit	(298,359)	(291,107)
Total stockholders equity	5,026	9,905
Total liabilities and stockholders equity	$ 116,954	$ 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)

	Three Months Ended		Six Months Ended	
(in thousands, except for share and per share amounts)	**June 30, 2013**	**June 30, 2012**	**June 30, 2013**	**June 30, 2012**
Revenues:				
Licensing agreement	$ 6,678	$ 6,678	$ 13,284	$ 13,284
Royalty revenue	1,641	1,700	3,103	3,235
Total revenues	8,319	8,378	16,387	16,519
Operating expenses:				
Research and development	5,982	12,490	13,942	24,670
General and administrative	5,074	3,601	9,032	7,510
Intangible asset amortization	372	372	741	741
Total operating expenses	11,428	16,463	23,715	32,921
Loss from operations	(3,109)	(8,085)	(7,328)	(16,402)
Other income	30	78	76	433
Loss before tax benefit	(3,079)	(8,007)	(7,252)	(15,969)
Tax benefit				
Net loss	$ (3,079)	$ (8,007)	$ (7,252)	$ (15,969)
Net loss per share:				
Basic	$ (0.11)	$ (0.28)	$ (0.26)	$ (0.57)
Diluted	$ (0.11)	$ (0.28)	$ (0.26)	$ (0.57)
Shares used in calculations of net loss per share:				
Basic	28,377,254	28,226,743	28,361,340	28,226,743
Diluted	28,377,254	28,226,743	28,361,340	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)

	Three Months Ended		Six Months Ended	
(in thousands)	**June 30, 2013**	**June 30, 2012**	**June 30, 2013**	**June 30, 2012**
Net loss	$ (3,079)	$ (8,007)	$ (7,252)	$ (15,969)
Other comprehensive loss:				
Change in net unrealized loss on marketable securities		(22)	(10)	(16)
Tax provision on other comprehensive loss				
Other comprehensive loss, net of tax		(22)	(10)	(16)
Comprehensive loss	$ (3,079)	$ (8,029)	$ (7,262)	$ (15,985)

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	Common Stock 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
Issuance of common stock from the exercise of stock options and settlement of restricted stock units	291,008		797			797
Shares withheld upon settlement of restricted stock units	(49,520)		(196)			(196)
Employee and non-employee stock-based compensation expense			1,782			1,782
Net loss					(7,252)	(7,252)
Other comprehensive loss, net of tax				(10)		(10)
Balances at June 30, 2013	28,483,231	$ 28	$ 303,357	$	$ (298,359)	$ 5,026

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)

	Six Months Ended	
(in thousands)	**June 30, 2013**	**June 30, 2012**
Cash flows from operating activities		
Net loss	$ (7,252)	$ (15,969)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	212	424
Employee and non-employee stock-based compensation expense	1,782	2,595
Amortization of discounts and premiums on marketable securities	121	282
Amortization of intangible asset	741	741
Landlord contributions for tenant improvements		1,825
Changes in assets and liabilities:		
Accounts receivable	(473)	(82)
Prepaid expenses and other assets	1,316	(505)
Accounts payable	880	693
Accrued liabilities	(1,417)	2,527
Other liabilities	206	(151)
Deferred revenue	(13,284)	(13,284)
Net cash used in operating activities	(17,168)	(20,904)
Cash flows from investing activities		
Purchases of property and equipment	(72)	(1,993)
Purchases of marketable securities		(49,967)
Proceeds from sales of marketable securities		1,998
Maturities of marketable securities	31,500	77,331
Net cash provided by investing activities	31,428	27,369
Cash flows from financing activities		
Tax obligations paid in connection with settlement of restricted stock units	(196)	
Proceeds from exercise of stock options	797	
Net cash provided by financing activities	601	
Net increase in cash and cash equivalents	14,861	6,465
Cash and cash equivalents		
Beginning of period	88,772	87,923
End of period	$ 103,633	$ 94,388

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 compound for the treatment of circadian rhythm sleep disorders, which is currently in clinical development for Non-24-Hour Disorder (Non-24) and has not been approved by the U.S. Food and Drug Administration (FDA), Fanapt®, a compound 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.

Vanda refers to tasimelteon, Fanapt® outside the U.S. and Canada and VLY-686 as its products and Fanapt® within the U.S. and Canada as its partnered product. All other compounds are referred to as Vanda s product candidates. In addition, Vanda refers to its products, partnered products and product candidates collectively as its compounds. Moreover, Vanda refers to drug products generally as drugs or products.

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 June 30, 2013 and for the three and six months ended June 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 RSUs, but only to the extent that their inclusion is dilutive.

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

	Three Months Ended		Six Months Ended	
(in thousands, except for share and per share amounts)	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012
Numerator:				
Net loss	$ (3,079)	$ (8,007)	$ (7,252)	$ (15,969)
Denominator:				
Weighted average shares of common stock outstanding, basic	28,377,254	28,226,743	28,361,340	28,226,743
Stock options and restricted stock units related to the issuance of common stock				
Weighted average shares of common stock outstanding, diluted	28,377,254	28,226,743	28,361,340	28,226,743
Net loss per share:				
Basic	$ (0.11)	$ (0.28)	$ (0.26)	$ (0.57)
Diluted	$ (0.11)	$ (0.28)	$ (0.26)	$ (0.57)
Anti-dilutive securities excluded from calculations of diluted net loss per share:				
Stock options and restricted stock units	4,118,184	5,199,705	4,934,432	5,201,746

The Company incurred net losses for the three and six months ended June 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 June 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 Marketable securities classified in Level 1 and Level 2 at December 31, 2012 consist of available-for-sale marketable securities. The Company did not hold any marketable securities as of June 30, 2013. 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.

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As of June 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 June 30, 2013 and December 31, 2012:

(in thousands)	June 30, 2013	December 31, 2012
Prepaid insurance	$ 432	$ 155
Other prepaid expenses and vendor advances	2,131	3,479
Inventory	28	57
Accrued interest income	60	276
Total prepaid expenses and other current assets	$ 2,651	$ 3,967

6. Intangible Asset

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

		June 30, 2013		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	8	$ 12,000	$ 6,209	$ 5,791

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 June 30, 2013 and 2012 and $0.7 million for the six months ended June 30, 2013 and 2012. The Company capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanapt®.

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

(in thousands)	Total	Remainder of 2013	2014	2015	2016	2017
Intangible asset	$ 5,791	$ 754	$ 1,495	$ 1,495	$ 1,495	$ 552

7. Accrued Liabilities

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

(in thousands)	June 30, 2013	December 31, 2012
Accrued research and development expenses	$ 1,598	$ 3,900
Accrued consulting and other professional fees	1,120	386
Compensation and employee benefits	956	127
Accrued lease exit liability (refer to note 10)	59	453
Other accrued expenses	37	321
Total accrued liabilities	$ 3,770	$ 5,187

8. Deferred Revenue

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

(in thousands)	Balance at Beginning of Period	Reduction from Licensing Revenue Recognized	Balance at End of Period
Six months ended June 30, 2013	$ 117,064	$ 13,284	$ 103,780

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

(in thousands)	Balance at Beginning of Period	Reduction from Licensing Revenue Recognized	Balance at End of Period
Six months ended June 30, 2012	$ 143,853	$ 13,284	$ 130,569

Vanda 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, Vanda 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 June 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.

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10. Commitments and Contingencies

Operating leases

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

		Cash payments due by period					
(in thousands)	**Total**	**Remainder of 2013**	**2014**	**2015**	**2016**	**2017**	**After 2017**
Operating leases	$ 11,265	$ 574	$ 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 June 30, 2013, the Company had received $1.8 million of the 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 $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 six months ended June 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**
Six months ended June 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 June 30, 2013 and 2012, respectively. Rent expense under operating leases, including lease exit costs, was $0.5 million and $1.6 million for the six months ended June 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 part of the engagement and subject to certain conditions, the Company would be obligated to make milestone payments upon the achievement of certain milestones, including $0.5 million in the event that the tasimelteon NDA is accepted for filing by the FDA and $2.0 million in the event that 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 will remain obligated to make

some or all of the milestone payments if the milestones are 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

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future payments the Company could be required to make under these indemnification agreements is unlimited. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain conditions. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

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 less than $40.0 million in the aggregate (the majority of which are tied to sales milestones). Under the license agreement, the Company will incur milestone obligations of $3.0 million in the event that a tasimelteon NDA is accepted for filing by the FDA and $8.0 million in the event that a tasimelteon NDA is approved by the FDA in the future. 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 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 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 by the earliest of: (i) the date mutually agreed upon by both parties following the provision by the Company to BMS of a full written report of the Phase III clinical studies on which the Company intends to rely for filing for marketing authorization for tasimelteon in its first major market country (such report, being referred to as the Phase III report); (ii) the date of the acceptance by a regulatory authority of the filing by the Company for marketing authorization for tasimelteon in a major market country following the provision by the Company to BMS of the Phase III report; or (iii) December 31, 2013. If the Company had not entered into such an agreement with respect to certain major market countries by this deadline, then BMS will have 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 by providing the Company with written notice that it does not wish to develop and commercialize tasimelteon itself in those countries. 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 compound. 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

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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 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.

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 three and six months ended June 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 contractual obligations relating to the license agreements included in the consolidated financial statements as of June 30, 2013 because the criteria for recording these 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. 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 restricted stock units (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 six months ended June 30, 2013 and 2012 was comprised of the following:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012
Research and development	$ 328	$ 520	$ 760	$ 1,113
General and administrative	460	668	972	1,466
Total employee stock-based compensation expense	$ 788	$ 1,188	$ 1,732	$ 2,579

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 provided 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 six months ended June 30, 2013 and 2012 were as follows:

	Six Months Ended	
	June 30, 2013	June 30, 2012
Expected dividend yield	%	%
Weighted average expected volatility	62%	68%
Weighted average expected term (years)	6.03	6.03
Weighted average risk-free rate	1.16%	1.08%
Weighted average fair value per share	$ 3.46	$ 2.75

As of June 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 June 30, 2013, and no additional options will be granted under this plan. As of June 30, 2013, there were 8,995,930 shares of common stock reserved for issuance under the 2006 Plan, of which 5,321,286 shares were subject to outstanding options and RSUs granted to employees and non-employees and 2,301,263 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

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in equal installments thereafter over three years. Certain service option awards granted to existing employees after December 31, 2006 vest and become exercisable monthly in equal installments over four years. The initial service option awards granted to directors upon their election vest and become exercisable in equal monthly installments over a period of four years, while the subsequent annual service option awards granted to directors vest and become exercisable in equal monthly installments over a period of one year. Certain service option awards to executives and directors provide for accelerated vesting if there is a change in control of the Company. Certain service option awards to employees and executives provide for accelerated vesting if the respective employee s or executive s service is terminated by the Company for any reason other than cause or permanent disability. As of June 30, 2013, there were 151,250 performance option awards outstanding. The performance option awards are subject to the same terms and conditions as option awards with the exception of their vesting requirements. The performance option awards vest upon the acceptance by the FDA of the Company s NDA for tasimelteon in the treatment of Non-24 (the Vesting Event), provided that the employee remains continuously employed through the Vesting Event. As of June 30, 2013, there was $2.4 million of unrecognized compensation costs related to unvested service option awards expected to be recognized over a weighted average period of 1.5 years and $0.3 million of unrecognized compensation costs related to unvested performance option awards expected to be recognized over the remaining service period beginning in the period the Company determines the performance goal is probable of achievement. Since the Company s management has not yet determined the goal is probable of achievement, no compensation expense has been recognized for the performance option awards. None of the service option awards or performance option awards are classified as a liability as of June 30, 2013.

A summary of option activity for the 2004 Plan for the six months ended June 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		6
Outstanding at June 30, 2013	670,744	1.79	2.28	4,219
Exercisable at June 30, 2013	670,744	1.79	2.28	4,219

A summary of option activity for the 2006 Plan for the six months ended June 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	286,500	6.07		
Forfeited	(50,533)	6.35		
Expired	(245,447)	10.50		
Exercised	(137,286)	5.77		793
Outstanding at June 30, 2013	4,718,721	10.76	6.85	7,963
Exercisable at June 30, 2013	3,059,580	13.79	5.76	2,865

Proceeds from the exercise of stock options amounted to $0.8 million for the six months ended June 30, 2013.

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. As of June 30, 2013, there were 48,750 performance RSUs

outstanding. The performance RSUs are subject to the same terms and conditions as service RSUs with the exception of their vesting requirements. The performance RSUs vest upon the Vesting Event, provided that the employee remains continuously employed through the Vesting Event. As of June 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 1.6 years and $0.2 million of unrecognized compensation costs related to unvested performance RSUs expected to be recognized over the remaining service period beginning in the period the Company determines the performance goal is probable of achievement. Since the Company s management has not yet determined the goal is probable of achievement no compensation expense has been recognized for the performance RSU awards. None of the service RSUs or performance RSUs are classified as a liability as of June 30, 2013.

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

	Number of Shares Underlying RSUs	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2012	705,376	$ 5.91
Granted	69,000	5.09
Forfeited	(19,375)	6.66
Vested	(152,436)	7.86
Outstanding at June 30, 2013	602,565	5.30

The fair value of 152,436 shares of common stock underlying RSUs that vested and settled was $0.6 million for the six months ended June 30, 2013. In order for certain employees to satisfy the minimum statutory employee tax withholding requirements related to the issuance of common stock underlying RSUs that vested and settled during the six months ended June 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.

12. 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.

13. Subsequent Event

In July 2013, the Company announced that the FDA accepted the filing of and granted a priority review classification to Vanda s NDA for tasimelteon for the treatment of Non-24 in the totally blind. The FDA determined the action target date under Prescription Drug User Fee Act (PDUFA-V) to be January 31, 2014. The FDA has also tentatively scheduled an advisory committee meeting to discuss the tasimelteon application on November 14, 2013. As a result of achieving this regulatory milestone, the Company will incur certain costs in the third quarter of 2013 including a $3.0 million cash milestone obligation under its license agreement with BMS, a $0.5 million cash milestone obligation under a regulatory consulting agreement and additional non-cash stock-based compensation expense of $0.3 million for performance-based stock options and $0.2 million for performance-based RSUs awards.

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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, would, and could, or the negative of these terms and similar expressions or words, forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in our forward-looking statements include, among others:

- the failure to obtain, or any delay in obtaining, regulatory approval for our products or product candidates, particularly tasimelteon for the treatment of Non-24-Hour Disorder (Non-24), or to comply with ongoing regulatory requirements;
- a loss of rights to develop and commercialize our products, product candidates or partnered products under our license and sublicense agreements;
- our failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage our growth;
- our ability to successfully commercialize tasimelteon following the receipt of regulatory approval, if any;
- the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives;
- our ability 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, product candidates or partnered product to be demonstrably safe and effective;
- a lack of acceptance of our products, product candidates or partnered product in the marketplace, or a failure to become or remain profitable;
- our expectations regarding trends with respect to our revenues, costs, expenses and liabilities;
- our inability to obtain the capital necessary to fund our research and development or commercial activities;
- the cost and effects of current or potential litigation;
- our failure to identify or obtain rights to new products or product candidates;

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

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

losses incurred from product liability claims made against us.

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

We encourage you to read Management s Discussion and Analysis of Financial Condition and Results of Operations as well as our unaudited condensed consolidated financial statements contained in this quarterly report on Form 10-Q. We also encourage you to read Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2012, which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of Part I of our annual report on Form 10-K for the year ended December 31, 2012, other unknown or unpredictable factors also could affect our results. Therefore, the information in this report should be read together with other reports and documents that we file with the Securities and Exchange Commission (SEC) from time to time, including Forms 10-Q, 8-K and 10-K, which may supplement, modify, supersede or update those risk factors. There can be no assurance that the actual results or developments

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anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

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, product candidates and partnered products will address a large market with significant unmet medical needs. Our product portfolio includes tasimelteon, a compound for the treatment of circadian rhythm sleep disorders, which is currently in clinical development for the treatment of Non-24 and has not been approved by the U.S. Food and Drug Administration (FDA), Fanapt® (iloperidone), a compound 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. We held a pre-NDA meeting with the FDA s Division of Neurology Products in the first quarter of 2013 to discuss the regulatory filing path for a New Drug Application (NDA) for tasimelteon in the treatment of patients with Non-24. At the pre-NDA meeting, the FDA confirmed that the efficacy and safety data that we proposed to submit in the tasimelteon NDA for the treatment of Non-24 was adequate to support filing. The NDA supporting package that included data from clinical pharmacology, pre-clinical pharmacology program, chemistry and manufacturing was also deemed adequate to support filing. 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 of 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 Prescription Drug User Fee Act (PDUFA-V) to be January 31, 2014. The FDA has also tentatively scheduled an advisory committee meeting to discuss the tasimelteon application on November 14, 2013. As a result of achieving this regulatory milestone, we will incur certain costs in the third quarter of 2013 including a $3.0 million cash milestone obligation under our license agreement with BMS, a $0.5 million cash milestone obligation under a regulatory consulting agreement and additional non-cash stock-based compensation expense of $0.3 million for performance-based stock options and $0.2 million for performance-based RSUs 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 $12.3 million in research and development costs for the six months ended June 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 we withdrew our Marketing Authorization Application in the first quarter of 2013 because the additional clinical data requested by the CHMP will not be available in the timeframe allowed by the EMA s Centralized Procedure. We 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 $0.3 million in research and development costs for the six months ended June 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 $0.8 million in research and development costs for the six months ended June 30, 2013 directly attributable to our development of VLY-686.

Since we began our operations in 2003, we have devoted substantially all of our resources to the in-licensing and clinical development of our compounds. Our ability to generate additional revenues largely depends upon our ability, alone or with others, to complete the development of our products or product candidates to obtain the regulatory approvals for and to manufacture, market and sell our products and product candidates and on 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 and industry, risks relating to intellectual property and other legal matters, risks related to our common stock, and other risks which are detailed in Risk Factors reported in Item 1A of Part I of our annual report on Form 10-K for the year ended December 31, 2012.

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

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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, 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 compounds 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 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 $13.9 million for the six months ended June 30, 2013 including employee stock-based compensation expense of $0.8 million. Milestone payments relating to research and development activities are accrued when it is deemed probable that the milestone event will be achieved. Upon FDA acceptance of an NDA filing for tasimelteon, we will be obligated to make milestone payments of $0.5 million under a regulatory consulting agreement and $3.0 million under the license agreement for tasimelteon. Upon and subsequent to FDA approval, manufacturing and milestone payments are capitalized. In the event that a tasimelteon NDA is approved by the FDA in the future, we will be obligated to make milestone payments of $2.0 million under a regulatory consulting agreement and $8.0 million under the license agreement for tasimelteon. 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, product candidates and partnered product and to evaluate potential in-license product candidates or compounds.

The following table summarizes the costs of our product development initiatives for the three and six months ended June 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		Six Months Ended	
(in thousands)	**June 30, 2013**	**June 30, 2012**	**June 30, 2013**	**June 30, 2012**
Direct project costs: (1)				
Tasimelteon	$ 5,020	$ 10,917	$ 12,270	$ 21,419
Fanapt®	109	318	293	750
VLY-686	519	1,014	771	1,014
Total direct project costs	5,648	12,249	13,334	23,183
Indirect project costs: (1)				
Facility	191	105	313	1,102
Depreciation	58	53	114	238
Other indirect overhead	85	83	181	147
Total indirect project costs	334	241	608	1,487
Total research and development expenses	$ 5,982	$ 12,490	$ 13,942	$ 24,670

(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.

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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 $9.0 million for the six months ended June 30, 2013, including employee stock-based compensation expense of $1.0 million.

Employee stock-based compensation expense

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

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012
Research and development	$ 328	$ 520	$ 760	$ 1,113
General and administrative	460	668	972	1,466
Total employee stock-based compensation expense	$ 788	$ 1,188	$ 1,732	$ 2,579

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, product candidates and partnered product. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses. As of June 30, 2013, our total stockholders equity was $5.0 million, including an accumulated deficit of $298.4 million.

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

Revenues. Total revenues decreased by $0.1 million, or 1%, to $8.3 million for the three months ended June 30, 2013 compared to $8.4 million for the three months ended June 30, 2012. Revenues for both quarterly periods includes licensing revenue of $6.7 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 June 30, 2013 included royalty revenue of $1.6 million from Novartis based on quarterly sales of Fanapt® by Novartis compared to $1.7 million for the three months ended June 30, 2012.

Intangible asset amortization. Intangible asset amortization was $0.4 million for the three months ended June 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 $6.5 million, or 52%, to $6.0 million for the three months ended June 30, 2013 compared to $12.5 million for the three months ended June 30, 2012. The primary driver of the lower expenses in the three month ended June 30, 2013 was the completion of the tasimelteon Non-24 and MDD efficacy studies. 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 June 30, 2013 and 2012:

	Three Months Ended	
	June 30, 2013	June 30, 2012
(in thousands)		
Direct project costs:		
Clinical trials	$ 2,184	$ 7,830
Contract research and development, consulting, materials and other direct costs	1,972	2,819
Salaries, benefits and related costs	1,164	1,080
Employee stock-based compensation expense	328	520
Total direct costs	5,648	12,249
Indirect project costs	334	241
Total research and development expenses	$ 5,982	$ 12,490

Total direct costs decreased by $6.6 million, or 54%, to $5.6 million for the three months ended June 30, 2013 compared to $12.2 million for the three months ended June 30, 2012 as a result of the completion of the tasimelteon Non-24 and MDD efficacy studies.

Clinical trials costs decreased by $5.6 million, or 72%, to $2.2 million for the three months ended June 30, 2013 compared $7.8 million for the three months ended June 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 decreased by $0.8 million, or 29%, to $2.0 million for the three months ended June 30, 2013 compared to $2.8 million for the three months ended June 30, 2012 as a result of the completion of the tasimelteon Non-24 and MDD efficacy studies, partially offset by costs related to the May 2013 submission of an NDA to the FDA for tasimelteon for the treatment of Non-24.

Salaries, benefits and related costs increased by $0.1 million, or 9%, to $1.2 million for the three months ended June 30, 2013 compared to $1.1 million for the three months ended June 30, 2012 as research and development staffing levels remained consistent.

Employee stock-based compensation expense decreased by $0.2 million, or 40%, to $0.3 million for the three months ended June 30, 2013 compared to $0.5 million for the three months ended June 30, 2012 primarily as a result of a lower fair value of equity awards granted during 2012 and 2013 compared to equity awards granted in prior years.

Indirect project costs increased by $0.1 million, or 50%, to $0.3 million for the three months ended June 30, 2013 compared to $0.2 million for the three months ended June 30, 2012 as a result of increased facility expenses.

General and administrative expenses. General and administrative expenses increased by $1.5 million, or 42%, to $5.1 million for the three months ended June 30, 2013 compared to $3.6 million for the three months ended June 30, 2012.

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

	Three Months Ended	
	June 30, 2013	June 30, 2012
(in thousands)		
Salaries, benefits and related costs	$ 914	$ 777
Employee stock-based compensation expense	460	668
Marketing, medical affairs, legal, accounting and other professional expenses	2,849	1,444
Other expenses	851	712

Total general and administrative expenses	$ 5,074	$ 3,601

Salaries, benefits and related costs increased by $0.1 million, or 13%, to $0.9 million for the three months ended June 30, 2013 compared to $0.8 million for the three months ended June 30, 2012 primarily due to increases in our employee headcount in 2012 and 2013.

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Employee stock-based compensation expense decreased by $0.2 million, or 29%, to $0.5 million for the three months ended June 30, 2013 compared to $0.7 million for the three months ended June 30, 2012 primarily as a result of a lower fair value of equity awards granted during 2012 and 2013 compared to equity awards granted in prior years.

Marketing, medical affairs, legal, accounting and other professional expenses increased by $1.4 million, or 100%, to $2.8 million for the three months ended June 30, 2013 compared to $1.4 million for the three months ended June 30, 2012 primarily due to increased market development expenses associated with tasimelteon and increased legal costs associated with developing Fanapt® outside the U.S. and Canada.

Other expenses increased by $0.2 million, or 29%, to $0.9 million for the three months ended June 30, 2013 compared to $0.7 million for the three months ended June 30, 2012 primarily due to increased overhead costs tied to the increase in our employee headcount in 2012 and 2013.

Six months ended June 30, 2013 compared to six months ended June 30, 2012

Revenues. Total revenues decreased by $0.1 million, or 1%, to $16.4 million for the six months ended June 30, 2013 compared to $16.5 million for the six months ended June 30, 2012. Revenues for both periods includes licensing revenue of $13.3 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 six months ended June 30, 2013 included royalty revenue of $3.1 million from Novartis based on year-to-date sales of Fanapt® by Novartis compared to $3.2 million for the six months ended June 30, 2012.

Intangible asset amortization. Intangible asset amortization was $0.7 million for the six months ended June 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 $10.8 million, or 44%, to $13.9 million for the six months ended June 30, 2013 compared to $24.7 million for the six months ended June 30, 2012. The primary driver of the lower expenses in the six months ended June 30, 2013 was the completion of the tasimelteon Non-24 and MDD efficacy studies. 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 six months ended June 30, 2013 and 2012:

	Six Months Ended	
	June 30, 2013	**June 30, 2012**
(in thousands)		
Direct project costs:		
Clinical trials	$ 6,041	$ 15,037
Contract research and development, consulting, materials and other direct costs	4,244	4,752
Salaries, benefits and related costs	2,289	2,281
Employee stock-based compensation expense	760	1,113
Total direct costs	13,334	23,183
Indirect project costs	608	1,487
Total research and development expenses	$ 13,942	$ 24,670

Total direct costs decreased by $9.9 million, or 43%, to $13.3 million for the six months ended June 30, 2013 compared to $23.2 million for the six months ended June 30, 2012 as a result of the completion of the tasimelteon Non-24 and MDD efficacy studies.

Clinical trials costs decreased by $9.0 million, or 60%, to $6.0 million for the six months ended June 30, 2013 compared $15.0 million for the six months ended June 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 decreased by $0.6 million, or 13%, to $4.2 million for the six months ended June 30, 2013 compared to $4.8 million for the six months ended June 30, 2012 as a result of the completion of the tasimelteon Non-24 and MDD efficacy studies, partially offset by costs related to the May 2013 submission of an NDA to the FDA for tasimelteon for the treatment of Non-24.

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Salaries, benefits and related costs remained consistent between the six months ended June 30, 2013 and the six months ended June 30, 2012 as research and development staffing levels remained consistent.

Employee stock-based compensation expense decreased by $0.3 million, or 27%, to $0.8 million for the six months ended June 30, 2013 compared to $1.1 million for the six months ended June 30, 2012 primarily as a result of a lower fair value of equity awards granted during 2012 and 2013 compared to equity awards granted in prior years.

Indirect project costs decreased by $0.9 million, or 60%, to $0.6 million for the six months ended June 30, 2013 compared to $1.5 million for the six months ended June 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 six months ended June 30, 2012.

General and administrative expenses. General and administrative expenses increased by $1.5 million, or 20%, to $9.0 million for the six months ended June 30, 2013 compared to $7.5 million for the six months ended June 30, 2012.

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

	Six Months Ended	
(in thousands)	**June 30, 2013**	**June 30, 2012**
Salaries, benefits and related costs	$ 1,858	$ 1,506
Employee stock-based compensation expense	972	1,466
Marketing, medical affairs, legal, accounting and other professional expenses	4,734	2,742
Other expenses	1,468	1,796
Total general and administrative expenses	$ 9,032	$ 7,510

Salaries, benefits and related costs increased by $0.4 million, or 27%, to $1.9 million for the six months ended June 30, 2013 compared to $1.5 million for the six months ended June 30, 2012 primarily due to new hires in 2012 and 2013.

Employee stock-based compensation expense decreased by $0.5 million, or 33%, to $1.0 million for the six months ended June 30, 2013 compared to $1.5 million for the six months ended June 30, 2012 primarily as a result of a lower fair value of equity awards granted during 2012 and 2013 compared to equity awards granted in prior years.

Marketing, medical affairs, legal, accounting and other professional expenses increased by $2.0 million, or 74%, to $4.7 million for the six months ended June 30, 2013 compared to $2.7 million for the six months ended June 30, 2012 primarily due to increased market development expenses associated with tasimelteon and increased legal costs associated with developing Fanapt® outside the U.S. and Canada.

Other expenses decreased by $0.3 million, or 17%, to $1.5 million for the six months ended June 30, 2013 compared to $1.8 million for the six months ended June 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.

Other income. Other income decreased by $0.3 million, or 75%, to $0.1 million for the six months ended June 30, 2013 compared to $0.4 million for the six months ended June 30, 2012 primarily due to income from a legal settlement we recognized in the six months ended June 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

As of June 30, 2013, our total cash and cash equivalents and marketable securities were $103.6 million 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.

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

(in thousands)	June 30, 2013	December 31, 2012
Cash and cash equivalents	$ 103,633	$ 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	$ 103,633	$ 120,403

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

Cash Flow

The following table summarizes our cash flows for the six months ended June 30, 2013 and 2012:

	Six Months Ended	
(in thousands)	June 30, 2013	June 30, 2012
Net cash provided by (used in):		
Operating activities	$ (17,168)	$ (20,904)
Investing activities	31,428	27,369
Financing activities	601	
Net increase in cash and cash equivalents	$ 14,861	$ 6,465

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, net change in deferred revenue, 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 $17.2 million for the six months ended June 30, 2013, a reduction of $3.7 million from net cash used in operating activities of $20.9 million for the six months ended June 30, 2012. The decrease in net cash used for operating activities of $3.7 million resulted from the reduction in the net loss of $8.7 million which was offset by a reduction of $1.2 million in non-cash charges primarily from lower stock-based compensation expense, a cash contribution of $1.8 million for tenant improvements that was received from the landlord in the six months ended June 30, 2012, and a net reduction of $2.0 million in the working capital components that had provided cash flow in the six months ended June 30, 2013 and June 30, 2012.

Net cash provided by investing activities for the six months ended June 30, 2013 and June 30, 2012 was $31.4 million and $27.4 million, respectively, and consisted of net purchases, sales and maturities of marketable securities reduced by purchases of property and equipment.

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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 June 30, 2013:

		Cash payments due by period					
(in thousands) **(1)(2)(3)**	**Total**	**Remainder of 2013**	**2014**	**2015**	**2016**	**2017**	**After 2017**
Operating leases	$ 11,265	$ 574	$ 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.

(2) This table does not include milestone payments 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 an NDA for tasimelteon. As part of the engagement and subject to certain conditions, we could be obligated to make milestone payments upon the achievement of certain milestones, including $0.5 million in the event that the tasimelteon NDA is accepted for filing by the FDA and $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 less than $40.0 million in the aggregate (the majority of which are tied to sales milestones). Under the license agreement, we will incur milestone obligations of $3.0 million in the event that a tasimelteon NDA is accepted for filing by the FDA and $8.0 million in the event that a tasimelteon NDA is approved by the FDA in the future. 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 June 30, 2013, we had received $1.8 million of the 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

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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 six months ended June 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
Six months ended June 30, 2013	$ 453	$ (10)	$ 384	$ 59
Year ended December 31, 2012	740	1,220	1,507	453
Year ended December 31, 2011		740		740

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 June 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 June 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 second 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.

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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.

Item 1A. Risk Factors.

In our annual report on Form 10-K for the year ended December 31, 2012, we identify under Part I, Item 1A important factors which could affect our business, financial condition, results of operations and future operations and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this quarterly report on Form 10-Q. There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the year ended December 31, 2012.

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
10.50	Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of April 25, 2013, by and between the Registrant and Bristol-Myers Squibb Company (filed as Exhibit 10.50 to the registrant s current report on Form 8-K filed on April 29, 2013 and incorporated herein by reference).
10.51	Employment Agreement, dated as of April 15, 2013, by and between the Registrant and Paolo Baroldi.
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2013 formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) Condensed Consolidated Balance Sheets as of June 30, 2013 and December 31, 2012; (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2013 and 2012; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three and six months ended June 30, 2013 and 2012; (iv) Condensed Consolidated Statement of Changes in Stockholders Equity for the six months ended June 30, 2013; (v) Condensed Consolidated Statements of Cash Flows for the six months ended June 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.

July 31, 2013 /s/ Mihael H. Polymeropoulos, M.D.
Mihael H. Polymeropoulos, M.D.

President and Chief Executive Officer

(Principal Executive Officer)

July 31, 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.

EXHIBIT INDEX

Exhibit Number	Description
10.50	Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of April 25, 2013, by and between the Registrant and Bristol-Myers Squibb Company (filed as Exhibit 10.50 to the registrant s current report on Form 8-K filed on April 29, 2013 and incorporated herein by reference).
10.51	Employment Agreement, dated as of April 15, 2013, by and between the Registrant and Paolo Baroldi.
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.
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