Vanda Pharmaceuticals Inc.
Form 10-Q
November 08, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2012

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 November 5, 2012, there were 28,226,743 shares of the registrant s common stock issued and outstanding.

Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q

For the Quarter Ended September 30, 2012

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Part I FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except for share and per share amounts)	September 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 104,515	$ 87,923
Marketable securities, current	29,889	60,961
Accounts receivable	1,535	1,618
Inventory	161	
Prepaid expenses and other current assets	3,323	2,999
Restricted cash, current	430	
Total current assets	139,853	153,501
Marketable securities, non-current		19,012
Property and equipment, net	2,446	964
Other assets, non-current		84
Intangible asset, net	6,909	8,027
Restricted cash, non-current	600	1,030
Total assets	$ 149,808	$ 182,618
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,090	$ 996
Accrued liabilities	6,753	3,381
Deferred rent, current		453
Deferred revenues, current	26,789	26,789
Total current liabilities	34,632	31,619
Deferred rent, non-current	2,797	461
Deferred revenues, non-current	97,027	117,064
Total liabilities	134,456	149,144
Commitments and contingencies		
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, 28,226,743 and 28,117,026 shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	28	28
Additional paid-in capital	300,039	296,868
Accumulated other comprehensive income	23	21
Accumulated deficit	(284,738)	(263,443)
Total stockholders equity	15,352	33,474
Total liabilities and stockholders equity	$ 149,808	$ 182,618

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

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VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(in thousands, except for share and per share amounts)	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011
Revenues:				
Licensing agreement	$ 6,753	$ 6,753	$ 20,037	$ 20,037
Royalty revenue	1,535	1,216	4,770	2,863
Total revenues	8,288	7,969	24,807	22,900
Operating expenses:				
Research and development	10,159	8,174	34,829	18,440
General and administrative	3,147	2,711	10,657	8,141
Intangible asset amortization	377	377	1,118	1,118
Total operating expenses	13,683	11,262	46,604	27,699
Loss from operations	(5,395)	(3,293)	(21,797)	(4,799)
Other income	69	106	502	362
Loss before tax benefit	(5,326)	(3,187)	(21,295)	(4,437)
Tax benefit		(113)		(158)
Net loss	$ (5,326)	$ (3,074)	$ (21,295)	$ (4,279)
Net loss per share:				
Basic	$ (0.19)	$ (0.11)	$ (0.75)	$ (0.15)
Diluted	$ (0.19)	$ (0.11)	$ (0.75)	$ (0.15)
Shares used in calculation of net loss per share:				
Basic	28,226,743	28,107,363	28,226,743	28,104,749
Diluted	28,226,743	28,107,363	28,226,743	28,104,749

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

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (Unaudited)

(in thousands)	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011
Net loss	$ (5,326)	$ (3,074)	$ (21,295)	$ (4,279)
Other comprehensive income (loss):				
Change in net unrealized gain (loss) on marketable securities	18	(41)	2	42
Tax provision on other comprehensive income (loss)				
Other comprehensive income (loss), net of tax	18	(41)	2	42
Comprehensive loss	$ (5,308)	$ (3,115)	$ (21,293)	$ (4,237)

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

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	Accumulated Deficit	Total
Balances at December 31, 2011	28,117,026	$ 28	$ 296,868	$ 21	$ (263,443)	$ 33,474
Issuance of common stock from exercised stock options and settlement of restricted stock units	109,717					
Employee and non-employee stock-based compensation expense			3,171			3,171
Net loss					(21,295)	(21,295)
Other comprehensive income, net of tax				2		2
Balances at September 30, 2012	28,226,743	$ 28	$ 300,039	$ 23	$ (284,738)	$ 15,352

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

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(in thousands)	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011
Cash flows from operating activities		
Net loss	$ (21,295)	$ (4,279)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	528	284
Employee and non-employee stock-based compensation expense	3,171	4,183
Amortization of premiums and discounts on marketable securities	416	774
Amortization of intangible asset	1,118	1,118
Landlord contributions for tenant improvements	1,826	
Changes in assets and liabilities:		
Accounts receivable	83	(705)
Inventory	(161)	
Prepaid expenses and other assets	(240)	(114)
Accounts payable	94	685
Accrued liabilities	3,372	2,086
Accrued income taxes		(158)
Other liabilities	57	110
Deferred revenue	(20,037)	(20,037)
Net cash used in operating activities	(31,068)	(16,053)
Cash flows from investing activities		
Purchases of property and equipment	(2,010)	(198)
Purchases of marketable securities	(49,967)	(140,637)
Proceeds from sales of marketable securities	2,497	
Maturities of marketable securities	97,140	175,250
Change in restricted cash		(600)
Net cash provided by investing activities	47,660	33,815
Cash flows from financing activities		
Proceeds from exercise of stock options		5
Net cash provided by financing activities		5
Net increase in cash and cash equivalents	16,592	17,767
Cash and cash equivalents		
Beginning of period	87,923	42,559
End of period	$ 104,515	$ 60,326

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

VANDA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Business Organization and Presentation

Business organization

Vanda Pharmaceuticals Inc. (Vanda or the Company) is a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders. Vanda commenced its operations in 2003. The Company s lead product, Fanapt® (iloperidone), which Novartis Pharma AG (Novartis) began marketing in the U.S. in the first quarter of 2010, is a compound for the treatment of schizophrenia. In May 2009, the U.S. Food and Drug Administration (FDA) granted U.S. marketing approval of Fanapt® for the acute treatment of schizophrenia in adults. In October 2009, Vanda entered into an amended and restated sublicense agreement with Novartis. Vanda had originally entered into a sublicense agreement with Novartis in June 2004 pursuant to which Vanda obtained certain worldwide exclusive licenses from Novartis relating to Fanapt®. 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 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 notified 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 at the end of 2009 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 injectible (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 continues to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. and Canada. In July 2011, the European Medicines Agency (EMA) notified Vanda that it had accepted for evaluation the Marketing Authorization Application (MAA) for oral iloperidone tablets. The review of Vanda s MAA for oral iloperidone tablets in the European Union is ongoing. Vanda is preparing for an expected oral hearing in November 2012 as it continues to evaluate its European strategy. 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.
Argentina	Biotoscana Farma S.A.
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 by its distribution partner, Biotoscana Farma S.A., that Fanapt® had been granted market approval in Argentina for the treatment of schizophrenia.

Tasimelteon is an oral compound in development for the treatment of sleep and mood disorders including Circadian Rhythm Sleep Disorders (CRSD). In January 2010, the FDA granted orphan drug designation status for tasimelteon in a specific CRSD, Non-24-Hour Disorder (N24HD) in blind individuals without light perception. The FDA grants orphan drug designation to drugs that may provide significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation provides potential financial and regulatory incentives including, study design assistance, waiver of FDA user fees, tax credits, and up to seven years of market exclusivity upon marketing approval. In February 2011, the European Commission (EC) designated tasimelteon as an orphan medicinal product for the same indication. Vanda has initiated four clinical trials to pursue FDA approval of tasimelteon for the treatment of N24HD in blind individuals without light perception. Two of the clinical trials were initiated in the third quarter of 2010, the third was initiated in the third quarter of 2011 and the fourth was initiated in the fourth quarter of 2011. The first clinical trial (SET-3201) is a randomized, double-blind, placebo-controlled study of 84 patients with N24HD. The trial has a six-month treatment period and includes measures of both nighttime and daytime sleep, as well as laboratory measures of the synchronization between the internal body clock and the 24-hour environmental light/dark cycle. The second clinical trial (3202) is a one-year safety study of tasimelteon for the treatment of N24HD. This trial is an open-label safety study with a planned enrollment of up to 140 patients with N24HD. The third clinical trial (RESET-3203) is a placebo-controlled, randomized withdrawal study of 20 patients with N24HD to examine the maintenance effect of tasimelteon for the treatment of N24HD. Patients will be

observed for 12 weeks during which nighttime and daytime sleep, as well as synchronization of their internal body clock to the 24-hour day, will continue to be evaluated. The fourth clinical trial (3204) is a two-year open-

label, multicenter, study in blind patients with N24HD to assess the safety of tasimelteon. The tasimelteon N24HD program continues towards its goal of a projected mid-2013 New Drug Application (NDA) filing with the FDA. Vanda is in continuing discussions with the FDA to confirm the path and requirements for this regulatory submission, and while no agreement has been reached with the agency, the FDA has suggested that Vanda present its N24HD study results to further the discussions. The SET Phase III efficacy study is fully enrolled and Vanda expects to report top-line results by the end of 2012. The RESET Phase III efficacy study is fully enrolled and Vanda expects to report top-line results in the first quarter of 2013.

In the third quarter of 2011, Vanda initiated a Phase IIb/III clinical trial (MAGELLAN-2301) to study the efficacy of tasimelteon for the treatment of Major Depressive Disorder (MDD). The clinical trial is a randomized, double-blind, placebo-controlled study with an enrollment of approximately 500 patients with MDD. The trial has an eight-week treatment period, followed by an optional one-year open-label extension, and includes measures of depression and anxiety symptoms and nighttime and daytime sleep, as well as laboratory measures of the internal body clock. The Phase IIb/III clinical trial, MAGELLAN-2301, is fully enrolled and Vanda expects to report top-line results in the first quarter of 2013. Given the range of potential indications for tasimelteon, Vanda may pursue one or more partnerships for the development and commercialization of tasimelteon worldwide.

VLY-686 is a small molecule neurokinin-1 receptor (NK-1R) antagonist. NK-1R antagonists have been evaluated in a number of indications including chemotherapy-induced nausea and vomiting (CINV), post-operative nausea and vomiting (PONV), alcohol dependence, anxiety, depression and pruritus. In 2012, Vanda intends to complete the technology transfer activities and further examine the clinical and commercial profile of VLY-686. This strategic evaluation will further inform potential indications for an early development clinical program.

Throughout this quarterly report on Form 10-Q, Vanda refers to Fanapt® within the U.S. and Canada as its partnered product and Vanda refers to Fanapt® outside the U.S. and Canada, tasimelteon and VLY-686 as its products. All other compounds are referred to as Vanda s product candidates. In addition, Vanda refers to its partnered products, 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, 2011 included in the Company s annual report on Form 10-K. The financial information as of September 30, 2012 and for the three and nine months ended September 30, 2012 and 2011, 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, 2011 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, 2011.

2. Summary of Significant Accounting Policies

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Cash and cash equivalents

For purposes of the condensed consolidated balance sheets and condensed consolidated statements of cash flows, cash equivalents represent highly-liquid investments with a maturity date of three months or less at the date of purchase.

Marketable securities

The Company classifies all of its marketable securities as available-for-sale securities. The Company s investment policy requires the selection of high-quality issuers, with bond ratings of AAA to A1+/P1. Available-for-sale securities are carried at fair market value, with unrealized gains and losses reported as a component of stockholders equity in accumulated other comprehensive income/loss. Interest and dividend income is

recorded when earned and included in interest income. Premiums and discounts on marketable securities are amortized and accreted, respectively, to maturity and included in interest income. The Company uses the specific identification method in computing realized gains and losses on the sale of investments, which would be included in the condensed consolidated statements of operations when generated. Marketable securities with a maturity of more than one year as of the balance sheet date, and which the Company does not intend to sell within the next twelve months are classified as non-current. All other marketable securities are classified as current.

Inventory

The Company values its inventory at acquisition cost following the first-in first-out method. The Company analyzes its inventory levels quarterly and writes down inventory that has become obsolete, has a cost basis in excess of its expected net realizable value or inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are written off to cost of sales.

Intangible asset

Costs incurred for products or product candidates not yet approved by the FDA and for which no alternative future use exists are recorded as expense. In the event a product or product candidate has been approved by the FDA or an alternative future use exists for a product or product candidate, patent and license costs are capitalized and amortized over the expected patent life of the related product or product candidate. Milestone payments to the Company s partners are recognized when it is deemed probable that the milestone event will occur.

As a result of the FDA s approval of the NDA for Fanapt® in May 2009, the Company met a milestone under its original sublicense agreement with Novartis which required the Company to make a 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 extends patent protection for drug compounds for a period of up to 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 carrying value of the intangible asset is periodically reviewed to determine if the facts and circumstances suggest that a potential impairment may have occurred. The Company has had no impairment of its intangible asset.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is provided on a straight-line basis over the estimated useful lives of the assets. Amortization of leasehold improvements is provided on a straight-line basis over the shorter of their estimated useful life or the lease term. The costs of additions and improvements are capitalized, and repairs and maintenance costs are charged to operations in the period incurred. Upon retirement or disposition of property and equipment, the cost and accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is reflected in the Company s statement of operations for that period.

Revenue recognition

The Company s revenues are derived primarily from the amended and restated sublicense agreement with Novartis and include an upfront payment, product sales and future milestone and royalty payments. Revenue is considered both realizable and earned when each one of the following four conditions is met: (1) persuasive evidence of an arrangement exists, (2) the arrangement fee is fixed or determinable, (3) delivery or performance has occurred and (4) collectability is reasonably assured. Pursuant to the amended and restated sublicense agreement, Novartis has the right to commercialize and develop Fanapt® in the U.S. and Canada. Under the agreement, the Company received an upfront payment of $200.0 million in December of 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). The Company recognizes revenue from Fanapt® royalties and commercial and development milestones from Novartis when realizable and earned.

Concentrations of credit risk

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company places its cash, cash equivalents and marketable securities with what the Company believes to be highly-rated financial institutions. At September 30, 2012, the Company maintained all of its cash, cash equivalents and marketable securities in two financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits.

Generally, these deposits may be redeemed upon demand, and the Company believes there is minimal risk of losses on such balances.

Accrued liabilities

The Company s management is required to estimate accrued expenses as part of the process of preparing financial statements. The estimation of accrued expenses involves identifying services that have been performed on the Company s behalf, and then estimating the level of service performed and the associated cost incurred for such services as of each balance sheet date in the financial statements. Accrued expenses include professional service fees, such as lawyers and accountants, contract service fees, such as those under contracts with clinical monitors, data management organizations and investigators in conjunction with clinical trials, fees to contract manufacturers in conjunction with the production of clinical materials, and fees for marketing and other commercialization activities. Pursuant to management s assessment of the services that have been performed on clinical trials and other contracts, the Company recognizes these expenses as the services are provided. Such management assessments include, but are not limited to: (1) an evaluation by the project manager of the work that has been completed during the period, (2) measurement of progress prepared internally and/or provided by the third-party service provider, (3) analyses of data that justify the progress, and (4) management s judgment. In the event that the Company does not identify certain costs that have begun to be incurred or the Company under- or over-estimates the level of services performed or the costs of such services, the Company s reported expenses for such period would be too low or too high.

Research and development expenses

The Company s 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 license fees, 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 the Company s research and development personnel. The Company expenses research and development costs as they are incurred for compounds in the development stage, including certain payments made under the license agreements prior to FDA approval. Prior to FDA approval, all Fanapt® manufacturing-related and milestone license payments were included in research and development expenses. Subsequent to FDA approval of Fanapt®, manufacturing and milestone license payments related to this product have been capitalized. Costs related to the acquisition of intellectual property have been expensed as incurred since the underlying technology associated with these acquisitions was developed in connection with the Company s research and development efforts and has no alternative future use. Milestone license payments are accrued in accordance with the Financial Accounting Standards Board (FASB) guidance on accounting for contingencies which requires that milestone payments be accrued when it is deemed probable that the milestone event will be achieved.

General and administrative expenses

General and administrative expenses consist primarily of salaries, other employee-related costs and stock-based compensation for personnel serving executive, business development, marketing, finance, accounting, information technology, marketing and human resource functions, facility costs not otherwise included in research and development expenses, insurance costs and professional fees for 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 related to Fanapt®.

Employee stock-based compensation

The Company accounts for its stock-based compensation expense in accordance with the FASB guidance on share-based payments. Accordingly, 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. Pre-vesting forfeitures on the options granted prior to 2009 were estimated to be approximately 2%. The forfeiture rate was increased to 4% in 2009 based on the Company s historical experience and this rate has been utilized for all subsequently granted options.

Total employee stock-based compensation expense recognized during the three and nine months ended September 30, 2012 and 2011 was comprised of the following:

	Three Months Ended	**Nine Months Ended**

(in thousands)	**September 30, 2012**	**September 30, 2011**	**September 30, 2012**	**September 30, 2011**
Research and development	$ (110)	$ 558	$ 1,003	$ 1,896
General and administrative	686	704	2,152	2,278
Total employee stock-based compensation expense	$ 576	$ 1,262	$ 3,155	$ 4,174

The research and development portion of employee stock-based compensation expense for the three and nine months ended September 30, 2012 was impacted by the termination of the Company s Chief Medical Officer in the third quarter 2012 and the reversal of employee stock-based compensation expense resulting from the cancellation of certain of his outstanding equity awards.

As of September 30, 2012, $5.0 million of total unrecognized compensation costs related to unvested awards are expected to be recognized over a weighted average period of 1.42 years.

As of September 30, 2012, the Company had two equity incentive plans, the Second Amended and Restated Management Equity Plan (the 2004 Plan) and the 2006 Equity Incentive Plan (the 2006 Plan) that were adopted in December 2004 and April 2006, respectively. An aggregate of 677,145 shares were subject to outstanding options granted under the 2004 Plan as of September 30, 2012, and no additional options will be granted under this plan. As of September 30, 2012, there were 7,866,260 shares of the Company s common stock reserved for issuance under the 2006 Plan of which 4,715,632 shares were subject to outstanding options and RSUs granted to employees and non-employees.

Options are subject to terms and conditions established by the compensation committee of the Company s board of directors. None of the stock-based awards are classified as a liability as of September 30, 2012. Option awards have 10-year contractual terms and all options granted prior to December 31, 2006, options granted to new employees, and certain options granted to existing employees vest and become exercisable on the first anniversary of the vesting commencement date with respect to 25% of the shares subject to the option awards. The remaining 75% of the shares subject to the option awards vest and become exercisable monthly in equal installments thereafter over three years. Certain option awards granted to existing employees after December 31, 2006 vest and become exercisable monthly in equal installments over four years. The initial stock options granted to directors upon their election vest and become exercisable in equal monthly installments over a period of four years, while the subsequent annual stock option grants to directors vest and become exercisable in equal monthly installments over a period of one year. Certain option awards to executives and directors provide for accelerated vesting if there is a change in control of the Company. Certain option awards to employees and executives provide for accelerated vesting if the respective employee s or executive s service is terminated by the Company for any reason other than cause or permanent disability. As of September 30, 2012, there was $2.3 million of unrecognized compensation expense related to unvested option awards granted under the Company s stock incentive plans.

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. Due to the limited historical information on the Company s publicly traded common stock, expected volatility rates are based on the historical volatility of the Company s publicly traded common stock blended with the historical volatility of the common stock of comparable entities. The expected term of options granted is based on the transition approach provided by FASB guidance as the options meet the plain vanilla criteria required by this guidance. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception (other than a dividend of preferred share purchase rights, which was declared in September 2008) and does not plan to pay dividends in the foreseeable future.

Assumptions used in the Black-Scholes-Merton option pricing model for employee and director stock options granted during the nine months ended September 30, 2012 and 2011 were as follows:

	Nine Months Ended	
	September 30, 2012	**September 30, 2011**
Expected dividend yield	%	%
Weighted average expected volatility	68%	73%
Weighted average expected term (years)	6.03	6.03
Weighted average risk-free rate	1.04%	2.42%

A summary of option activity for the 2004 Plan as of September 30, 2012, and changes during the nine months then ended is presented below:

(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, 2011	677,145	$ 1.78	3.78	$ 2,016
Exercised				
Forfeited				

Cancelled						
Outstanding at September 30, 2012	677,145	$	1.78	3.03	$	1,679
Exercisable at September 30, 2012	677,145	$	1.78	3.03	$	1,679

A summary of option activity for the 2006 Plan as of September 30, 2012, and changes during the nine months then ended is presented below:

(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, 2011	4,254,681	$ 12.16	7.65	$ 396
Granted	187,000	$ 4.46		
Exercised				
Forfeited	(69,334)	$ 11.07		
Cancelled	(149,091)	$ 7.50		
Outstanding at September 30, 2012	4,223,256	$ 12.01	6.97	$ 319
Exercisable at September 30, 2012	2,848,680	$ 14.45	6.18	$ 319

The weighted average grant-date fair value of options granted during the nine months ended September 30, 2012 was $2.71 per share. For the nine months ended September 30, 2012 and 2011, the amounts received by the Company in cash from options exercised under the stock-based arrangements were not material.

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, which equals the RSUs intrinsic value. As of September 30, 2012, there was $2.7 million of unrecognized compensation cost related to unvested RSU awards granted under the Company s stock incentive plans.

A summary of RSU activity for the 2006 Plan as of September 30, 2012, and changes during the nine months then ended is presented below:

(in thousands, except for share and per share amounts)	Number of Shares	Weighted Average Price/Share	Aggregate Intrinsic Value
Unvested at December 31, 2011	522,346	$ 7.43	$ 2,486
Granted	32,000	$ 4.30	
Vested			
Cancelled	(61,970)	$ 7.74	
Unvested at September 30, 2012	492,376	$ 7.19	$ 1,984

Income taxes

The Company accounts for income taxes in accordance with the FASB guidance on accounting for income taxes, which requires companies to account for deferred income taxes using the asset and liability method. Under the asset and liability method, current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credits and loss carryforwards. 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. Tax rate changes are reflected in income during the period such changes are enacted. Changes in ownership may limit the amount of net operating loss (NOL) carryforwards that can be utilized in the future to offset taxable income.

Recent accounting pronouncements

There are no new accounting pronouncements that have had or that the Company expects will have a material effect on our condensed consolidated financial statements.

3. Earnings per Share

Net income (loss) per share is calculated in accordance with FASB guidance on 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 nine months ended September 30, 2012 and 2011:

	Three Months Ended		Nine Months Ended	
(in thousands, except for share and per share amounts)	**September 30, 2012**	**September 30, 2011**	**September 30, 2012**	**September 30, 2011**
Numerator:				
Net loss	$ (5,326)	$ (3,074)	$ (21,295)	$ (4,279)
Denominator:				
Weighted average shares of common stock outstanding, basic	28,226,743	28,107,363	28,226,743	28,104,749
Stock options and restricted stock units related to the issuance of common stock				
Weighted average shares of common stock outstanding, diluted	28,226,743	28,107,363	28,226,743	28,104,749
Net loss per share:				
Basic	$ (0.19)	$ (0.11)	$ (0.75)	$ (0.15)
Diluted	$ (0.19)	$ (0.11)	$ (0.75)	$ (0.15)
Anti-dilutive securities excluded from calculation of diluted net loss per share:				
Options to purchase common stock and restricted stock units	5,150,778	4,035,526	5,184,757	3,719,099

4. Marketable Securities

The following is a summary of the Company s available-for-sale marketable securities as of September 30, 2012:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Current:				
U.S. Treasury and government agencies	$ 7,639	$ 4	$	$ 7,643
Corporate debt	22,226	20		22,246
	$ 29,865	$ 24	$	$ 29,889

The following is a summary of the Company s available-for-sale marketable securities as of December 31, 2011:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Current:				
U.S. Treasury and government agencies	$ 23,747	$ 10	$ (2)	$ 23,755
Corporate debt	37,205	8	(7)	37,206
	$ 60,952	$ 18	$ (9)	$ 60,961
Non-current:				
U.S. Treasury and government agencies	$ 19,000	$ 12	$	$ 19,012

5. Prepaid Expenses and Other Current Assets

The following is a summary of the Company s prepaid expenses and other current assets, as of September 30, 2012 and December 31, 2011:

(in thousands)	September 30, 2012	December 31, 2011
Prepaid insurance	$ 316	$ 165
Other prepaid expenses and vendor advances	2,734	2,474
Accrued interest income	252	244
Other receivables	21	116
Total prepaid expenses and other current assets	$ 3,323	$ 2,999

6. Property and Equipment, Net

The following is a summary of the Company s property and equipment-at cost, as of September 30, 2012 and December 31, 2011:

(in thousands)	Estimated Useful	September 30, 2012	December 31, 2011

	Life (Years)		
Laboratory equipment	5	$ 1,273	$ 1,273
Computer equipment	3	1,252	1,105
Furniture and fixtures	7	853	700
Leasehold improvements	10-11	1,826	844
Leasehold improvements-in-progress	N/A		116
		5,204	4,038
Less accumulated depreciation and amortization		(2,758)	(3,074)
Property and equipment, net		$ 2,446	$ 964

Depreciation expense for the nine months ended September 30, 2012 and 2011 was $0.5 million and $0.3 million, respectively.

7. Intangible Asset, Net

The following is a summary of the Company s intangible asset as of September 30, 2012:

		September 30, 2012		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	8	$ 12,000	$ 5,091	$ 6,909

The following is a summary of the Company s intangible asset as of December 31, 2011:

		December 31, 2011		
(in thousands)	Estimated Useful Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	8	$ 12,000	$ 3,973	$ 8,027

In May 2009, the Company announced that the FDA had approved the NDA for Fanapt®. As a result of the FDA s approval of the NDA for Fanapt®, the Company met a milestone under its original sublicense agreement with Novartis which required the Company to make a 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 amortized over its estimated useful economic life using the straight-line method. Amortization expense was $1.1 million for each of the nine months ended September 30, 2012 and 2011. The Company capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanapt®.

8. Accrued Liabilities

The following is a summary of the Company s accrued liabilities as of September 30, 2012 and December 31, 2011:

(in thousands)	September 30, 2012	December 31, 2011
Accrued research and development expenses	$ 4,095	$ 1,967
Accrued consulting and other professional fees	296	317
Employee benefits	931	100
Accrued lease exit liability (refer to footnote 10)	798	740
Other accrued liabilities	633	257
Total accrued liabilities, current	$ 6,753	$ 3,381

9. Revenue Recognition

The following is a summary of the Company s revenues for the nine months ended September 30, 2012:

(in thousands)	December 31, 2011 Total Deferred Revenue	Revenue Recognized	September 30, 2012 Total Deferred Revenue

Licensing agreement	$ 143,853	$ 20,037	$ 123,816
Royalty revenue		4,770	
Total revenue for the nine months ended September 30, 2012		$ 24,807	

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. 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). 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. For the nine months ended September 30, 2012, the Company recognized $20.0 million of revenue from the amended and restated

sublicense agreement. Vanda recognized royalty revenue of $4.8 million for the nine months ended September 30, 2012. Royalty revenue is based on a percentage of the quarterly net sales of Fanapt® sold in the U.S. and Canada by Novartis and is recorded when realizable and earned.

10. Commitments and Contingencies

The following is a summary of the Company s long-term contractual cash obligations and commitments as of September 30, 2012:

		Cash payments due by period					
(in thousands)	**Total**	**October to December 2012**	**2013**	**2014**	**2015**	**2016**	**After 2016**
Operating leases	$ 11,550	$	$ 859	$ 1,052	$ 1,079	$ 1,106	$ 7,454
Lease exit liability	798	182	616				
Total	$ 12,348	$ 182	$ 1,475	$ 1,052	$ 1,079	$ 1,106	$ 7,454

Operating leases

The Company s commitments related to operating leases shown above consist of future payments relating to a real estate lease for its current headquarters located in Washington, D.C. In July 2011, the Company entered into a lease with Square 54 Office Owner LLC (the Landlord) for Vanda s current headquarters, consisting of 21,400 square feet at 2200 Pennsylvania Avenue, N.W. in Washington, D.C. (the Lease). Under the Lease, which has an 11-year term that commenced in April 2012, the Company will pay $1.6 million in annual rent over the term of the Lease; however, rent is abated for the first 12 months. The Landlord agreed to provide the Company with an allowance of $1.9 million for leasehold improvements. As of September 30, 2012, the Company had received $1.8 million of the allowance. Subject to the prior rights of other tenants in the building, the Company will have the right to renew the Lease for five years following the expiration of its original term. The Company will also have the right to sublease or assign all or a portion of the premises, subject to standard conditions. The Lease may be terminated early by the Company or the Landlord upon certain conditions. The Company paid a security deposit of $0.5 million upon execution of the Lease.

As a result of the Company s relocation from Rockville, Maryland to Washington, D.C., the Company provided notice to its previous landlord that it was terminating its prior lease effective June 2013. As a result of terminating this lease, the Company recognized expenses of $0.7 million in the fourth quarter of 2011 related to a lease termination penalty. Of this amount, $0.6 million was presented as research and development expense on the consolidated statement of operations for the year ended December 31, 2011 and $0.1 million was presented as general and administrative expense on the consolidated statement of operations for the year ended December 31, 2011. In the first quarter of 2012, the Company ceased using the Rockville, Maryland location and, as a result, recognized additional rent expense of $0.8 million. This $0.8 million consisted of a lease exit liability of $1.3 million for the remaining payments required under the lease and the reversal of the deferred rent liability of $0.5 million related to the Rockville, Maryland lease. The remaining costs associated with the lease exit liability are included in the table above. Of the $0.8 million, $0.6 million is presented as research and development expense on the condensed consolidated statement of operations for the nine months ended September 30, 2012 and $0.2 million is presented as general and administrative expense on the condensed consolidated statement of operations for the nine months ended September 30, 2012.

The following is a summary of the Company s lease exit activity:

(in thousands)	**Balance at Beginning of Period**	**Costs Incurred and Charged to Expense**	**Costs Paid or Otherwise Settled**	**Adjustments**	**Balance at End of Period**
Three months ended December 31, 2011	$	$ 740	$	$	$ 740
Nine months ended September 30, 2012	$ 740	$ 1,344	$ 1,232	$ (54)	$ 798

Rent expense, including lease exit costs, for the nine months ended September 30, 2012 and 2011 was $1.8 million and $0.9 million, respectively.

Consulting fees

The Company has engaged a regulatory consultant to assist in the Company s efforts to prepare, file and obtain FDA approval of an NDA for tasimelteon. As part of this engagement, and subject to certain conditions, the Company will be obligated to make milestone payments in the aggregate amount of $2.8 million upon the achievement of certain milestones, including $2.0 million in the event that a tasimelteon NDA is approved by the FDA. In addition to these 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 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. The Company believes that the fair value of the indemnification agreements is minimal, and accordingly the Company has not recognized any liabilities relating to these agreements as of September 30, 2012.

License agreements

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

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 this sublicense agreement relating to the acceptance of its filing of the NDA for Fanapt® for the treatment of schizophrenia and made a milestone payment of $5.0 million to Novartis. As a result of the FDA s approval of the NDA for Fanapt® in May 2009, the Company met an additional milestone under this 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. In addition, Vanda is no longer required to make any future milestone payments with respect to sales of Fanapt® or any future royalty payments with respect to 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. In July 2011, the European Medicines Agency (EMA) notified Vanda that it had accepted for evaluation the Marketing Authorization Application (MAA) for oral iloperidone tablets. The review of Vanda s MAA for oral iloperidone tablets in the European Union is ongoing. Vanda is preparing for an expected oral hearing in November 2012 as it continues to evaluate its European strategy. 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.
Argentina	Biotoscana Farma S.A.
Israel	Megapharm Ltd.

In August 2012, the Israeli Ministry of Health granted market approval for Fanapt® for the treatment of schizophrenia.

Vanda may lose its rights to develop and commercialize Fanapt® outside the U.S. and Canada if it fails to comply with certain requirements in the amended and restated sublicense agreement regarding its financial condition, or if Vanda fails to comply with certain diligence obligations regarding its development or commercialization activities or if Vanda otherwise breaches the agreement and fails to cure such breach. Vanda s rights to develop and commercialize Fanapt® outside the U.S. and Canada may

be impaired if it does not cure breaches by Novartis of similar obligations contained its sublicense agreement with Titan for Fanapt®. In addition, if Novartis breaches the amended and restated sublicense agreement with respect to its commercialization activities in the U.S. or Canada, Vanda may terminate Novartis commercialization rights in the applicable country and Vanda would no longer receive royalty payments from Novartis in connection with such country in the event of such termination.

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. The Company is also 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) as well as royalty payments based on the net sales of tasimelteon at a rate which, as a percentage of net sales, is in the low teens. The Company made a milestone payment to BMS of $1.0 million under this license agreement in 2006 relating to the initiation of its first Phase III clinical trial for tasimelteon. The Company is also obligated under this 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 has agreed with BMS in the license agreement for tasimelteon to use commercially reasonable efforts to develop and commercialize tasimelteon and to meet certain milestones in initiating and completing certain clinical work. The license agreement with BMS was amended in May 2012 to, among other things, extend the deadline by which the Company must enter into a development and commercialization agreement with a third party for tasimelteon until the earliest of: (i) the date mutually agreed upon by the Company and BMS 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 (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 has not entered into such a development and commercialization agreement with respect to certain major market countries by the foregoing deadline, then BMS will have the option to exclusively develop and commercialize tasimelteon on its own in those countries not covered by such an agreement on pre-determined financial terms, including milestone and royalty payments. In addition to the foregoing, pursuant to the May 2012 amendment, Vanda s deadline for filing an NDA for tasimelteon was extended until January 1, 2014.

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 this agreement will revert or otherwise be licensed back to BMS on an exclusive basis.

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 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 an expense in the second quarter of 2012 and is presented as research and development expense on the condensed consolidated statement of operations for the nine months ended September 30, 2012. Lilly is also eligible to receive additional payments based upon achievement of specified development and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. These milestones include $4.0 million for pre-NDA approval milestones and up to $95.0 million for future regulatory approval and sales milestones. Vanda has agreed to use its commercially reasonable efforts to develop and commercialize VLY-686.

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

Future license payments. No amounts were recorded as liabilities nor were any contractual obligations relating to the license agreements included in the condensed consolidated financial statements as of September 30, 2012, since the amounts, timing and likelihood of these future payments are unknown and will depend on 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.

11. Income Taxes

The tax benefit for the nine months ended September 30, 2012 and 2011 was $0 and $0.2 million, respectively. As of September 30, 2012, the Company has provided a valuation allowance for the full amount of its net deferred tax asset since realization of any future benefit from deductible temporary differences and NOLs could not be sufficiently assured. As of September 30, 2011, the Company reflected a net deferred tax asset of $1.8 million associated with the Company s ability to carryback taxable losses.

12. Fair Value Measurements

FASB 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 September 30, 2012 and December 31, 2011 consist of available-for-sale marketable securities. The valuation of Level 1 instruments is determined using a market approach, and is based upon unadjusted quoted prices for identical assets in active markets. The valuation of investments classified in Level 2 also is determined using a market approach based upon quoted prices for similar assets in active markets, or other inputs that are observable for substantially the full term of the financial instrument. Level 2 securities include certificates of deposit, commercial paper, corporate notes and U.S. government agency notes that use as their basis readily observable market parameters.

As of September 30, 2012, the Company held certain assets that are required to be measured at fair value on a recurring basis.

		Fair Value Measurements at Reporting Date Using		
(in thousands)	**September 30, 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	$ 29,889	$ 7,643	$ 22,246	$

As of December 31, 2011, the Company held certain assets that are required to be measured at fair value on a recurring basis.

		Fair Value Measurements at Reporting Date Using		
(in thousands)	**December 31, 2011**	**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	$ 79,973	$ 42,767	$ 37,206	$

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 and accounts payable, the carrying value of which materially approximate their fair values.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

Various statements in 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, project goal, intend, plan, target, likely, will, would, and could, or the negative of these terms and similar expressions or words, identify for 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 inability to reach agreement with the U.S. Food and Drug Administration (FDA) regarding our regulatory approval strategy or proposed path to approval for tasimelteon;

the failure of our clinical trials to demonstrate the safety and/or efficacy of tasimelteon in the treatment of Non-24-Hour Disorder (N24HD) or Major Depressive Disorder (MDD);

our failure to obtain regulatory approval for our products or product candidates or to comply with ongoing regulatory requirements;

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 products to be demonstrably safe and effective;

a lack of acceptance of our products, product candidates or partnered products 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 activities;

our failure to identify or obtain rights to new products or product candidates;

our failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage our growth;

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

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

losses incurred from product liability claims made against us; and

a loss of rights to develop and commercialize our products or product candidates under our license and sublicense agreements.

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 condensed consolidated financial statements contained in this quarterly report on Form 10-Q. We also encourage you to read Item 1A of Part II of this quarterly report on Form 10-Q entitled Risk Factors and Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2011, which contain 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 II of this report and Item 1A of Part I of our annual report on Form 10-K for the fiscal year ended December 31, 2011, 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 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 and partnered products will address a large market with significant unmet medical needs by offering advantages over currently available therapies. Our product portfolio includes 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), tasimelteon, a compound for the treatment of sleep and mood disorders, including circadian rhythm sleep disorders (CRSD), which is currently in clinical development, and VLY-686, a small molecule neurokinin-1 receptor (NK-1R) antagonist.

Pursuant to our amended and restated sublicense agreement with Novartis, we received an upfront payment of $200.0 million and are eligible for additional payments totaling up to $265.0 million upon Novartis achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. Based on the current sales performance of Fanapt® in the U.S. and the decision by Novartis to cease development of the long-acting injectible (or depot) formulation of Fanapt®, we expect that some or all of these commercial and development milestones will not be achieved by Novartis. We also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. We retain exclusive rights to Fanapt® outside the U.S. and Canada and we have exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. For the nine months ended September 30, 2012, we incurred $1.2 million in research and development costs directly attributable to our development of Fanapt®.

We are conducting four clinical trials to pursue FDA approval of tasimelteon for the treatment of N24HD in blind individuals without light perception. Two of the clinical trials were initiated in the third quarter of 2010, the third was initiated in the third quarter of 2011 and the fourth was initiated in the fourth quarter of 2011. In addition, in the third quarter of 2011, we initiated a Phase IIb/III clinical trial to study the efficacy of tasimelteon for the treatment of MDD. During the nine months ended September 30, 2012, we incurred $30.9 million in research and development costs directly attributable to our development of tasimelteon.

Since we began our operations in March 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 on Novartis ability to successfully commercialize Fanapt® in the U.S. and to successfully develop and commercialize Fanapt® in Canada and upon our ability, alone or with others, to complete the development of our products or product candidates, and to obtain the regulatory approvals for and manufacture, market and sell our products and product candidates.

The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks which are detailed in Item 1A of Part II of this quarterly report on Form 10-Q, entitled Risk Factors and in Item 1A of Part I of our annual report on Form 10-K for the year ended December 31, 2011.

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. Revenue is considered both realizable and earned when each one of the following four conditions is met: (1) persuasive evidence of an arrangement exists, (2) the arrangement fee is fixed or determinable, (3) delivery or performance has occurred and (4) collectability is reasonably assured. Revenue related to the $200.0 million upfront payment will be 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 revenue from Fanapt® royalties and commercial and development milestones from Novartis when realizable.

Research and development expenses. Our research and development expenses consist primarily of fees paid to third-party professional service providers in connection with the services they provide for our clinical trials, costs of contract manufacturing services, costs of materials used in clinical trials and research and development, costs for regulatory consultants and filings, depreciation of capital resources used to develop our products, all related facilities costs, and salaries, benefits and stock-based compensation expense related to our research and development personnel. We expense research and development costs as incurred for compounds in the development stage, including certain payments made under our license agreements prior to FDA approval. Prior to FDA approval, all Fanapt® manufacturing-related and milestone costs were included in research and development expenses. Subsequent to FDA approval of Fanapt®, manufacturing and milestone costs related to this product are being capitalized. Costs related to the acquisition of intellectual property have been expensed as incurred since the underlying technology associated with these acquisitions was developed in connection with the Company s research and development efforts and has no alternative future use. Milestone payments are accrued in accordance with the Financial Accounting Standards Board (FASB) guidance on accounting for contingencies which requires that milestone payments be accrued when it is deemed probable that the milestone event will be achieved. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to realize the potential of our products and product candidates and pharmacogenetics and pharmacogenomics expertise. For the nine months ended September 30, 2012, we incurred research and development expenses in

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the aggregate of $34.8 million, including stock-based compensation expense of $1.0 million. We expect our research and development expenses to increase 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 products and to evaluate potential in-license product candidates or compounds.

The following table summarizes our product development initiatives for the three and nine months ended September 30, 2012 and 2011. Included in this table are the research and development expenses recognized in connection with the clinical development of Fanapt®, tasimelteon and VLY-686.

	Three Months Ended		Nine Months Ended	
(in thousands)	**September 30, 2012**	**September 30, 2011**	**September 30, 2012**	**September 30, 2011**
Direct project costs(1)				
Fanapt®	$ 423	$ 890	$ 1,173	$ 1,851
Tasimelteon	9,437	6,893	30,856	15,709
VLY-686	42		1,056	
Total direct project costs	9,902	7,783	33,085	17,560
Indirect project costs(1)				
Facility	114	280	1,216	591
Depreciation	57	78	295	147
Other indirect overhead	86	33	233	142
Total indirect project costs	257	391	1,744	880
Total research and development expenses	$ 10,159	$ 8,174	$ 34,829	$ 18,440

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

General and administrative expenses. General and administrative expenses consist primarily of salaries, other related costs for personnel, including stock-based compensation, related to executive, finance, accounting, information technology, marketing, and human resource functions. Other costs include facility costs not otherwise included in research and development expenses and fees for 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 related to Fanapt®. For the nine months ended September 30, 2012, we incurred general and administrative expenses in the aggregate of $10.7 million, including stock-based compensation expense of $2.2 million.

Other income. Other income consists of interest income earned on our cash and cash equivalents, marketable securities and restricted cash and non-recurring income (expense) transactions which are outside of our normal business operations.

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.

Our significant accounting policies are described in the notes to our audited consolidated financial statements for the year ended December 31, 2011 included in our annual report on Form 10-K. However, we believe that the following critical accounting policies are important to understanding and evaluating our reported financial results, and we have accordingly included them in this quarterly report on Form 10-Q.

Accrued liabilities. As part of the process of preparing financial statements, we are required to estimate accrued expenses. The estimation of accrued expenses involves identifying services that have been performed on our behalf, and then estimating the level of service performed and the associated cost incurred for such services as of each balance sheet date in the financial statements. Accrued expenses include professional service fees, such as lawyers and accountants, contract service fees, such as those under contracts with clinical monitors, data management organizations and investigators in conjunction with clinical trials, fees to contract manufacturers in conjunction with the production of clinical materials, and fees for marketing and other commercialization activities. Pursuant to our assessment of the services that have been performed on clinical trials and other contracts, we recognize these expenses as the services are provided. Our assessments include, but are not limited to: (1) an evaluation by the project manager of the work that has been completed during the period, (2) measurement of progress prepared internally and/or provided by the third-party service provider, (3) analyses of data that justify the progress, and (4) our judgment. In the event that we do not identify certain costs that have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high.

Revenue recognition. Our revenues are derived primarily from our amended and restated sublicense agreement with Novartis and include an upfront payment, product revenue and future milestone and royalty revenues. 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®, 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 revenue related to Fanapt® royalties and commercial and development milestones as they are realizable and earned.

Stock-based compensation. We currently use the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The determination of the fair value of stock options on the date of grant using an option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the expected stock price volatility over the expected term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Due to the limited historical information on our publicly traded common stock, expected volatility rates are based on the historical volatility of our publicly traded common stock blended with the historical volatility of the common stock of comparable entities and other factors. The expected term of options granted is based on the transition approach provided by FASB guidance as the options meet the plain vanilla criteria required by this method. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have not paid dividends to our stockholders since our inception (other than a dividend of preferred share purchase rights which was declared in September 2008) and do not plan to pay dividends in the foreseeable future. The stock-based compensation expense for a period is also affected by the expected forfeiture rate for the respective option grants. If our estimates of the fair value of these equity instruments or expected forfeitures are too high or too low, it would have the effect of overstating or understating expenses.

Total employee stock-based compensation expense related to all of our stock-based awards during the three and nine months ended September 30, 2012 and 2011 was comprised of the following:

	Three Months Ended		Nine Months Ended	
(in thousands)	**September 30, 2012**	**September 30, 2011**	**September 30, 2012**	**September 30, 2011**
Research and development	$ (110)	$ 558	$ 1,003	$ 1,896
General and administrative	686	704	2,152	2,278
Total employee stock-based compensation expense	$ 576	$ 1,262	$ 3,155	$ 4,174

The research and development portion of employee stock-based compensation expense for the three and nine months ended September 30, 2012 was impacted by the termination of our Chief Medical Officer in the third quarter of 2012 and the reversal of employee stock-based compensation expense resulting from the cancellation of certain of his outstanding equity awards.

Income taxes. On a periodic basis, we evaluate the realizability of our deferred tax assets and liabilities and will adjust such amounts in light of changing facts and circumstances, including but not limited to future projections of taxable income, the reversal of deferred tax liabilities, tax legislation, rulings by relevant tax authorities and tax planning strategies. Settlement of filing positions that may be challenged by tax authorities could impact our income taxes in the year of resolution.

In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences becomes deductible or the NOLs and credit carryforwards can be utilized. When considering the reversal of the valuation allowance, we consider the level of past and future taxable income, the reversal of deferred tax liabilities, the utilization of the carryforwards and other factors. Revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period.

Recent Accounting Pronouncements

There are no new accounting pronouncements that have had or that we expect will have a material effect on our condensed consolidated financial statements.

Results of Operations

We have a limited history 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 products. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses. As of September 30, 2012, we had an accumulated deficit of $284.7 million.

Three months ended September 30, 2012 compared to three months ended September 30, 2011

Revenues. Revenues were $8.3 million for the three months ended September 30, 2012, compared to revenues of $8.0 million for the three months ended September 30, 2011. Revenues for the three months ended September 30, 2012 included $6.8 million recognized from Novartis related to straight-line recognition of up-front license fees and $1.5 million in royalty revenue based on third quarter 2012 sales of Fanapt®. Revenues for the three months ended September 30, 2011 included $6.8 million recognized from Novartis related to straight-line recognition of upfront license fees and $1.2 million in royalty revenue based on third quarter 2011 sales of Fanapt®.

Intangible asset amortization. Intangible asset amortization was $0.4 million for both the three months ended September 30, 2012 and the three months ended September 30, 2011. Intangible amortization relates to the capitalized intangible asset related to the $12.0 million milestone payment to Novartis in May 2009.

Research and development expenses. Research and development expenses increased by $2.0 million, or 24.3%, to $10.2 million for the three months ended September 30, 2012 compared to $8.2 million for the three months ended September 30, 2011.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the three months ended September 30, 2012 and 2011:

	Three Months Ended	
	September 30, 2012	**September 30, 2011**
(in thousands)		
Direct project costs:		
Clinical trials	$ 6,794	$ 4,698
Contract research and development, consulting, materials and other direct costs	1,759	1,460
Salaries, benefits and related costs	1,459	1,067
Employee stock-based compensation expense	(110)	558
Total direct costs	9,902	7,783
Indirect project costs	257	391
Total research and development expenses	$ 10,159	$ 8,174

Direct costs increased by $2.1 million for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 primarily as a result of increases in clinical trial costs, contract research and development, consulting, materials and other direct costs, salaries, benefits and related costs partially offset by lower stock based compensation. Clinical trials costs increased by $2.1 million for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 primarily due to costs related to the tasimelteon trials for the treatment of N24HD in blind individuals without light perception and the tasimelteon trial for the treatment of MDD. Contract research and development consulting, materials and other direct costs increased by $0.3 million for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 due to costs related to the tasimelteon N24HD and MDD trials and costs related to the preparation of a future tasimelteon New Drug Application (NDA) filing with the FDA. Salaries, benefits and related costs increased by $0.4 million for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 due to new employees hired in 2011 and 2012 and the termination of our Chief Medical Officer in the third quarter 2012 and the severance costs associated with his termination. Employee stock-based compensation expense decreased by $0.7 million for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 due to the termination of our Chief Medical Officer in the third quarter of 2012 and the reversal of employee stock-based compensation expense resulting from the cancellation of certain of his outstanding equity awards and the lower fair value of equity awards granted during 2011 and 2012 compared to equity awards granted in prior periods.

General and administrative expenses. General and administrative expenses increased by $0.4 million, or 16.1%, to $3.1 million for the three months ended September 30, 2012 from $2.7 million for the three months ended September 30, 2011.

The following table discloses the components of our general and administrative expenses for the three months ended September 30, 2012 and 2011:

(in thousands)	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011
Salaries, benefits and related costs	$ 808	$ 433
Employee stock-based compensation expense	686	704
Marketing, legal, accounting and other professional expenses	847	918
Other expenses	806	656
Total general and administrative expenses	$ 3,147	$ 2,711

Salaries, benefits and related costs increased by $0.4 million for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 primarily due to the hiring of an executive in the fourth quarter of 2011 and other new hires made in the fourth quarter of 2011 and throughout 2012.

Nine months ended September 30, 2012 compared to nine months ended September 30, 2011

Revenues. Revenues were $24.8 million for the nine months ended September 30, 2012, compared to revenues of $22.9 for the nine months ended September 30, 2011. Revenues for the nine months ended September 30, 2012 included $20.0 million recognized

from Novartis related to straight-line recognition of up-front license fees and $4.8 million in royalty revenue based on sales of Fanapt® in the nine months ended September 30, 2012. Revenues for the nine months ended September 30, 2011 included $20.0 million recognized from Novartis related to the straight-line recognition of up-front license fees and $2.9 million in royalty revenue based on sales of Fanapt® in the nine months ended September 30, 2011.

Intangible asset amortization. Intangible asset amortization was $1.1 million for both the nine months ended September 30, 2012 and the nine months ended September 30, 2011. Intangible amortization relates to the capitalized intangible asset related to the $12.0 million payment to Novartis in May 2009.

Research and development expenses. Research and development expenses increased by $16.4 million, or 88.9%, to $34.8 million for the nine months ended September 30, 2012 compared to $18.4 million for the nine months ended September 30, 2011.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the nine months ended September 30, 2012 and 2011:

	Nine Months Ended	
(in thousands)	**September 30, 2012**	**September 30, 2011**
Direct project costs:		
Clinical trials	$ 21,831	$ 9,086
Contract research and development, consulting, materials and other direct costs	6,511	3,635
Salaries, benefits and related costs	3,740	2,943
Employee stock-based compensation expense	1,003	1,896
Total direct costs	33,085	17,560
Indirect project costs	1,744	880
Total research and development expenses	$ 34,829	$ 18,440

Direct costs increased by $15.5 million for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 primarily as a result of increases in clinical trial costs, contract research and development, consulting, materials and other direct costs and salaries, benefits and related costs partially offset by lower stock-based compensation. Clinical trials costs increased by $12.7 million for the nine months ended September 30, 2012 relative to the nine months ended September 30, 2011, primarily due to costs related to the tasimelteon trials for the treatment of N24HD in blind individuals without light perception and the tasimelteon trial for the treatment of MDD. Contract research and development, consulting, materials and other direct costs increased $2.9 million for the nine months ended September 30, 2012 relative to the nine months ended September 30, 2011, primarily due to costs related to the tasimelteon N24HD and MDD trials, costs related to the preparation of a future tasimelteon NDA filing with the FDA, and the $1.0 initial license fee associated with VLY-686. Salaries, benefits and related costs increased by $0.8 million due to new employees hired in 2011 and 2012 and the termination of our Chief Medical Officer in the third quarter of 2012 and the severance costs associated with his termination. Employee stock-based compensation expense decreased by $0.9 million for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 due to the termination of our Chief Medical Officer in the third quarter of 2012 and the reversal of employee stock-based compensation expense resulting from the cancellation of certain of his outstanding equity awards and the lower fair value of equity awards granted during 2011 and 2012 compared to equity awards granted in prior periods. Indirect project costs increased by $0.9 million for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 primarily as a result of lease exit costs for our former headquarters in Rockville, Maryland and the related accelerated depreciation recognized in the first quarter of 2012.

General and administrative expenses. General and administrative expenses increased by $2.5 million, or 30.9%, to $10.7 million for the nine months ended September 30, 2012 from $8.1 million for the nine months ended September 30, 2011.

The following table discloses the components of our general and administrative expenses for the nine months ended September 30, 2012 and 2011:

Nine Months Ended

(in thousands)	September 30, 2012	September 30, 2011
Salaries, benefits and related costs	$ 2,314	$ 1,436
Employee stock-based compensation expense	2,152	2,278
Marketing, legal, accounting and other professional expenses	3,589	2,530
Other expenses	2,602	1,897
Total general and administrative expenses	$ 10,657	$ 8,141

Salaries, benefits and related costs increased by $0.9 million primarily due to the hiring of an executive in the fourth quarter of 2011 and other new hires made in the 2011 and 2012. Marketing, legal, accounting and other professional expenses increased by $1.1 million primarily due to increased legal costs associated with developing Fanapt® outside the U.S. and Canada and increased marketing expenses associated with tasimelteon. Other expenses increased by $0.7 million primarily as a result of lease exit costs for our former headquarters in Rockville, Maryland and the related accelerated depreciation recognized in the first quarter of 2012.

Other income. Other income increased by $0.1 million to $0.5 million for the nine months ended September 30, 2012 from $0.4 million for the nine months ended September 30, 2011 primarily as a result of a legal settlement related to a lawsuit filed against one of our shareholders partially offset by lower interest income. While we did not participate in the lawsuit proceedings, we received a portion of the settlement.

Liquidity and Capital Resources

As of September 30, 2012, our total cash and cash equivalents and marketable securities were $134.4 million compared to $167.9 million at December 31, 2011. 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, asset-backed commercial paper and commercial paper of high-quality corporate issuers. Our marketable securities consist of investments in U.S. government sponsored enterprises and commercial paper. As of September 30, 2012, we also held current deposits and non-current deposits totaling $0.4 million and $0.6 million, respectively. The current deposit of $0.4 million was used to collateralize a letter of credit issued for our office lease in Rockville, Maryland, which expires in 2013. The non-current deposit of $0.6 million consists of $0.1 million used to collateralize a letter of credit issued as a requirement for our license renewal with the Maryland Board of Pharmacy, and $0.5 million used to collateralize a letter of credit issued for our office lease in Washington, D.C., which expires in 2023.

As of September 30, 2012, 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 efforts, as we focus on clinical trials and manufacturing required for the development of our product candidates. The duration and cost of clinical trials are a function of numerous factors such as the number of patients to be enrolled in the trial, the amount of time it takes to enroll them, the length of time they must be treated and observed, and the number of clinical sites and countries for the trial. In addition, orphan clinical trials create an additional challenge due to the limited number of available patients afflicted with the disease.

We must receive regulatory approval to launch any of our products commercially. 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 clinical development programs, the scope and costs of our manufacturing and process development activities, the magnitude of our discovery and preclinical development programs and the level of our pre-commercial launch activities. There can be no assurance that any additional financing required in the future will be available on acceptable terms, if at all.

Cash Flow

The following table summarizes our cash flows for the nine months ended September 30, 2012 and 2011:

	Nine Months Ended	
(in thousands)	**September 30, 2012**	**September 30, 2011**
Net cash provided by (used in):		
Operating activities	$ (31,068)	$ (16,053)
Investing activities	47,660	33,815
Financing activities		5
Net increase in cash and cash equivalents	$ 16,592	$ 17,767

Net cash used in operations was $31.1 million and $16.1 million for the nine months ended September 30, 2012 and 2011, respectively. The increase in net cash used in operations for the nine months ended September 30, 2012 as compared to September 30, 2011 was primarily due to the costs associated with four Phase III clinical trials for tasimelteon in N24HD, which were initiated in 2010 and 2011, and one Phase IIb/III clinical trial for tasimelteon in MDD, which was initiated in the third quarter of 2011. Adjustments to reconcile net loss to net cash used in operating activities for the nine months ended September 30, 2012, included non-cash charges for depreciation and amortization of $2.1 million and stock-based compensation of $3.2 million, a net increase of $3.9 million in inventory, prepaid expenses and other assets, accounts payable, accrued liabilities and other liabilities, an increase in landlord contributions for tenant improvements of $1.8 million, a decrease in accounts receivable of $0.1 million and a decrease in deferred revenue of $20.0 million. Net cash provided by investing activities for the nine months ended September 30, 2012 was $47.7 million and consisted of net purchases, sales and maturities of marketable securities of $49.7 million and

purchases of property and equipment of $2.0 million.

Effects of Inflation

Inflation does not have a material impact on our results of operations.

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 long-term contractual cash obligations and commitments as of September 30, 2012:

		Cash payments due by period					
(in thousands)	**Total**	**October to December 2012**	**2013**	**2014**	**2015**	**2016**	**After 2016**
Operating leases	$ 11,550	$	$ 859	$ 1,052	$ 1,079	$ 1,106	$ 7,454
Lease exit liability	798	182	616				
Total	$ 12,348	$ 182	$ 1,475	$ 1,052	$ 1,079	$ 1,106	$ 7,454

Operating leases

Our commitments related to operating leases shown above consist of payments relating to a real estate lease for our current headquarters located in Washington, D.C. In July 2011, we entered into a 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, which has an 11-year term that commenced in April 2012, we will pay $1.6 million in annual rent over the term of the Lease; however, rent is abated for the first 12 months. The Landlord agreed to provide us with an allowance of $1.9 million for leasehold improvements. As of September 30, 2012, we had received $1.8 million of the allowance. Subject to the prior rights of other tenants in the building, we will have the right to renew the Lease for five years following the expiration of its original term. We will also have the right to sublease or assign all or a portion of the premises, subject to standard conditions. The Lease may be terminated early by us or the Landlord upon certain conditions. We paid a security deposit of $0.5 million upon execution of the Lease.

As a result of our relocation from Rockville, Maryland to Washington, D.C., we provided notice to our previous landlord that we were terminating our prior lease effective June 2013. As a result of terminating this lease, we recognized expenses of $0.7 million in the fourth quarter of 2011 related to a lease termination penalty. Of this amount, $0.6 million was presented as research and development expense on the consolidated statement of operations for the year ended December 31, 2011 and $0.1 million is presented as general and administrative expense on the consolidated statement of operations for the year ended December 31, 2011. In the first quarter of 2012, we ceased using the Rockville, Maryland location and, as a result, recognized additional rent expense of $0.8 million. This $0.8 million consisted of a lease exit liability of $1.3 million for the remaining payments required under the lease and the reversal of the deferred rent liability of $0.5 million related to the Rockville, Maryland lease. The remaining costs associated with the lease exit liability are included in the table above. Of the $0.8 million, $0.6 million is presented as research and development expense on the condensed consolidated statement of operations for the nine months ended September 30, 2012 and $0.2 million is presented as general and administrative expense on the condensed consolidated statement of operations for the nine months ended September 30, 2012.

The following is a summary of our lease exit activity:

(in thousands)	**Balance At Beginning Of Period**	**Costs Incurred and Charged to Expense**	**Costs Paid or Otherwise Settled**	**Adjustments**	**Balance At End Of Period**
Three months ended December 31, 2011	$	$ 740	$	$	$ 740
Nine months ended September 30, 2012	$ 740	$ 1,344	$ 1,232	$ (54)	$ 798

Rent expense, including lease exit costs, for the nine months ended September 30, 2012 and 2011 was $1.8 million and $0.9 million, respectively.

Consulting fees

We have engaged a regulatory consultant to assist in our efforts to prepare, file and obtain FDA approval of a New Drug Application (NDA) for tasimelteon. As part of this engagement, and subject to certain conditions, we will be obligated to make milestone payments in the aggregate amount of $2.8 million upon the achievement of certain milestones, including $2.0 million in the event that a tasimelteon NDA is approved by the FDA. In addition to these fees and milestone payments, we are obligated to reimburse the consultant for ordinary and necessary business expenses incurred in connection with the engagement. We may terminate the engagement at any time upon prior notice; however, subject to certain conditions, we will remain obligated to make some or all of the milestone payments if the milestones are achieved following such termination.

Clinical research organization contracts and other contracts

Other contracts. We have entered into agreements for tasimelteon with clinical supply manufacturing organizations and other outside contractors who will be responsible for additional services supporting our ongoing clinical development processes. These contractual obligations are not reflected in the table above because we may terminate them 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 our contractors in closing out work in progress as of the effective date of termination).

License agreements. In February 2004, we entered into a license agreement with Bristol-Myers Squibb (BMS) for the exclusive rights to develop and commercialize tasimelteon. The license agreement with BMS was most recently amended in May 2012. In June 2004, we entered into a sublicense agreement with Novartis for the exclusive rights to develop and commercialize Fanapt®. In October 2009, we entered into an amended and restated sublicense agreement with Novartis. In April 2012, we entered into a license agreement with Eli Lilly and Company (Lilly) for the exclusive rights to develop and commercialize VLY-686. We are obligated to make (in the case of tasimelteon and VLY-686 and, in the case of Fanapt® in the U.S. and Canada, are entitled to receive) payments under the conditions in the agreements upon the achievement of specified clinical, regulatory and commercial milestones. If the products are successfully commercialized, we will be required to pay (and in the case of Fanapt® in the U.S. and Canada, will be entitled to receive) certain royalties based on net sales for each of the licensed products.

As a result of the successful commencement of a Phase III clinical study of tasimelteon in March 2006, we met the first milestone specified in our license agreement with BMS and subsequently paid a license fee of $1.0 million. We are also obligated to make future milestone payments of less than $40.0 million in the aggregate (the majority of which are tied to sales milestones) as well as royalty payments based on the net sales of tasimelteon at a rate which, as a percentage of net sales, is in the low teens. We are also obligated under this license agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that we receive from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties.

As a result of the acceptance by the FDA of the NDA for Fanapt® in October 2007, we met a milestone under our original sublicense agreement with Novartis and subsequently paid a $5.0 million milestone fee. As a result of the FDA s approval of the NDA for Fanapt® in May 2009, we met an additional milestone under the original sublicense agreement with Novartis which required us to make a payment of $12.0 million to Novartis. The $12.0 million was capitalized and will be amortized over the remaining life of the U.S. patent for Fanapt®, which we expect 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 we expect that Fanapt® will be eligible for six months of pediatric exclusivity. This term is our 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. No amounts were recorded as liabilities relating to the license agreements included in the condensed consolidated financial statements as of September 30, 2012, since the amounts, timing and likelihood of these payments are unknown and will depend on the successful outcome of future clinical trials, regulatory filings, favorable regulatory approvals, growth in product sales and other factors.

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 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 us 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, we received an upfront payment of $200.0 million and are eligible for additional payments totaling up to $265.0 million upon Novartis achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. Based on the current sales performance of Fanapt® in the U.S. and the decision by Novartis to cease development of the long-acting injectible (or depot) formulation of Fanapt®, we expect that some or all of these commercial and development milestones will not be achieved by Novartis. We also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. We retain exclusive rights to Fanapt® outside the U.S. and Canada and have exclusive rights to use any of Novartis data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. At Novartis option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt® outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt® outside of the U.S. and Canada. Novartis has chosen not to co-commercialize Fanapt® with us in Europe and certain other countries and will instead receive a royalty on net sales in those countries. These include, but are not limited to, the countries in the European Union as well as Switzerland, Norway, Liechtenstein and Iceland. We have 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.
Argentina	Biotoscana Farma S.A.
Israel	Megapharm Ltd.

In August 2012, the Israeli Ministry of Health granted market approval for Fanapt® for the treatment of schizophrenia.

Pursuant to our license agreement with Lilly for VLY-686, we paid an initial license fee of $1.0 million and will be responsible for all development costs. 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.

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.

Item 4. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (Exchange Act)) as of September 30, 2012. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of September 30, 2012, the end of the period covered by this quarterly report, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the third quarter of 2012 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.

None.

Item 1A. Risk Factors.

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, filed with the Securities and Exchange Commission on March 9, 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. Except as set forth below, there have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2011.

Novartis began selling, marketing and distributing our first approved product, Fanapt®, in the U.S. in the first quarter of 2010 and we will depend heavily on the success of this product in the marketplace.

Our ability to generate revenue for the next few years will depend substantially on the success of Fanapt® and the sales of this product by Novartis in the U.S. and Canada. The ability of Fanapt® to generate revenue at the levels we expect will depend on many factors, including the following:

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

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

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

Novartis ability to expand the indications for which Fanapt® can be marketed in the U.S.

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

our ability to successfully develop and commercialize Fanapt®, including a long-acting injectable (or depot) formulation of Fanapt®, outside of the U.S. and Canada

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

We entered into an amended and restated sublicense agreement with Novartis to commercialize Fanapt® in the U.S. and Canada. As such, we are not directly involved in the marketing or sales efforts for Fanapt® in the U.S. and Canada. Our future revenues depend substantially on royalties and milestone payments we may receive from Novartis. Pursuant to the amended and restated sublicense agreement with Novartis, we received an upfront payment of $200.0 million and are eligible for additional payments totaling up to $265.0 million upon Novartis achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. Based on the current sales performance of Fanapt® in the U.S. and the decision by Novartis to cease development of the long-acting injectable (or depot) formulation of Fanapt®, we expect that some or all of these commercial and development milestones will not be achieved by Novartis. We also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. Such royalties may not be significant and will depend on numerous factors. We cannot control the amount and timing of resources that Novartis may devote to Fanapt®. If Novartis fails to successfully commercialize Fanapt® in the U.S. or fails to develop and commercialize Fanapt® in Canada, if Novartis efforts are not effective, or if Novartis focuses its efforts on other schizophrenia therapies or schizophrenia drug candidates, our business will be negatively affected. If Novartis does not successfully commercialize Fanapt® in the U.S. or Canada, we will receive limited revenues from them. Although we have developed and continue to develop additional products and product candidates for commercial introduction, we expect to be substantially dependent on sales from Fanapt® for the foreseeable future. For reasons outside of our control, including those mentioned above, sales of Fanapt® may not meet our or financial or industry analysts expectations. Any significant negative developments relating to Fanapt®, such as safety or efficacy issues, the introduction or greater acceptance of competing products or adverse regulatory or legislative developments, will have a material adverse effect on our financial condition and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit	Description

Number	
10.49	Separation and Release Agreement for John Feeney, M.D. dated September 18, 2012.
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2012, formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) Condensed Consolidated Balance Sheets as of September 30, 2012 and December 31, 2011; (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2012 and 2011; (iii) Condensed Consolidated Statement of Comprehensive Loss for the three and nine months ended September 30, 2012 and 2011; (iv) Condensed Consolidated Statement of Changes in Stockholders Equity for the nine months ended September 30, 2012; (v) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2012 and 2011; and (vi) Notes to Condensed Consolidated Financial Statements.

The certification attached as Exhibit 32.1 that accompanies this quarterly report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Vanda Pharmaceuticals Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this quarterly report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Vanda Pharmaceuticals Inc.

November 8, 2012 /s/ Mihael H. Polymeropoulos, M.D.
Mihael H. Polymeropoulos, M.D.

President and Chief Executive Officer

(Principal Executive Officer)

November 8, 2012 /s/ James P. Kelly
James P. Kelly

Senior Vice President, Chief Financial Officer, Secretary and Treasurer

(Principal Financial Officer and Principal Accounting Officer)

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

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