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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 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, Suite 300 E Washington, D.C.	**20037**
(Address of principal executive offices)	**(Zip Code)**

(202) 734-3400
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of July 31, 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 June 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)	June 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 94,388	$ 87,923
Marketable securities, current	50,313	60,961
Accounts receivable	1,700	1,618
Inventory	165	—
Prepaid expenses, deposits and other current assets	3,423	2,999
Total current assets	149,989	153,501
Marketable securities, non-current	—	19,012
Property and equipment, net	2,533	964
Other assets, non-current	—	84
Intangible asset, net	7,286	8,027
Restricted cash	1,030	1,030
Total assets	$ 160,838	$ 182,618
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,689	$ 996
Accrued liabilities	5,908	3,381
Deferred rent, current	—	453
Deferred revenues, current	26,789	26,789
Total current liabilities	34,386	31,619
Deferred rent, non-current	2,588	461
Deferred revenues, non-current	103,780	117,064
Total liabilities	140,754	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 June 30, 2012 and December 31, 2011, respectively	28	28
Additional paid-in capital	299,463	296,868
Accumulated other comprehensive income	5	21
Accumulated deficit	(279,412)	(263,443)
Total stockholders' equity	20,084	33,474
Total liabilities and stockholders' equity	$ 160,838	$ 182,618

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

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(in thousands, except for share and per share amounts)	Three Months Ended June 30, 2012	Three Months Ended June 30, 2011	Six Months Ended June 30, 2012	Six Months Ended June 30, 2011
Revenues:				
Licensing agreement	$ 6,678	$ 6,678	$ 13,284	$ 13,284
Royalty revenue	1,700	752	3,235	1,647
Total revenues	8,378	7,430	16,519	14,931
Operating expenses:				
Research and development	12,490	5,999	24,670	10,266
General and administrative	3,601	2,572	7,510	5,430
Intangible asset amortization	372	372	741	741
Total operating expenses	16,463	8,943	32,921	16,437
Loss from operations	(8,085)	(1,513)	(16,402)	(1,506)
Other income	78	121	433	256
Loss before tax benefit	(8,007)	(1,392)	(15,969)	(1,250)
Tax benefit	—	(51)	—	(45)
Net loss	$ (8,007)	$ (1,341)	$ (15,969)	$ (1,205)
Net loss per share:				
Basic	$ (0.28)	$ (0.05)	$ (0.57)	$ (0.04)
Diluted	$ (0.28)	$ (0.05)	$ (0.57)	$ (0.04)
Shares used in calculation of net loss per share:				
Basic	28,226,743	28,103,441	28,226,743	28,102,774
Diluted	28,226,743	28,103,441	28,226,743	28,102,774

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		Six Months Ended	
	June 30, 2012	June 30, 2011	June 30, 2012	June 30, 2011
Net loss	$(8,007)	$(1,341)	$(15,969)	$(1,205)
Other comprehensive loss				
Change in net unrealized gain (loss) on marketable securities	(22)	(14)	(16)	83
Comprehensive loss before tax provision	(8,029)	(1,355)	(15,985)	(1,122)
Tax provision related to other comprehensive loss	—	—	—	—
Comprehensive loss	$(8,029)	$(1,355)	$(15,985)	$(1,122)

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	—	—	2,595	—	—	2,595
Net loss	—	—	—	—	(15,969)	(15,969)
Other comprehensive loss	—	—	—	(16)	—	(16)
Balances at June 30, 2012	28,226,743	$ 28	$299,463	$ 5	$ (279,412)	$ 20,084

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)	Six Months Ended June 30, 2012	Six Months Ended June 30, 2011
Cash flows from operating activities		
Net loss	$(15,969)	$ (1,205)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	424	138
Employee and non-employee stock-based compensation	2,595	2,929
Amortization of premiums and discounts on marketable securities	282	574
Amortization of intangible asset	741	741
Changes in assets and liabilities:		
Accounts receivable	(82)	(241)
Inventory	(165)	—
Prepaid expenses, deposits and other assets	(340)	(349)
Accounts payable	693	689
Accrued liabilities,	2,527	1,189
Accrued income taxes	—	(45)
Other liabilities	(151)	(19)
Landlord contributions for tenant improvements	1,825	—
Deferred revenue	(13,284)	(13,284)
Net cash used in operating activities	(20,904)	(8,883)
Cash flows from investing activities		
Purchases of property and equipment	(1,993)	(164)
Purchases of marketable securities	(49,967)	(89,576)
Proceeds from sale of marketable securities	1,998	—
Maturities of marketable securities	77,331	106,550
Change in restricted cash	—	(100)
Net cash provided by investing activities	27,369	16,710
Net change in cash and cash equivalents	6,465	7,827
Cash and cash equivalents		
Beginning of period	87,923	42,559
End of period	$ 94,388	$ 50,386

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. On May 6, 2009, the U.S. Food and Drug Administration (FDA) granted U.S. marketing approval of Fanapt® for the acute treatment of schizophrenia in adults. On October 12, 2009, Vanda entered into an amended and restated sublicense agreement with Novartis. Vanda had originally entered into a sublicense agreement with Novartis on June 4, 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®. 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 the achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. 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. Vanda continues to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. and Canada. On July 22, 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. In July 2012, the Committee for Medicinal Products for Human Use (CHMP) provided Vanda with the Day 180 List of Outstanding Issues. Vanda expects to be granted an extension to reply by mid-October 2012 and will prepare to participate in an 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.

Tasimelteon is an oral compound in development for the treatment of sleep and mood disorders including Circadian Rhythm Sleep Disorders (CRSD). On January 19, 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. On February 23, 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 with a planned enrollment of up to 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 to examine the maintenance effect of tasimelteon for the treatment of N24HD with a planned enrollment of up to 20 patients with 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 subjects with N24HD to assess the safety of tasimelteon. The tasimelteon N24HD program continues to advance towards its goal of a projected mid-2013 NDA filing with the FDA. Vanda is in continuing discussions with the FDA to confirm the path and requirements for this regulatory submission. The SET Phase III efficacy study is fully enrolled and Vanda expects to report top-line results by the end of 2012. Vanda expects to report top-line results from the RESET Phase III efficacy study 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 a planned 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, is ongoing and Vanda expects to report top-line results in the first half 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 initiate and 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 and tasimelteon 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 June 30, 2012 and for the three and six months ended June 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, net

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 values of intangible assets are periodically reviewed to determine if the facts and circumstances suggest that a potential impairment may have occurred. The Company had no impairments of its intangible assets for the six months ended June 30, 2012.

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 27, 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 June 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 expenses

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) the Company's 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 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 six months ended June 30, 2012 and 2011 was comprised of the following:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2012	June 30, 2011	June 30, 2012	June 30, 2011
Research and development	$ 520	$ 618	$1,113	$1,338
General and administrative	668	696	1,466	1,574
Stock-based compensation expense	$1,188	$ 1,314	$2,579	$2,912

As of June 30, 2012, $6.5 million of total unrecognized compensation costs related to non-vested awards are expected to be recognized over a weighted average period of 1.28 years.

As of June 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 June 30, 2012, and no additional options will be granted under this plan. As of June 30, 2012, there were 7,866,260 shares of the Company's common stock reserved under the 2006 Plan of which 4,835,620 shares were subject to outstanding options and RSUs issued to employees and non-employees.

Options are subject to terms and conditions established by the compensation committee of the board of directors. None of the stock-based awards are classified as a liability as of June 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 June 30, 2012, there was $3.2 million of total 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 on September 25, 2008) and does not plan to pay dividends in the foreseeable future.

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

	Six Months Ended	
	June 30, 2012	June 30, 2011
Expected dividend yield	0%	0%
Weighted average expected volatility	68%	73%
Weighted average expected term (years)	6.03	6.03
Weighted average risk-free rate	1.08%	2.50%

A summary of option activity for the 2004 Plan as of June 30, 2012, and changes during the six 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 June 30, 2012	677,145	$ 1.78	3.28	$ 1,847
Exercisable at June 30, 2012	677,145	$ 1.78	3.28	$ 1,847

A summary of option activity for the 2006 Plan as of June 30, 2012, and changes during the six 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	148,000	$ 4.50		
Exercised	—	—		
Forfeited	69,334	$ 11.07		
Cancelled	25,541	$ 6.85		
Outstanding at June 30, 2012	4,307,806	$ 11.95	7.24	$ 388
Exercisable at June 30, 2012	2,655,213	$ 14.90	6.31	$ 332

The weighted average grant-date fair value of options granted during the six months ended June 30, 2012 was $2.75 per share. For the six months ended June 30, 2012 and 2011, the amounts received by the Company in cash from options exercised under the stock-based arrangements were not material.

A 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 June 30, 2012, there was $3.3 million of total 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 June 30, 2012, and changes during the six 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	11,500	$ 4.33	
Vested	—	—	
Cancelled	6,032	$ 6.72	
Unvested at June 30, 2012	527,814	$ 7.37	$ 2,322

Income taxes

The Company accounts for income taxes in accordance with the FASB provisions 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 carryforwards that can be utilized in the future to offset taxable income.

Recent Accounting Pronouncements

In June 2011, the FASB issued an Accounting Standards Update which eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders' equity. It requires an entity to present total comprehensive income, which includes the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for financial statements issued for annual and interim periods within the first annual period beginning after December 15, 2011 and must be applied retroactively. The pronouncement, adopted by the Company in the first quarter of 2012, did not have a material impact on the Company's financial position or results of operations.

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 six months ended June 30, 2012 and 2011:

(in thousands, except for share and per share amounts)	Three Months Ended June 30, 2012	Three Months Ended June 30, 2011	Six Months Ended June 30, 2012	Six Months Ended June 30, 2011
Numerator:				
Net loss	$ (8,007)	$ (1,341)	$ (15,969)	$ (1,205)
Denominator:				
Weighted average shares of common stock outstanding, basic	28,226,743	28,103,441	28,226,743	28,102,774
Stock options and restricted stock units related to the issuance of common stock	—	—	—	—
Weighted average shares of common stock outstanding, diluted	28,226,743	28,103,441	28,226,743	28,102,774
Net loss per share:				
Basic	$ (0.28)	$ (0.05)	$ (0.57)	$ (0.04)
Diluted	$ (0.28)	$ (0.05)	$ (0.57)	$ (0.04)
Anti-dilutive securities not included in diluted net loss per share calculation:				
Options to purchase common stock and restricted stock units	5,199,705	3,974,965	5,201,746	3,560,885

4. Marketable Securities

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

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Current:				
U.S. Treasury and government agencies	$ 21,394	$ 1	$ (1)	$ 21,394
U.S. corporate debt	28,915	23	(19)	28,919
	$ 50,309	$ 24	$ (20)	$ 50,313

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
U.S. 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, Deposits and Other Current Assets

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

(in thousands)	June 30, 2012	December 31, 2011
Prepaid insurance	$ 486	$ 165
Other prepaid expenses and vendor advances	2,530	2,474
Accrued interest income	381	244
Other receivable	26	116
Total prepaid expenses, deposits and other current assets	$3,423	$ 2,999

6. Property and Equipment, Net

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

(in thousands)	Estimated Useful Life (Years)	June 30, 2012	December 31, 2011
Laboratory equipment	5	$ 1,273	$ 1,273
Computer equipment	3	1,236	1,105
Furniture and fixtures	7	853	700
Leasehold improvements	10-11	1,825	844
Leasehold improvements-in-progress	N/A	—	116
		5,187	4,038
Less—accumulated depreciation and amortization		(2,654)	(3,074)
		$ 2,533	$ 964

Depreciation expense for the six months ended June 30, 2012 and 2011 was $0.4 million and $0.1 million, respectively.

7. Intangible Asset, Net

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

(in thousands)	Estimated Useful Life (Years)	June 30, 2012 Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	8	$12,000	$ 4,714	$ 7,286

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

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

On May 6, 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.

Intangible assets are amortized over their estimated useful economic life using the straight-line method. Amortization expense was $0.7 million for each of the six months ended June 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 June 30, 2012 and December 31, 2011:

(in thousands)	June 30, 2012	December 31, 2011
Accrued research and development expenses	$3,723	$ 1,967
Accrued consulting and other professional fees	259	317
Employee benefits	744	100
Accrued lease termination penalty (refer to footnote 10)	—	740
Accrued lease exit liability (refer to footnote 10)	1,013	—
Other accrued liabilities	169	257
Total accrued liabilities, current	$5,908	$ 3,381

9. Revenue Recognition

The following is a summary of the Company's revenues:

(in thousands)	December 31, 2011 Deferred Revenue	Revenue Recognized	June 30, 2012 Deferred Revenue
Revenues:			
Licensing agreement	$ 143,853	$ 13,284	$ 130,569
Royalty revenue	—	3,235	—
Total	$ 143,853	$ 16,519	$ 130,569

Vanda entered into an amended and restated sublicense agreement with Novartis on October 12, 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 of 2009. Revenue related to the upfront payment will be recognized ratably from the date the amended and restated sublicense agreement became effective (November 27, 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 six months ended June 30, 2012, the Company recognized $13.3 million of revenue from the amended and restated sublicense agreement. Vanda recognized royalty revenue of $3.2 million for the six months ended June 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 as of June 30, 2012:

	Cash payments due by period						
(in thousands)	Total	July 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	1,013	456	557	—	—	—	—
Consulting fees	1,000	1,000	—	—	—	—	—
Total	$13,563	$ 1,456	$1,416	$1,052	$1,079	$1,106	$7,454

Operating leases

The Company's commitments related to operating leases shown above consist of payments relating to a real estate lease for its current headquarters located in Washington, D.C. On July 25, 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 commencing on April 1, 2012, the Company will pay $1.6 million in annual rent over the term of the Lease; however, rent will be abated for the first 12 months. The Landlord will provide the Company with an allowance of $1.9 million for leasehold improvements. As of June 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 previous lease effective June 30, 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 balance 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 was presented as research and development expense on the consolidated statement of operations for the quarter ended March 31, 2012 and $0.2 million was presented as general and administrative expense on the consolidated statement of operations for the quarter ended March 31, 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
Period ended:					
December 31, 2011	$ —	$ 740	$ —	$ —	$ 740
March 31, 2012	$ 740	$ 1,285	$ —	$ —	$ 2,025
June 30, 2012	$ 2,025	$ —	$ 958	$ (54)	$ 1,013

Rent expense for the six months ended June 30, 2012 and 2011 was $1.6 million and $0.5 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 a NDA for tasimelteon. The initial term of the engagement is for the 15-month period from October 2011 to December 2012. The Company is obligated to pay the consultant $1.0 million between July 2012 and December 2012. 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 its ordinary and necessary business expenses incurred in connection with its 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 June 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.

On October 12, 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®. Pursuant to the amended and restated sublicense agreement, Vanda received an upfront payment of $200.0 million and Vanda is eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. 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. On July 22, 2011, the EMA notified Vanda that it had accepted for evaluation the MAA for oral iloperidone tablets. The review of Vanda's MAA for oral iloperidone tablets in the European Union is ongoing. In July 2012, the Committee for Medicinal Products for Human Use (CHMP) provided Vanda with the Day 180 List of Outstanding Issues. Vanda expects to be granted an extension to reply by mid-October 2012 and will prepare to participate in an 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.

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 a 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 a neurokinin-1 receptor (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 agreed to pay 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 presented as research and development expense on the consolidated statement of operations for the quarter ended June 30, 2012. Lilly is also eligible to receive additional payments based upon achievement of specified development and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. These milestones include $4.0 million for pre-NDA approval milestones and up to $95.0 million for future regulatory approval and sales milestones. Vanda 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 June 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 Company did not record any tax provision or benefit for the six months ended June 30, 2012. For the six months ended June 30, 2011, the Company recorded a tax benefit of $0.05 million. As of June 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 net operating losses could not be sufficiently assured. As of June 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 June 30, 2012 and December 31, 2011 include 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 commercial paper, corporate notes and government agency notes that use as their basis readily observable market parameters.

As of June 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)	June 30, 2012	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Description:				
Available-for-sale securities	$ 50,313	$ 21,394	$ 28,919	$ —

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)
Description:				
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 forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in our forward-looking statements include, among others:

- our 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 costs and expenses;
- 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 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 the discussion and analysis of our financial condition and 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, 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 the achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. 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 six months ended June 30, 2012, we incurred $0.8 million in research and development costs directly attributable to our development of Fanapt®.

We are conducting four clinical trials to pursue U.S. Food and Drug Administration (FDA) approval of tasimelteon for the treatment of Non-24-Hour Disorder (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 Major Depressive Disorder (MDD). During the six months ended June 30, 2012, we incurred $21.4 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 27, 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 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 six months ended June 30, 2012, we incurred research and development expenses in the aggregate of $24.7 million, including stock-based compensation expense of $1.1 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 six months ended June 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.

(in thousands)	Three Months Ended June 30, 2012	Three Months Ended June 30, 2011	Six Months Ended June 30, 2012	Six Months Ended June 30, 2011
Direct project costs(1)				
Fanapt®	$ 318	$ 612	$ 750	$ 961
Tasimelteon	10,917	5,131	21,419	8,816
VLY-686	1,014	—	1,014	—
Total direct project costs	12,249	5,743	23,183	9,777
Indirect project costs(1)				
Facility	105	156	1,102	311
Depreciation	53	27	238	69
Other indirect overhead	83	73	147	109
Total indirect project costs	241	256	1,487	489
Total research and development expenses	$12,490	$5,999	$24,670	$10,266

(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 six months ended June 30, 2012, we incurred general and administrative expenses in the aggregate of $7.5 million, including stock-based compensation expense of $1.5 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 expenses. 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 27, 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 on September 25, 2008) and do not plan to pay dividends in the foreseeable future. The stock-based compensation expense for a period is also affected by 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 six months ended June 30, 2012 and 2011 was comprised of the following:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2012	June 30, 2011	June 30, 2012	June 30, 2011
Research and development	$ 520	$ 618	$1,113	$1,338
General and administrative	668	696	1,466	1,574
Stock-based compensation expense	$1,188	$ 1,314	$2,579	$2,912

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

In June 2011, the FASB issued an Accounting Standards Update which eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders’ equity. It requires an entity to present total comprehensive income, which includes the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for financial statements issued for annual and interim periods within the first annual period beginning after December 15, 2011 and must be applied retroactively. The pronouncement, which we adopted in the first quarter of 2012, did not have a material impact on our financial position or results of operations.

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 June 30, 2012, we had a deficit accumulated of $279.4 million.

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

Revenues. Revenues were $8.4 million for the three months ended June 30, 2012, compared to revenues of $7.4 million for the three months ended June 30, 2011. Revenues for the three months ended June 30, 2012 included $6.7 million recognized from Novartis related to straight-line recognition of up-front license fees and $1.7 million in royalty revenue based on second quarter 2012 sales of Fanapt®. Revenues for the three months ended June 30, 2011 included $6.7 million recognized from Novartis related to straight-line recognition of upfront license fees and $0.8 million in royalty revenue based on second quarter 2011 sales of Fanapt®.

Intangible asset amortization. Intangible asset amortization was $0.4 million for both the three months ended June 30, 2012 and the three months ended June 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 $6.5 million, or 108.2%, to $12.5 million for the three months ended June 30, 2012 compared to $6.0 million for the three months ended June 30, 2011.

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

	Three Months Ended	
(in thousands)	**June 30, 2012**	**June 30, 2011**
Direct project costs:		
Clinical trials	$ 7,830	$2,862
Contract research and development, consulting, materials and other direct costs	2,819	1,280
Salaries, benefits and related costs	1,080	983
Stock-based compensation	520	618
Total direct costs	12,249	5,743
Indirect project costs	241	256
Total	$12,490	$5,999

Direct costs increased by $6.5 million 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 $5.0 million primarily due to costs related to the tasimelteon trials in N24HD and MDD. Contract research and development consulting, materials and other direct costs increased by $1.5 million 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. Salaries, benefits and related costs increased by $0.1 million primarily due to new employees hired in 2011 to support the tasimelteon trials.

General and administrative expenses. General and administrative expenses increased by $1.0 million, or 40.0%, to $3.6 million for the three months ended June 30, 2012 from $2.6 million for the three months ended June 30, 2011.

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

	Three Months Ended	
(in thousands)	**June 30, 2012**	**June 30, 2011**
Salaries, benefits and related costs	$ 777	$ 474
Stock-based compensation	668	696
Marketing, legal, accounting and other professional expenses	1,444	724
Other expenses	712	678
Total	$3,601	$ 2,572

Salaries, benefits and related costs increased by $0.3 million primarily as a result of an executive hire made in the fourth quarter of 2011. Marketing, legal, accounting and other professional expenses increased by $0.7 million primarily due to increased legal and marketing expenses associated with our compounds.

Other income. Other income was unchanged for the three months ended June 30, 2012 as compared to the three months ended June 30, 2011.

Six months ended June 30, 2012 compared to six months ended June 30, 2011

Revenues. Revenues were $16.5 million for the six months ended June 30, 2012, compared to revenues of $14.9 for the six months ended June 30, 2011. Revenues for the six months ended June 30, 2012 included $13.3 million recognized from Novartis related to straight-line recognition of up-front license fees and $3.2 million in royalty revenue based on sales of Fanapt® in the six months ended June 30, 2012. Revenues for the six months ended June 30, 2011 included $13.3 million recognized from Novartis related to the straight-line recognition of up-front license fees and $1.6 million in royalty revenue based on sales of Fanapt® in the six months ended June 30, 2011. Novartis launched Fanapt® commercially in the U.S. in January 2010.

Intangible asset amortization. Intangible asset amortization was $0.7 million for both the six months ended June 30, 2012 and the six months ended June 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 $14.4 million, or 140.3%, to $24.7 million for the six months ended June 30, 2012 compared to $10.3 million for the six months ended June 30, 2011.

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

	Six Months Ended	
(in thousands)	June 30, 2012	June 30, 2011
Direct project costs:		
Clinical trials	$15,037	$ 4,387
Contract research and development, consulting, materials and other direct costs	4,752	2,175
Salaries, benefits and related costs	2,281	1,877
Stock-based compensation	1,113	1,338
Total direct costs	23,183	9,777
Indirect project costs	1,487	489
Total	$24,670	$10,266

Direct costs increased by $13.4 million for the six months ended June 30, 2012 compared to the six months ended June 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 $10.7 million for the six months ended June 30, 2012 relative to the six months ended June 30, 2011, primarily due to costs related to the tasimelteon trials in N24HD and MDD. Contract research and development, consulting, materials and other direct costs increased $2.6 million for the six months ended June 30, 2012 relative to the six months ended June 30, 2011, primarily due to costs related to these trials.

General and administrative expenses. General and administrative expenses increased by $2.1 million, or 38.3%, to $7.5 million for the six months ended June 30, 2012 from $5.4 million for the six months ended June 30, 2011.

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

	Six Months Ended	
(in thousands)	June 30, 2012	June 30, 2011
Salaries, benefits and related costs	$1,506	$1,003
Stock-based compensation	1,466	1,574
Marketing, legal, accounting and other professional expenses	2,742	1,612
Other expenses	1,796	1,241
Total	$7,510	$5,430

Salaries, benefits and related costs increased by $0.5 million primarily as a result of an executive hiring made in the fourth quarter of 2011. Marketing, legal, accounting and other professional expenses increased by $1.1 million primarily due to increased legal and marketing expenses associated with our compounds. Other expenses increased by $0.6 million primarily as a result of the lease exit liability and accelerated depreciation recognized in the first quarter of 2012.

Other income. Other income increased by $0.2 million to $0.4 million for the six months ended June 30, 2012 from $0.2 million for the six months ended June 30, 2011 primarily as a result of a legal settlement related to a lawsuit filed against one of our shareholders. While we did not participate in the lawsuit proceedings, we received a portion of the settlement.

Liquidity and Capital Resources

As of June 30, 2012, our total cash and cash equivalents and marketable securities were $144.7 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, and commercial paper of high-quality corporate issuers. Our marketable securities consist of investments in government sponsored enterprises and commercial paper. As of June 30, 2012, we also held non-current deposits totaling $1.0 million, consisting of $0.4 million used to collateralize a letter of credit issued for our office lease in Rockville, Maryland, which expires in 2013, $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 June 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 drugs or that our drugs 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 six months ended June 30, 2012 and 2011:

	Six Months Ended	
(in thousands)	June 30, 2012	June 30, 2011
Net cash provided by (used in)		
Operating activities	$(20,904)	$ (8,883)
Investing activities	27,369	16,710
Net change in cash and cash equivalents	$ 6,465	$ 7,827

Net cash used in operations was $20.9 million and $8.9 million for the six months ended June 30, 2012 and 2011, respectively. The increase in net cash used in operations for the six months ended June 30, 2012 as compared to June 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 six months ended June 30, 2012, included non-cash charges for depreciation and amortization of $1.4 million and stock-based compensation of $2.6 million, increases in prepaid expenses and other current assets, accounts receivable, inventory, accounts payable and accrued liabilities of $2.6 million, an increase in landlord contributions for tenant improvements of $1.8 million, a decrease in other liabilities of $0.2 million and a decrease in deferred revenue of $13.3 million. Net cash provided by investing activities for the six months ended June 30, 2012 was $27.4 million and consisted of net purchases, sales and maturities of marketable securities of $29.4 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 as of June 30, 2012:

	Cash payments due by period						
(in thousands)	Total	July 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	1,013	456	557	—	—	—	—
Consulting fees	1,000	1,000	—	—	—	—	—
Total	$13,563	$ 1,456	$1,416	$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. On July 25, 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 commencing on April 1, 2012, we will pay $1.6 million in annual rent over the term of the Lease; however, rent will be abated for the first 12 months. The Landlord will provide us with an allowance of $1.9 million for leasehold improvements. As of June 30, 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 previous lease effective June 30, 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 balance 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 was presented as research and development expense on the consolidated statement of operations for the quarter ended March 31, 2012 and $0.2 million was presented as general and administrative expense on the consolidated statement of operations for the quarter ended March 31, 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
Period ended:					
December 31, 2011	$ —	$ 740	$ —	$ —	$ 740
March 31, 2012	$ 740	$ 1,285	$ —	$ —	$ 2,025
June 30, 2012	$ 2,025	$ —	$ 958	$ (54)	$ 1,013

Rent expense for the six months ended June 30, 2012 and 2011 was $1.6 million and $0.5 million, respectively.

Consulting fees

We have engaged a regulatory consultant to assist in our efforts to prepare, file and obtain FDA approval of a NDA for tasimelteon. The initial term of the engagement is for the 15-month period from October 2011 to December 2012. We are obligated to pay the consultant $1.0 million between July 2012 and December 2012. 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 its ordinary and necessary business expenses incurred in connection with its 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 and June 2004, we entered into separate license agreements with BMS and Novartis, respectively, for the exclusive rights to develop and commercialize tasimelteon and Fanapt®. On April 15, 2010, we entered into an amended license agreement with BMS. On October 12, 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 the 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 the Company receives 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 consolidated financial statements as of June 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®. 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 the achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. 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. In addition, we are no longer required to make any future milestone payments with respect to sales of Fanapt® or any royalty payments with respect to 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.

Pursuant to our license agreement with Lilly for VLY-686, we agreed to pay 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 Exchange Act) as of June 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 June 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 SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the second quarter of 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 SEC on March 9, 2012, we identify under 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 Form 10-Q. There have been no material changes in our risk factors subsequent to the filing of our Form 10-K for the fiscal year ended December 31, 2011.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
10.47	Amendment to Amended and Restated License, Development and Commercialization Agreement, dated as of May 24, 2012 (filed as Exhibit 10.46 to the registrant's current report on Form 8-K filed on May 30, 2012 and incorporated herein by reference).
10.48#	License, Development and Commercialization Agreement, dated as of April 12, 2012, by and between Eli Lilly and Company and the Registrant.
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2012, formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) Condensed Consolidated Balance Sheets as of June 30, 2012 and December 31, 2011; (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2012 and 2011; (iii) Condensed Consolidated Statement of Comprehensive Income for the three and six months ended June 30, 2012 and 2011; (iv) Condensed Consolidated Statement of Changes in Stockholders' Equity for the six months ended June 30, 2012; (v) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2012 and 2011; and (vi) Notes to Condensed Consolidated Financial Statements.

Confidential treatment has been requested with respect to certain provisions of this exhibit.

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.

August 3, 2012 /s/ Mihael H. Polymeropoulos, M.D.

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

August 3, 2012 /s/ James P. Kelly

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

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

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Exhibit 10.48

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

by and between

ELI LILLY AND COMPANY
(an Indiana corporation)

and

VANDA PHARMACEUTICALS INC.
(a Delaware corporation)

Dated as of April 12, 2012

TABLE OF CONTENTS

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT ("Agreement"), effective as of April , 2012 ("Effective Date") is entered into by and between Vanda Pharmaceuticals Inc., a Delaware corporation, with offices at 2200 Pennsylvania Avenue, NW, Suite 300E, Washington, DC 20037 and its Affiliates (collectively, "Vanda") and Eli Lilly and Company, an Indiana corporation, with offices at Lilly Corporate Center, Indianapolis, Indiana 46285 and its Affiliates (collectively, "Lilly"). Lilly and Vanda may be referred to as a "Party" or together, the "Parties".

RECITALS

WHEREAS, Lilly owns or otherwise Controls certain rights in and to the Compound;

WHEREAS, Vanda desires to license Lilly's rights to such Compound on an exclusive basis to further Develop, Manufacture and Commercialize the Compound and Licensed Products;

NOW, THEREFORE, in consideration of the foregoing premises and the representations, covenants and agreements contained herein, Lilly and Vanda, intending to be legally bound, hereby agree as follows:

AGREEMENT

1. DEFINITIONS. For purposes of this Agreement, the following capitalized terms, whether used in the singular or plural, shall have the following meanings:

1.1 "Affiliate" means any Person that, directly or indirectly, controls, is controlled by or is under common control with a Party for so long as such control exists, where "control" means the decision making authority as to such Person and, further, where such control shall be presumed to exist where a Person owns more than fifty percent (50%) of the equity (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) entitled to vote regarding composition of the board of directors or other body entitled to direct the affairs of such Person.

1.2 "Agreement" shall have the meaning assigned thereto in the Preamble to this Agreement together with all Exhibits attached hereto.

1.3 "Annual Net Sales" shall have the meaning assigned thereto in Section 9.3.

1.4 "Business Day" means a day other than Saturday, Sunday or any day on which commercial banks located in New York, NY are authorized or obligated by law to close.

1.5 "Calendar Quarter" means each consecutive three (3) calendar month period starting January 1 (i.e., January 1 – March 31; April 1 – June 30; July 1 – September 30; and October 1 – December 31).

1.6 “Claim” means any charge, complaint, action, suit, proceeding, hearing, investigation, claim or demand, including but not limited to, any investigation by a Regulatory Authority.

1.7 “Combination Product” means a Licensed Product that is sold in combination with other active, therapeutic components, including as a bundle of products or services, for a single price.

1.8 “Commercialization” or “Commercialize” means engaging in any and all activities directed to obtaining pricing and reimbursement approvals, marketing, promoting, distributing, offering for sale, selling, importing, exploiting, and conducting post Marketing Authorization Approval studies.

1.9 “Commercially Reasonable Efforts” means the carrying out of obligations in a sustained manner consistent with the efforts a Party would be expected to devote to a product of similar market potential, profit potential or strategic value resulting from its own research efforts, based on conditions then prevailing. Without limiting the foregoing, Commercially Reasonable Efforts in all cases requires at least that: [****].

1.10 “Compound” means the chemical compound known as LY686017, a neurokinin-1 (NK-1) antagonist, [****].

1.11 “Confidential Information” shall have the meaning assigned thereto in Section 10.1.

1.12 “Controlled” or “Controls” means, when used in reference to intellectual property, the legal authority or right of a Party hereto (or any of its Affiliates) to grant a license or sublicense of intellectual property rights to another Party, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party.

1.13 “Development” or “Develop” means engaging in non-clinical and clinical drug development activities reasonably related to the development and submission of information to a Regulatory Authority, including but not limited to, toxicology, pharmacology and other discovery efforts, test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical studies (including but not limited to, pre- and post-approval studies, and specifically excluding regulatory activities directed to obtaining pricing and reimbursement approvals).

1.14 “Development Plan” means the outline plan designed to achieve the Development for a Licensed Product, including but not limited to, the nature, number and schedule of Development activities necessary to implement such activities as may be amended in accordance with the terms of this Agreement. An initial Development Plan is attached hereto as Exhibit 2.

1.15 “Disclosing Party” shall have the meaning assigned thereto in Section 10.1.

1.16 “Dollar” or “$” means the lawful currency of the United States.

1.17 “Effective Date” shall have the meaning assigned thereto in the Preamble to this Agreement.

1.18 “EMEA” means the European Medicines Agency and any successor agency thereto.

1.19 “Existing Applications and Approvals” shall have the meaning assigned thereto in Section 4.4.

1.20 “FD&C Act” means the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301ff), as amended from time to time.

1.21 “FDA” means the United States Food and Drug Administration and any successor agency thereto.

1.22 “Field” means the diagnosis, treatment, palliation or prevention of all conditions, disorders and diseases in humans, [****].

1.23 “First Commercial Sale” means the first invoice for commercial quantities of a Licensed Product sold to a Third Party in any country after receipt of Marketing Authorization Approval for such Licensed Product in such country. Sales for test marketing, sampling and promotional uses, clinical trial purposes or compassionate or similar uses shall not be considered to constitute a First Commercial Sale.

1.24 “Force Majeure Event” shall have the meaning assigned thereto in Section 15.4.

1.25 “GAAP” means United States Generally Accepted Accounting Procedures, consistently applied.

1.26 “Generic Competition” shall have the meaning assigned thereto in Section 9.4.3.

1.27 “Generic Product” means any pharmaceutical product that (i) is lawfully sold by a Third Party that is not a Sublicensee of Vanda, (ii) contains the same Compound as an

active pharmaceutical ingredient as the relevant Licensed Product, and (iii) is bioequivalent to and intended for the same indication as the relevant Licensed Product.

1.28 “Good Laboratory Practices” means, with respect to the United States, the then-current requirements for non-clinical (animal or laboratory) studies that will be submitted to a Regulatory Authority to support a marketing application, specified in 21 C.F.R. § 58, as may be amended, and, with respect to any other country or jurisdiction, the equivalent regulations in such other country or jurisdiction.

1.29 “Good Manufacturing Practices” means, with respect to the United States, the minimum then-current good manufacturing practices for methods, facilities, and controls to be used for the manufacture, processing, packing, or holding of a drug to assure that it meets the requirements of the FD&C Act for safety and has the identity and strength and meets the quality and purity characteristics, specified in 21 C.F.R. §§ 210 and 211, as may be amended, and, with respect to any other country or jurisdiction, the equivalent regulations in such other country or jurisdiction.

1.30 “Indemnified Party” shall have the meaning assigned thereto in Section 12.3.1.

1.31 “Indemnifying Party” shall have the meaning assigned thereto in Section 12.3.1.

1.32 “Joint Inventions” shall have the meaning assigned thereto in Section 13.1.1.

1.33 “Laws” means all laws, statutes, rules, regulations (including but not limited to, current Good Manufacturing Practice regulations as specified in 21 C.F.R. §§ 210 and 211; Investigational New Drug Application regulations at 21 C.F.R. § 312; NDA regulations at 21 C.F.R. § 314; relevant provisions of the FD&C Act, and other laws and regulations enforced by the FDA), ordinances and other pronouncements having the binding effect of law of any Regulatory Authority.

1.34 “Licensed IP” means the Licensed Patents and the Licensed Know-How owned or Controlled by Lilly or its Affiliates.

1.35 “Licensed Know-How” means information, trade secrets, and data relating to or useful for a Licensed Product in the Field (including but not limited to, the Development, Manufacturing, or use of the Licensed Product for the Field), in each case, that are owned or Controlled by Lilly or its Affiliates as of the Effective Date or during the Term of this Agreement. Licensed Know-How does not include Licensed Patents.

1.36 “Licensed Patents” means all Patents that have at least one claim infringed by the manufacture, use, import or sale of a Compound or Licensed Product, in each case, that are owned or Controlled by Lilly or its Affiliates as of the Effective Date or during the Term of this Agreement. As of the Effective Date, the Licensed Patents are specified on Exhibit 1 attached hereto.

1.37 “Licensed Product(s)” means a pharmaceutical product containing or comprising the Compound in any form, dosage, presentation formulation (regardless of the delivery mechanism), and whether alone, or in combination with, one or more other pharmaceutically active or inactive ingredients, the manufacture, use, import or sale of which utilizes the Licensed IP or which, absent the license granted to Vanda by Lilly, would infringe, misappropriate or violate the Licensed IP.

1.38 “Lilly” shall have the meaning assigned thereto in the Preamble to this Agreement.

1.39 “Losses” means any and all damages (including but not limited to, all loss of profits, diminution in value, and incidental, indirect, consequential, special, reliance, exemplary, punitive, statutory and treble damages), awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses, lost profits, and expenses (including but not limited to, court costs, interest and reasonable fees of attorneys, accountants and other experts) incurred by or awarded to Third Parties and required to be paid to Third Parties with respect to a Claim by reason of any judgment, order, decree, stipulation or injunction, or any settlement entered into in accordance with the provisions of this Agreement, together with all documented out-of-pocket costs and expenses incurred in complying with any judgments, orders, decrees, stipulations and injunctions that arise from or relate to a Claim of a Third Party.

1.40 “Major EU Country” means one or more of the following countries within the European Union: [****].

1.41 “Major Market” means one or more of the following countries: [****].

1.42 “Manufacture” or “Manufacturing” means to manufacture or have manufactured.

1.43 “Marketing Authorization Approval” means approval by a Regulatory Authority, including but not limited to, any applicable pricing, final labeling or reimbursement approvals, necessary to Manufacture and Commercialize a Licensed Product within an applicable country of the Territory.

1.44 “NDA” means a new drug application, abbreviated new drug application or supplemental new drug application or any amendments or supplements thereto submitted to the FDA under Sections 505, 507 or 512 of the FD&C Act and applicable regulations promulgated by the FDA from time to time, and with respect to any other country or jurisdiction, the equivalent Law in such other country or jurisdiction.

1.45 “Net Sales” means, with respect to a Licensed Product [****]

1.46 “Party” or “Parties” shall have the meaning assigned thereto in the Preamble to this Agreement.

1.47 “Patent” means patents and patent applications, including but not limited to, United States provisional applications and any continuations, continuations-in-part, divisionals, registrations, confirmations, revalidations, reissues, PCT applications, patent term extensions, supplementary protection certificates, utility models, as well as all related extensions or restorations of terms thereof.

1.48 “Patent Challenge” shall have the meaning assigned thereto in Section 13.5.1.

1.49 “Patent Infringement Claim” shall have the meaning assigned thereto in Section 13.2.

1.50 “Person” means any natural person, corporation, general partnership, limited partnership, limited liability company, joint venture, proprietorship or other de jure entity organized under the Laws of any jurisdiction.

1.51 “Phase III Studies” means large, adequate and well controlled clinical studies that are conducted in human patients designed to demonstrate definitive information about safety and efficacy of the Licensed Product that is needed to evaluate the overall benefit-risk relationship with the primary objective being to obtain regulatory approval(s) and product labeling, as described in 21 C.F.R. § 312.12(c), or a similar clinical study prescribed by the Regulatory Authorities in a country other than the United States. These studies and the approach are generally discussed with applicable Regulatory Authorities prior to initiation, but Regulatory Authority approval is not required prior to initiation of such studies.

1.52 “Program Liaison” shall have the meaning assigned thereto in Section 3.1.

1.53 “Receiving Party” shall have the meaning assigned thereto in Section 10.1.

1.54 “Regulatory Authority” means any court, tribunal, arbitrator, agency, legislative body, commission, official or other instrumentality of (i) any government of any country; (ii) a federal, state, province, county, city or other political subdivision thereof or (iii) any supranational body, including but not limited to, the FDA and EMEA.

1.55 “Royalty Term” shall have the meaning assigned thereto in Section 9.4.4.

1.56 “Sole Inventions” shall have the meaning assigned thereto in Section 13.1.1.

1.57 “Sublicensee” means a Third Party to whom Vanda sublicenses rights to Manufacture and sell (or have Manufactured and sold) the Compound under the Licensed IP, any Third Parties to whom rights to sell the Compound have been granted but not Third Parties that Manufacture Compound or Licensed Products solely on behalf of Vanda.

1.58 “Taxes” shall have the meaning assigned thereto in Section 9.11.

1.59 “Term” shall have the meaning assigned thereto in Section 14.1.

1.60 “Terminated Licensed Products” shall have the meaning assigned thereto in Section 14.3.

1.61 “Territory” means worldwide, excluding any country or jurisdiction in which this Agreement has been terminated in accordance with its terms.

1.62 “Third Party” means a Person who is not a Party or an Affiliate of a Party.

1.63 “Third Party Claim” shall have the meaning assigned thereto in Section 12.3.1.

1.64 “Trademarks” shall have the meaning assigned thereto in Section 2.5.

1.65 “United States” means the United States of America and its territories and possessions.

1.66 “Valid Claim” means any claim pending in a patent application or in an unexpired patent which has not been held unenforceable, unpatentable or invalid by a decision of a court or other Regulatory Authority of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer.

1.67 “Vanda” shall have the meaning assigned thereto in the Preamble to this Agreement.

2. LICENSE GRANTS, OWNERSHIP AND EXCLUSIVITY.

2.1 Exclusive License Grant. Subject to the terms and conditions of this Agreement, Lilly grants to Vanda, and Vanda accepts, an exclusive license (with the right to sublicense through multiple tiers of distribution as set forth in Section 2.2) in the Field under the Licensed IP to make, have made, use, register, sell, offer to sell, import, export, Develop, Manufacture and Commercialize Licensed Products in the Territory.

2.2 Sublicensing. The rights licensed to Vanda under Section 2.1 shall be sublicensable to Sublicensees only as part of a license of rights to a Licensed Product in the Field, and only where (i) the Sublicensee has agreed first in writing to be bound by the terms and conditions of this Agreement in the same manner as Vanda [****]. Vanda shall (a) use Commercially Reasonable Efforts to enforce any such sublicense [****]. Each sublicense granted by Vanda to any right licensed to it hereunder shall terminate immediately upon the termination of the license from Lilly to Vanda with respect to such right. [****] the following Third Parties shall not be considered Sublicensees under this Agreement: [****].

2.3 Subcontracting. Vanda may subcontract its rights to Develop, Manufacture or Commercialize Licensed Products in whole or in part to any of its Affiliates and Third Parties. Vanda shall secure all appropriate covenants, obligations and rights from any such subcontractor, including but not limited to, licenses, intellectual property rights and confidentiality obligations, to ensure that such subcontractor is subject to, and Vanda can comply with, all of Vanda’s covenants and obligations to Lilly under this Agreement. Vanda shall (i) use Commercially Reasonable Efforts to enforce any such subcontract [****].

2.4 Exclusivity. Lilly shall not directly or indirectly itself or through an Affiliate or Third Party, Develop, Commercialize, Manufacture, license or otherwise engage in any activities with respect to the Compound in the Field [****].

2.5 Trademarks. Licensed Products shall be Commercialized under trademarks and trade dress selected by Vanda (collectively, “Trademarks”). Vanda shall

exclusively own all Trademarks for Licensed Products, and shall be responsible for the procurement, filing and maintenance of trademark registrations for such Trademarks and all related costs and expenses.

2.6 Disclosure of Inventions. Lilly shall promptly disclose to Vanda all Sole Inventions made by it prior to the Effective Date or during the Term to the extent necessary, useful or relevant for the performance of the rights or obligations of this Agreement by Vanda, including but not limited to, in the event that the Parties determine that there are additional Patents Controlled by Lilly that are necessary, useful or relevant for the performance of the rights or obligations of this Agreement by Vanda. Inventorship for Inventions shall be determined in accordance with the patent laws of the United States (Title 35, United States Code).

3. GOVERNANCE AND REPORTING.

3.1 Program Liaison. As soon as practicable after the Effective Date, each Party will provide the other, in writing with the name and contact information for its "Program Liaison". The Program Liaisons will review the Development Plan, coordinate technology transfer issues pursuant to Section 4 and otherwise coordinate the Parties' activities hereunder.

3.2 Development Reports. Beginning in [****], Vanda shall provide annual written reports to Lilly, no later than [****] of each calendar year, presenting a meaningful summary of the Development activities accomplished by Vanda and results obtained through the end of such calendar year. Such reports shall include a summary of material results, information and data generated in the course of Development of Licensed Products. In addition, on reasonable request by Lilly not more frequently than [****], Vanda will meet with Lilly to make presentations of the Development activities taken relating to the Licensed Products. The obligation to provide such reports shall cease on the earliest to occur of (i) the receipt of Marketing Authorization Approval in each Major Market; (ii) the end of the Royalty Term or (iii) the cessation of on-going Development activities.

4. TECHNOLOGY TRANSFER.

4.1 Transfer. Within [****] following the Effective Date, Lilly shall provide Vanda with copies of the documents (pursuant to Section 4.2) and the assistance of certain Lilly employees having knowledge relevant to the Compound and Lilly's Development efforts prior to the Effective Date to provide Vanda with a reasonable level of technical assistance and consultation in connection with the transfer of the Licensed IP. Vanda shall be responsible for ensuring that its personnel who receive such assistance are appropriately qualified and experienced for such purpose. Vanda shall have a period of [****] following completion of such transfer to review the materials provided to determine if they are reasonably adequate and complete. During such [****] period, Lilly shall promptly respond to any follow-up requests from Vanda for additional information.

4.2 Copies of Documents. Lilly shall provide Vanda with a technology transfer package that will include all related clinical, preclinical, regulatory, and Manufacturing information, including but not limited to, all documents, data, studies, or other information owned or Controlled by Lilly to the extent that such documents, data and information are the

subject of the Licensed IP and are, in Lilly's good faith judgment, reasonably necessary for the Development, Manufacture or Commercialization of the Compound. Lilly shall be responsible for the cost of providing one set of copies in a mutually agreed upon format, and in addition to paper and other tangible copies, Lilly shall, upon Vanda's request and where already available to Lilly, also provide to Vanda electronic copies of such documents, data and other information.

4.3 Ongoing Assistance. Following the initial transfer pursuant to Section 4.1 and until [****], Lilly shall provide reasonable on-going consulting advice over the Term of this Agreement, [****], as may be requested by Vanda. Lilly will be reimbursed by Vanda for its documented out-of-pocket costs incurred to provide such advice or services in accordance with Section 9.7.2. In the event that Vanda requires consultation with Lilly over and above [****] provided in this Section 4.3, Vanda shall submit a request for consultation to Lilly, in writing, stating in reasonable detail the subject matter and number of hours likely required. Lilly shall consider each such request in good faith, and will inform Vanda in a timely manner if Lilly will be able to provide the consulting time requested.

4.4 Regulatory Filings. As soon as reasonable and practicable after the Effective Date, Lilly will promptly effectuate the assignment of filings, applications and approvals made by or on behalf of Lilly to Regulatory Authorities with respect to the Compound and Licensed Products ("Existing Applications and Approvals") in order to effect the transfer of each of the Existing Applications and Approvals from Lilly or its Affiliates to Vanda, including but not limited to, the information required pursuant to 21 C.F.R. § 314.72, or any successor regulation or equivalent thereto of any Regulatory Authority. Lilly will be responsible for any personnel and other expenses incurred in connection with such assignment. In addition, Lilly shall promptly file the information required of a former owner and Vanda shall promptly file the information required of a new owner, in each case to the extent required by applicable Law. Pending transfer of the applicable Existing Applications and Approvals (and, in the case of any Existing Applications and Approvals which are not transferable, on a continuing basis), Lilly hereby grants to Vanda an exclusive right of reference to all such Existing Applications and Approvals for all uses in connection with the Compound and Licensed Product in the Territory, in each case, including the research, Development (including but not limited to, obtaining and maintaining regulatory approvals) and Manufacture thereof. The Parties also agree to use all Commercially Reasonable Efforts to take any other actions required by the applicable Regulatory Authorities to effect the transfer of each of the Existing Applications and Approvals to Vanda.

5. DEVELOPMENT OF LICENSED PRODUCTS.

5.1 General. Vanda shall use Commercially Reasonable Efforts in, and have the overall responsibility for, the performance of all such Development activities with respect to the Compound and Licensed Products. Unless otherwise provided for in this Agreement, Vanda shall bear all costs and expenses associated with Development of Licensed Products Vanda deems necessary and appropriate in the exercise of Commercially Reasonable Efforts, including but not limited to, all costs associated with the execution of the Development Plan and making all filings with applicable Regulatory Authorities.

5.2 Development Decisions. Vanda shall have the final discretion with respect to Development decisions for Licensed Products subject to and in accordance with this Section 5. Vanda shall Develop the Compound and Licensed Products in compliance with all applicable Law, including but not limited to, all legal and regulatory requirements pertaining to the design and conduct of clinical studies.

5.3 Development Plan. As soon as reasonably practicable after the Effective Date, Vanda shall use Commercially Reasonable Efforts to commence Development activities. When Vanda achieves the [****] milestone in the initial Development Plan, Vanda will use Commercially Reasonable Efforts to update the Development Plan and provide a copy thereof to Lilly. Thereafter, the Development Plan may be updated by Vanda from time-to-time. Lilly agrees that Vanda shall not be in breach of its Development obligations where evidence shows that Vanda has been making good faith and diligent efforts to proceed in accordance with the then-current Development Plan.

5.4 Records. Vanda shall maintain complete and accurate records of all work conducted in furtherance of the Development of the Compound and Licensed Products and all results, data and Developments made in furtherance thereof. Such records shall be complete and accurate and shall fully and properly reflect all work done and results achieved in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Such records shall be maintained for at least [****] after the Term or pursuant to Vanda's retention policy whichever is longer.

6. COMMERCIALIZATION.

6.1 General. Following receipt of Marketing Authorization Approval in an applicable country within the Territory, Vanda shall use Commercially Reasonable Efforts to Commercialize Licensed Products in such Territory.

6.2 Vanda Responsibilities. Vanda and its designees shall have the sole right and responsibility for Commercialization of Licensed Products for distribution and sale in the Field in the Territory. Vanda shall bear all costs and expenses associated with the Commercialization of Licensed Products for sale or distribution as Vanda deems necessary and appropriate in the use of Commercially Reasonable Efforts. Without limiting the foregoing, Vanda shall have the sole right and responsibility to:

(a) Receive, accept and fill orders for Licensed Products;

(b) Distribute, sell, record sales and collect payments for Licensed Products;

(c) Establish and modify the terms and conditions with respect to the sale of Licensed Products, including but not limited to, the price or prices at which Licensed Products will be sold, any discount, rebates or other deductions applicable to payments or receivables, and similar matters; and

(d) Record Licensed Product sales in its books of account.

7. MANUFACTURING AND INVENTORIES.

7.1 Transfer of Existing Compound. As soon as possible (and no later than [****]) after the Effective Date, Lilly will transfer at no cost to Vanda any available quantities of LY686017 active pharmaceutical ingredient that Lilly has in inventory and, if available, the most recent reference standard that has been submitted.

7.2 Manufacturing. Vanda shall manufacture or otherwise obtain supply of the requirements of formulated, packaged and labeled Licensed Products for Development and Commercialization, in accordance with all applicable Laws, current Good Manufacturing Practices and this Agreement.

7.3 Inventory. Vanda shall use Commercially Reasonably Efforts to maintain an inventory of Licensed Products in accordance with Vanda's normal practices with the goal of ensuring fulfillment of global demand for Licensed Products.

8. REGULATORY MATTERS.

8.1 General. Vanda shall be solely responsible for, and shall use Commercially Reasonable Efforts in connection with, filing, communicating with, and seeking approvals from Regulatory Authorities in respect of Licensed Products, and will keep Lilly reasonably informed of all significant issues arising therefrom.

8.2 Filings. Vanda shall be solely responsible for filing drug approval applications for Licensed Products and will use Commercially Reasonable Efforts in seeking appropriate approvals in those countries of the Territory for Licensed Products in accordance with this Agreement and as Vanda otherwise reasonably determines. [****] Such regulatory documents for each filing will be held at the offices of Vanda. Vanda shall be responsible for maintaining the approvals obtained under this Section 8.2 and shall solely own all such approvals in the Territory. As between Vanda and Lilly, Vanda shall be fully responsible for bearing all costs and expenses associated with undertaking and completing said registration activities in the Territory, including but not limited to, the costs of preparing and prosecuting applications for such approvals and fees payable to regulatory agencies in obtaining and maintaining same.

8.3 Drug Safety Information. Vanda shall be responsible for recording, investigating, summarizing, notifying, reporting and reviewing all adverse drug experiences and product complaints in accordance with Law and shall adhere to all requirements of applicable Laws which relate to the reporting and investigation of adverse drug experiences.

8.4 Recalls or Corrective Action. Vanda shall have sole responsibility for and shall make all decisions with respect to any recall, market withdrawal or other corrective action related to Licensed Products. Vanda shall, as soon as practicable, notify Lilly of any recall information received by it in reasonable detail. All costs and expenses with respect to a recall, market withdrawal, or other corrective action shall be borne by Vanda.

9. FINANCIAL PROVISIONS.

9.1 Upfront Payment. Vanda shall pay to Lilly a [****] amount of US$1,000,000, payable as follows: [****].

9.2 Development and Regulatory Milestone Payments. In the event Vanda achieves a Development or regulatory milestone specified below with respect to the Licensed Product, Vanda shall promptly, but in no event more than [****] after the achievement of each such milestone, notify Lilly in writing of the achievement of same. Vanda shall pay to Lilly the non-refundable, non-creditable milestone payments as specified below within [****] following notification of achievement of the particular clinical milestone, or in the event of regulatory milestones, within [****] after Vanda achieves such regulatory milestone. The full milestone payments shall be payable only for the first indication of a Licensed Product to reach that milestone (i.e., each milestone payment is payable only one time). All milestone payments will apply whether Licensed Products are Developed as single or Combination Products.

9.2.1 Development/Regulatory Milestones.

Milestone	Amount
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

9.3 Commercialization Milestone Payments. In the event that Vanda achieves a Commercialization milestone, Vanda shall promptly, but in no event more than [****] after the end of the Calendar Quarter in which each such milestone is achieved, notify Lilly in writing of the achievement of same. The following [****] milestone payments will be payable one time only, and will apply to all Licensed Products across all indications. Each Commercialization milestone payment or payments shall be paid within [****] following the end of the Calendar Quarter in which such milestone or milestones have been achieved. “Annual Net Sales” shall mean [****]. For the avoidance of doubt, Vanda shall pay only once for each of the respective milestones set forth below, the first time Annual Net Sales exceeds such milestone. For example, [****].

Milestone	Amount
Upon reaching [****] in Annual Net Sales	[****]
Upon reaching [****] in Annual Net Sales	[****]
Upon reaching [****] in Annual Net Sales	[****]
Upon reaching [****] in Annual Net Sales	[****]

9.4 Royalties.

9.4.1 Net Sales Royalties. Beginning upon First Commercial Sale, within [****] following the end of each Calendar Quarter, Vanda will pay Lilly a tiered royalty based on year-to-date, cumulative Net Sales of all Licensed Products, for the previous Calendar Quarter, at the rates specified below. All royalties on Net Sales will apply whether Licensed Products are Developed and Commercialized as single or Combination Products.

Annual Net Sales	Royalty Percentage of Year-to-Date Net Sales
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

For example, [****].

9.4.2 Royalties on Combination Products.

(a) In the event that the Licensed Product is sold as part of a Combination Product, the Net Sales of the Licensed Product, for the purposes of determining royalty payments, shall be determined by [****].

(b) In the event that the weighted average sale price of the Licensed Product can be determined but the weighted average sale price of the other product(s) cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated [****].

(c) In the event that the weighted average sale price of the other product(s) can be determined but the weighted average sale price of the Licensed Product cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by [****].

(d) In the event that the weighted average sale price of both the Licensed Product and the other product(s) in the Combination Product cannot be determined, the Net Sales of the Licensed Product shall be [****].

(e) [****].

9.4.3 Royalty Adjustments. In the event that the Royalty Term is still in effect, but there is Generic Competition in a country, then, on a country-by-country and Licensed Product-by-Licensed Product basis, the applicable Net Sales of such Licensed Product reportable for royalty calculation in Section 9.4.1, above for such country shall be reduced by [****]. "Generic Competition" means the occurrence of the following: [****].

9.4.4 Royalty Offset. During the Royalty Term, Vanda shall be entitled to offset up to [****] of any royalties due to Lilly by the amount of any royalties and license fees paid to a Third Party reasonably necessary to enable Vanda, its Affiliates or Sublicensees to make, have made, use, register, sell, offer to sell, import, export, Develop, Manufacture and Commercialize such Licensed Product in an applicable country in the

Territory; provided that, the royalty payable to Lilly shall not be reduced below [****] of what Lilly would have otherwise received in the absence of this Section 9.4.4.

9.5 Royalty Term. Vanda shall pay to Lilly the royalties specified in Section 9.4 on a country-by-country basis until the latest of: [****] ("Royalty Term").

9.6 Net Sales Report. Within [****] following the end of each Calendar Quarter, Vanda shall submit to Lilly a written report setting forth Net Sales in the Territory on a country-by-country basis and total royalty payments due Lilly in respect of Licensed Products.

9.7 Payment Terms.

9.7.1 All sums due to Lilly shall be payable in Dollars by bank wire transfer in immediately available funds to such bank account(s) as Lilly shall designate.

9.7.2 Except as otherwise set forth herein, all other payments due hereunder shall be paid within [****] days following receipt of Lilly's invoice.

9.8 Currency. All payments hereunder shall be in Dollars.

9.9 Financial Standards. All financial terms and standards used in this Agreement shall be governed by and determined in accordance with Vanda's audited consolidated financial statements, which are GAAP.

9.10 Late Payments. Any payment that is not paid on or before the date such payment is due under this Agreement shall bear interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal [****].

9.11 Tax Withholding. Any taxes, levies, or other duties ("Taxes") paid or required to be withheld under the appropriate local tax laws by Vanda on account of monies payable to Lilly under this Agreement will be deducted from the amount of monies otherwise payable to Lilly under this Agreement. Vanda will secure and send to Lilly within a reasonable period of time proof of any such Taxes paid or required to be withheld by Vanda for the benefit of Lilly.

9.12 Financial Records; Audits. Vanda shall keep at its corporate headquarters, accurate and complete records of Net Sales necessary to determine the amounts due to Lilly under this Agreement. Such records shall be retained by Vanda for at least the [****] preceding calendar years to which the Net Sales relate. During normal business hours and with reasonable advance notice to Vanda, such records shall be made available for inspection, review and audit, at the request of Lilly, by an independent certified public accountant, or the local

equivalent, appointed by Lilly and reasonably acceptable to Vanda for the purpose of verifying the accuracy of Vanda's accounting reports and payments pursuant to this Agreement. Such independent auditor shall provide both Parties with a written report setting forth Net Sales in the Territory on a country-by-country basis, and total royalty payments due hereunder. Such audits may not be performed by Lilly more than [****]. All costs and expenses incurred in performing any such audit shall be paid by Lilly unless the audit discloses at least a [****] shortfall, in which case Vanda will bear the full cost of the audit. Lilly will be entitled to recover any shortfall in payments as determined by such audit, plus interest thereon, calculated in accordance with Section 9.10.

10. CONFIDENTIAL INFORMATION.

10.1 Definition. "Confidential Information" means confidential or proprietary information, data or know-how, whether provided in written, oral, visual or other form, provided by one Party (the "Disclosing Party") to the other Party (the "Receiving Party") in connection with this Agreement, including but not limited to, the terms of this Agreement and information relating to the Disclosing Party's existing or proposed research, development efforts, patent applications, business or products. Confidential Information shall not include any such information that: (i) is already known to the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure (as evidenced by written records of the Receiving Party); (ii) is or becomes generally available to the public other than through any act or omission of the Receiving Party; (iii) is disclosed to the Receiving Party by a Third Party who had no separate nondisclosure obligation in respect of such information; or (iv) is independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information of the Disclosing Party (as evidenced by written records of the Receiving Party).

10.2 Confidentiality. The Receiving Party shall keep in confidence all Confidential Information of the Disclosing Party with the same degree of care it employs to maintain the confidentiality of its own Confidential Information, but no less than a reasonable degree of care. The Receiving Party shall not use such Confidential Information for any purpose other than in performance of this Agreement or disclose the same to any other Person other than to such of its own and its Affiliates' employees and agents who have a need to know such Confidential Information to implement the terms of this Agreement. A Receiving Party shall advise any employee and agent who receives Confidential Information of such obligations, and the Receiving Party shall ensure that all such employees and agents comply with such obligations as if they had been a Party hereto. The Receiving Party will be liable for breach of this Section 10 by any of its employees and agents.

10.3 Permitted Disclosure and Use. A Party may disclose the Confidential Information belonging to the Disclosing Party to the extent such disclosure is reasonably necessary in the following instances:

10.3.1 filing or prosecuting Patents;

10.3.1 regulatory filings;

10.3.2 prosecuting or defending litigation;

10.3.3 complying with applicable governmental laws and regulations and with judicial process (as described in Section 10.4);

10.3.4 to collaborators, partners, counterparties (including potential distribution, co-marketing and co-promotion contractors), research collaborators, potential investment bankers, investors, lenders, employees, consultants, or agents, each of whom, prior to disclosure, must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Section 10; and

10.3.5 for purposes of raising capital, provided that prior to disclosure, each Third Party to whom Confidential Information is disclosed must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Section 10.

10.4 Disclosure Required by Law. The foregoing confidentiality and nondisclosure obligations shall not apply to information to the extent required to be disclosed by applicable Law, provided that: (i) the Receiving Party gives the Disclosing Party reasonable advance notice of the disclosure, to the extent reasonably practicable and legally permissible; (ii) the Receiving Party uses reasonable efforts to resist disclosing the Confidential Information; (iii) the Receiving Party reasonably cooperates with the Disclosing Party on request to obtain a protective order or otherwise limit the disclosure; and (iv) to the extent that the Receiving Party is required to disclose the Confidential Information, the Receiving Party limits the disclosure to only that that is necessary to comply with the applicable Law. Notwithstanding the foregoing, the Parties acknowledge that Vanda will be permitted, and may be required pursuant to the rules and regulations promulgated under the Securities Exchange Act of 1934, as amended, to file a report on Form 8-K disclosing the entry into this Agreement by Vanda and a brief description of the terms and conditions hereof that are material to Vanda. To the extent that either Party reasonably determines that it is required to make a filing or any other public disclosure (other than as set forth in the preceding sentence) with respect to this Agreement or the terms or existence hereof to comply with the requirements, rules, laws or regulations of any applicable stock exchange, NASDAQ or any Regulatory Authority or body, including but not limited to, the U.S. Securities and Exchange Commission, such Party shall promptly inform the other Party thereof, and shall use reasonable efforts to maintain the confidentiality of the other Party's Confidential Information in any such filing or disclosure.

10.5 Exception for Disclosure of Tax Treatment. Notwithstanding anything else in this Agreement to the contrary, each Party hereto (and each employee, representative, or other agent of any Party) may disclose to any and all Persons, without limitation of any kind, the Federal income tax treatment and Federal income tax structure of any and all transaction(s) contemplated herein and all materials of any kind (including opinions or other tax analyses) that are or have been provided to any Party (or to any employee, representative, or other agent of any Party) relating to such tax treatment or tax structure, provided that this authorization of disclosure shall not apply to restrictions reasonably necessary to comply with securities laws. This authorization of disclosure is retroactively effective immediately upon commencement of

the first discussions regarding the transactions contemplated herein, and the Parties aver and affirm that this tax disclosure authorization has been given on a date which is no later than [****] days from the first day that any Party hereto (or any employee, representative, or other agent of any Party hereto) first made or provided a statement as to the potential tax consequences that may result from the transactions contemplated hereby.

10.6 Return. Upon termination of this Agreement, the Receiving Party shall return or destroy all documents or other media containing Confidential Information of the Disclosing Party with the exception of one (1) copy for the sole purpose of monitoring and documenting the confidentiality obligations hereunder.

10.7 Remedies. Money damages will not be an adequate remedy if this Section 10 is breached and, therefore, either Party may, in addition to any other legal or equitable remedies, seek an injunction or other equitable relief against such breach or threatened breach without the necessity of posting any bond or surety.

10.8 Survival. This Section 10 shall survive the expiration or termination of this Agreement for a period of [****].

11. REPRESENTATIONS AND WARRANTIES.

11.1 Mutual Representations and Warranties. Lilly and Vanda each represents and warrants to the other as of the Effective Date that:

11.1.1 Such Party (i) is a company duly organized, validly existing and in good standing under the Laws of its organization; (ii) has the requisite corporate power and authority and the legal right to conduct its business as now conducted and hereafter contemplated to be conducted; and (iii) has or will obtain all necessary licenses, permits, consents, or approvals from or by, and has made or will make all necessary notices to, all Regulatory Authorities having jurisdiction over such Party and required for performance of this Agreement;

11.1.2 The execution, delivery and performance of this Agreement by such Party (i) are within the corporate power of such Party; (ii) have been duly authorized by all necessary or proper corporate action; (iii) do not conflict with any provision of the organizational documents of such Party; (iv) will not, to the best of such Party's knowledge, violate any Law or any order or decree of any court or Regulatory Authority; and (v) will not violate or conflict with any terms of any indenture, mortgage, deed of trust, lease, agreement or other instrument to which such Party is a party, or by which such Party is bound;

11.1.3 This Agreement has been duly executed and delivered by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms;

11.1.4 Neither such Party, nor to the best of either Party's knowledge any of its employees, has been debarred by the FDA (or similar action by the

EMEA), or subject to an FDA debarment investigation or proceeding (or similar proceeding of the EMEA) for any reason;

11.1.5 No government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any applicable Laws, rules or regulations currently in effect, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, provided that prior to execution, the Parties shall determine if notification is required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended; and

11.1.6 Neither it nor its Affiliates, nor their respective stockholders, directors, officers, or employees, have retained any broker, finder, or investment banker in connection with this Agreement or the transactions contemplated hereby.

11.2 Vanda Representations and Warranties. Vanda represents, warrants and covenants to Lilly that:

11.2.1 It has utilized scientific, marketing and distribution expertise and experience to analyze and evaluate both the scientific and commercial value of this relationship;

11.2.2 To Vanda's knowledge, Vanda is not currently a party to, and during the Term of this Agreement will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement;

11.2.3 All of its activities related to its use of the Licensed IP and the Development and Commercialization of the Compound and Licensed Products pursuant to this Agreement shall comply in all material respects with all applicable Law; and

11.2.4 It shall not knowingly engage in any activities that use the Licensed IP in a manner that is outside the scope of the license rights granted to it hereunder.

11.3 Lilly Representations and Warranties. Lilly represents, warrants and covenants to Vanda that:

11.3.1 Lilly has furnished Vanda with all material information relating to Lilly's program concerning the Compound and Licensed Product, including but not limited to [****] and such material is accurate in all material respects;

11.3.2 To Lilly's knowledge, neither Lilly nor any of its Affiliates is a party to or otherwise bound by any oral or written contract or agreement

that will result in any Person obtaining any interest in, or that would give to any Person any right to assert any Claim in or with respect to, any of Vanda's rights granted under this Agreement or that restrict or will result in a restriction on Vanda's ability to Develop, Manufacture or Commercialize the Compound or the Licensed Product in the Field in the Territory;

11.3.3 To Lilly's knowledge, Lilly is not currently a party to, and during the Term of this Agreement will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement;

11.3.4 As of the Effective Date, to the best of Lilly's knowledge, Exhibit 1 attached hereto contains a full and complete list of all Patents owned or Controlled by Lilly that are necessary or useful to the Development, Manufacture or Commercialization of the Compound and the Licensed Product;

11.3.5 All of the Licensed Patents listed on Exhibit 1 attached hereto are pending or issued and have not been abandoned, and that the claims included in any issued Licensed Patents are in full force and effect as of the Effective Date;

11.3.6 Lilly has paid all fees required to be paid by Lilly in order to maintain the Licensed Patents;

11.3.7 The Licensed Patents are subsisting and not invalid or unenforceable;

11.3.8 Lilly is the sole and exclusive owner of or has obtained exclusive licenses to the Licensed Patents and Licensed Know-How;

11.3.9 Lilly (i) has not previously assigned, transferred, conveyed, licensed or otherwise encumbered its right, title and interest in Licensed Patents, or any component of the Licensed Know-How, and (ii) there is no Patent owned or Controlled by Lilly, other than the Licensed Patent rights, in case of either (i) or (ii), that would prevent Vanda and its subcontractors from Developing, Manufacturing or Commercializing the Compound and Licensed Products in accordance with this Agreement, and from exploiting its rights granted under Section 2;

11.3.10 All non-clinical, clinical and other studies or research conducted by Lilly prior to the Effective Date have been, to the extent applicable, conducted in accordance with all applicable Law, including but not limited to, Good Laboratory Practices;

11.3.11 Any Compound transferred hereunder has been Manufactured and tested in accordance with all applicable Law, including but not limited to, Good Manufacturing Practices;

11.3.12 As of the Effective Date, Lilly has no knowledge of the existence of any patent or intellectual property right owned or Controlled by a Third Party that would materially conflict with the grant of the license set forth in Section 2 of

this Agreement or potentially claim the composition of matter or use of the Compound or the Licensed Product; and

11.3.13 There are no Claims, judgments or settlements against, pending with respect to the Licensed Patents or any component of Licensed Know-How, and, as of the Effective Date, to the best of Lilly's knowledge, Lilly has not received written notice that any such Claims, judgments or settlements are threatened.

11.4 Disclaimer of Warranty. Except for Sections 11.1, 11.2 and 11.3, nothing in this Agreement shall be construed as a representation or warranty by either Party (i) regarding the effectiveness, value, safety, non-toxicity or patentability of any technology, Licensed Products or any results provided by either Party pursuant to this Agreement; or (ii) that any Licensed Product will obtain Marketing Authorization Approval in any country. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES AND EACH PARTY EXPRESSLY DISCLAIMS ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, and all WARRANTIES ARISING FROM ANY COURSE OF DEALING OR PERFORMANCE OR USAGE OF TRADE.

12. INDEMNIFICATION.

12.1 Indemnification by Vanda. Subject to Section 12.3 and except to the extent as set forth in Section 12.2, Vanda shall defend, indemnify and hold harmless Lilly and its Affiliates and each of their officers, directors, shareholders, employees, successors and assigns from and against all Claims of Third Parties, and all associated Losses, to the extent arising out of [****].

12.2 Indemnification by Lilly. Subject to Section 12.3, Lilly shall defend, indemnify and hold harmless Vanda and its Affiliates and each of their officers, directors, shareholders, employees, successors and assigns from and against all Claims of Third Parties, and all associated Losses, to the extent arising out of [****].

12.3 Procedure for Indemnification.

12.3.1 Notice. Each Party ("Indemnified Party") will notify promptly the other Party ("Indemnifying Party") in writing if it becomes aware of a Claim (actual or potential) by any Third Party or any proceeding (including any investigation by a Regulatory Authority) ("Third Party Claim") for which

indemnification may be sought and will give such related information as the Indemnifying Party shall reasonably request.

12.3.2 Defense of Claim. The Indemnifying Party shall defend or control the defense of Third Party Claims. The Indemnifying Party shall be responsible for satisfying and discharging any award made to or settlement reached with the Third Party pursuant to the terms of this Agreement. The Indemnifying Party shall retain counsel reasonably acceptable to the Indemnified Party (such acceptance not to be unreasonably withheld, refused, conditioned or delayed) to represent the Indemnified Party and shall pay the reasonable fees and expenses of such counsel related to such proceeding. In any such proceeding, the Indemnified Party, at its sole expense, shall have the right to retain its own counsel. The Indemnified Party shall not settle any Third Party Claim for which it is seeking indemnification without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, refused, conditioned or delayed. The Indemnified Party shall cooperate in all reasonable respects in the defense of such Third Party Claim, as requested by the Indemnifying Party. The Indemnifying Party shall not, without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld, refused, conditioned or delayed), effect any settlement of any such Third Party Claim, unless such settlement includes an unconditional release of the Indemnified Party from all liability on such Third Party Claims.

12.4 Consequential Damages. IN NO EVENT WILL EITHER PARTY OR THEIR AFFILIATES BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, TREBLE OR CONSEQUENTIAL DAMAGES OR LOST PROFITS, WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY; [****].

12.5 Insurance. During the Term of this Agreement and for a period of [****] after the termination or expiration of this Agreement, Vanda shall obtain and maintain at its sole cost and expense, adequate liability insurance in such amounts and with such scope of coverage as is customary for a pharmaceutical company of comparable size. This insurance shall include comprehensive general liability insurance and product liability coverage, including but not limited to [****]. Vanda shall provide written proof of the existence of such insurance to Lilly upon request.

13. PATENTS.

13.1 Prosecution and Maintenance of Patents.

13.1.1 General. With respect to the subject matter of this Agreement, specifically inventions covering and Patents claiming the Compound and Licensed Product(s), each Party shall own the entire right, title and interest in and to any and all inventions conceived solely by its employees and agents (“Sole Inventions”).

With respect to the subject matter of this Agreement, specifically inventions covering and Patents claiming the Compound and Licensed Product(s), Lilly and Vanda shall each own an undivided one-half interest in and to any and all inventions conceived jointly after the Effective Date by (i) employees and agents of Lilly and (ii) employees and agents of Vanda, and in and to any Patents and other intellectual property rights claiming or covering such joint inventions ("Joint Inventions"). Any such Joint Inventions shall be deemed to be Licensed Patents hereunder, and shall be subject to the terms and conditions of this Agreement.

13.1.2 Licensed Patents. Vanda shall have the exclusive right and the obligation to use Commercially Reasonable Efforts to prepare, file, prosecute in a diligent manner (including but not limited to, by conducting interferences, oppositions and reexaminations or other similar proceedings), maintain (by timely paying all maintenance fees, renewal fees and other applicable fees and costs) and extend all Licensed Patents. Vanda shall consult with Lilly prior to abandoning any Licensed Patent that is material to this Agreement. [****].

13.1.3 Patent Costs. Following the Effective Date, Vanda shall be responsible for the costs incurred in connection with the prosecution, maintenance and defense of the Licensed Patents, including but not limited to, application preparation, filing fees, prosecution, maintenance and all costs associated with reexamination, oppositions and interference proceedings in the United States Patent and Trademark Office, United States Courts, and all similar actions in respect of filings outside the United States, including but not limited to, PCT and individual country filing fees, translations, maintenance, annuities and protest or appeal proceedings.

13.1.4 Sole Inventions. Each Party shall direct and control at its expense the filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all patents covering its Sole Inventions.

13.1.5 Execution of Documents by Agents. Each of the Parties shall execute or have executed by its appropriate agents such documents as may be necessary to obtain, perfect or maintain any Licensed Patent rights filed or to be filed pursuant to this Agreement, and shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession reasonably necessary to obtain or maintain such Licensed Patent rights.

13.1.6 Patent Term Extensions. Vanda shall have the right to determine, in its sole discretion, for which Licensed Patents to apply for Licensed Patent

term extension in the Territory. Vanda shall be responsible for any such applications for Licensed Patent term extension. Vanda shall be responsible for listing to the list entitled "Approved Drug Licensed Products with Therapeutic Equivalence Evaluation" known as the "Orange Book" in case of United States, and any and all similar procedures in the other countries, provided that Vanda shall consult with Lilly in advance.

13.2 Patent Infringement. With respect to any and all Claims instituted by Third Parties against Lilly or Vanda or any of their respective Affiliates for patent infringement involving the manufacture, use, license, marketing or sale of a Licensed Product during the Term (each, a "Patent Infringement Claim") as applicable, Lilly and Vanda will assist one another and cooperate in the defense and settlement of such Patent Infringement Claims at the other Party's request. The Parties agree to respond to or defend against any Patent Infringement Claims as follows:

13.2.1 Vanda shall have the sole right to manage the defense of the Parties against the Patent Infringement Claim, at Vanda's sole expense. If Vanda elects to exercise such right as to the Patent Infringement Claim, Lilly shall cooperate with Vanda at Vanda's request and expense, and shall have the right to be represented by counsel selected and paid for by Lilly. If Vanda elects not to exercise such right as to the Patent Infringement Claim, Lilly may defend such Patent Infringement Claim, at Vanda's expense, and Vanda shall cooperate with Lilly at Lilly's request and shall have the right to be represented by counsel selected and paid for by Vanda.

13.2.2 Vanda shall also have the right to settle such Patent Infringement Claim on terms deemed appropriate by Vanda, provided that any such settlement that would have the effect of reducing royalties payable to Lilly hereunder or includes any liability or admission on behalf of Lilly, shall be subject to Lilly's prior written consent, which shall not be unreasonably withheld or delayed.

13.3 Infringement of the Licensed IP. In the event that Lilly becomes aware of actual or threatened infringement of the Licensed IP within the Field during the Term, Lilly will promptly notify Vanda in writing. Vanda will have the right, but not the obligation, to bring an infringement action under the Licensed IP within the Field against any Third Party including the defense against counter-claims of invalidity and unenforceability. If Vanda is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then Vanda may join Lilly as a party-plaintiff. If Vanda elects to pursue such infringement action, Vanda shall be solely responsible and have the full control of the proceedings and any recoveries (including settlements) will be applied as follows: [****]. If Vanda elects to pursue such infringement action, Lilly may be represented in such action by attorneys of its own choice and its own expense with Vanda having the lead in such action, subject to recovery of such expenses as set forth above. Lilly shall cooperate with and support Vanda at Vanda's request in such infringement procedure. During the Term, in the event that Vanda does not undertake such an infringement action, Lilly will be permitted to do so, at Lilly's sole expense, and, if required, in Vanda's name and on Vanda's behalf. If Vanda has consented

to an infringement action but Lilly is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then Lilly may join Vanda as a party-plaintiff. If Lilly elects to pursue such infringement action, Vanda may be represented in such action by attorneys of its own choice and at its own expense, with Lilly taking the lead in such action. In the event that Lilly brings any such action after Vanda has elected not to pursue such action, it will retain all recoveries, provided that Vanda shall be reimbursed its expenses from such recoveries. If either Party brings such an action or defends such a proceeding under this Section 13.3 and subsequently ceases to pursue or withdraws from such action or proceeding, it shall promptly notify the other Party and the other Party may substitute itself for the withdrawing Party under the terms of this Section 13.3.

13.4 Notice of Certification. Vanda and Lilly each shall immediately give notice to the other of any certification filed under the "U.S. Drug Price Competition and Patent Term Restoration Act of 1984" (or its foreign equivalent) claiming that a Licensed Patent is invalid or that infringement will not arise from the manufacture, use or sale of a product by a Third Party. Vanda shall have the first option in such and similar proceedings in other countries to take action according to the legal requirement. Lilly shall cooperate with and support Vanda at Vanda's request and expense in such litigation procedure. If Vanda decides not to bring infringement proceedings against the entity making such a certification, Vanda will give notice to Lilly of its decision not to bring suit within [****] after receipt of notice of such certification. Lilly then may, but is not required to, bring suit against the entity that filed the certification. Any suit by Lilly or Vanda will either be in the name of Lilly or in the name of Vanda (or any Affiliate) or jointly in the name of Lilly and Vanda (or any Affiliate), as required by Law.

13.5 Validity Challenge.

13.5.1 In the event that a Third Party commences any re-examination, interference, opposition or nullity proceeding or challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Licensed Patent (each such action a "Patent Challenge") in any country of the Territory, then Vanda shall take such legal action as is required to defend the validity of such particular Licensed Patents. Lilly shall give all reasonable assistance (excluding financial assistance) to Vanda. Each Party may also be represented by counsel of its own selection at its own expense in any such legal action. Any settlement shall be subject to the Parties' mutual agreement, which shall not be unreasonably withheld or delayed.

13.5.2 For the avoidance of doubt, this Section 13.5 shall not apply to the defense of any Patent Challenge that is raised as a counter-claim or defense by a Third Party that is the subject of an infringement action pursuant to Section 13.2, in which case the defense of such Patent Challenge will be governed by such Section 13.2.

13.6 Settlement. No settlement, consent judgment or other voluntary final disposition of a suit under this Section 13 by Lilly may be entered into without the prior written consent of Vanda, which consent will not be withheld unreasonably.

14. TERM AND TERMINATION.

14.1 Term and Expiration of Term. This Agreement shall commence upon the Effective Date and, unless sooner terminated in accordance with the terms hereof or by mutual written consent, shall continue until neither Party has any obligation to the other remaining hereunder ("Term").

14.2 Termination for Material Breach. Either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement in the event that the other Party shall have materially breached in the performance of its material obligations under this Agreement; provided that the breaching Party shall, (i) if such breach can be cured, have [****] after receipt of written notice thereof from the non-breaching Party to remedy such breach (or, if such breach cannot be cured within such period, the breaching Party must commence and use Commercially Reasonable Efforts to cure such breach during such period), or (ii) if such breach is not capable of being cured, use and continue to use Commercially Reasonable Efforts to mitigate the impact of such breach, as demonstrated by written evidence, provided that such breach is not due to willful misconduct or gross negligence. Any such termination shall become effective at the end of such [****] unless the breaching Party has cured any such breach prior to the expiration of such [****] (or, if such breach is capable of being cured but cannot be cured within such [****], the breaching Party has commenced and used Commercially Reasonable Efforts to cure such breach, provided that in such instance, such cure must have occurred within [****] after receipt of written notice thereof from the non-breaching Party).

14.3 Other Termination Rights. Any Licensed Product in any country of the Territory that is terminated in accordance with this Section 14.3 shall be referred to as a "Terminated Licensed Product".

14.3.1 By Lilly. Lilly may terminate this Agreement on a [****].

14.3.1 By Vanda. At Vanda's discretion, [****].

14.4 Effects of Termination; Terminated Licensed Products.

14.4.1 Effect of Termination for Material Breach.

(a) Material Breach by Lilly. In the event this Agreement is terminated by Vanda pursuant to Section 14.2 for material breach by Lilly, all licenses granted by Lilly to Vanda (but not other restrictions on Lilly) under this Agreement shall survive, subject

to [****].

(b) Material Breach by Vanda. In the event this Agreement is terminated by Lilly pursuant to Section 14.2 for material breach by Vanda: [****]

14.4.2 Terminated Licensed Products. Notwithstanding anything else, with respect to each country in which this Agreement is terminated (to the extent that Vanda has no continuing rights to such Licensed Product in such jurisdiction):

[****]

14.5 Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration. Such termination or expiration shall not relieve any Party from obligations which are expressly or by implication intended to survive termination or expiration of this Agreement, including but not limited to, definitions, rights to payment, Sections 1, 2.6, 8.3, 8.4, 9.11, 9.12 (for the period stated therein), 10 (for the period stated therein), 11, 12, 14.4, 14.5, 15.2, 15.5, 15.6, 15.9, 15.10, 15.11, 15.12, 15.13, 15.14, 15.15, 15.16 and shall not affect or prejudice any provision of this Agreement which is expressly or by implication provided to come into effect on, or continue in effect after, such termination or expiration.

14.6 Bankruptcy. All rights and licenses granted under or pursuant to this Agreement, including amendments hereto, by each Party to the other Party are, for all purposes of Section 365(n) of Title 11 of the U.S. Code, licenses of rights to intellectual property as defined therein.

15. MISCELLANEOUS.

15.1 Public Announcements. Except as may be expressly permitted under this Section 15.1 or required by applicable Laws or the rules of any stock exchange, neither Party will make any public announcement of any information regarding this Agreement without the prior written approval of the other Party, which approval will not be unreasonably withheld or delayed. Vanda shall at all times have the right to publish the results of its Development work regarding the Licensed Product. Once any statement is approved for disclosure by the Parties or information is otherwise made public in accordance with the preceding two (2) sentences, either Party may make a subsequent public disclosure of the contents of such statement without further approval of the other Party. Neither Party will disclose the financial elements of this Agreement unless, (i) in the reasonable opinion of its legal counsel, it is required by Law to do so, (ii) as may be required in connection with any private financing or merger transactions, subject to confidentiality, or (iii) as previously approved for release by the Parties.

15.2 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, Vanda's legal relationship under this Agreement to Lilly shall be that of independent contractor. This Agreement is not a partnership agreement and nothing in this Agreement shall be construed to establish a relationship of partners or joint venturers between the Parties.

15.3 Registration of This Agreement. To the extent, if any, that either Party concludes in good faith that it or the other Party is required to file or register this Agreement or a notification thereof with any Regulatory Authority, such Party shall inform the other Party thereof. Should both Parties jointly agree that either of them is required to submit or obtain any such filing, registration or notification, they shall cooperate, at Vanda's expense, in such filing, registration or notification and shall execute all documents reasonably required in connection therewith. In such filing, registration or notification, the Parties shall request confidential treatment of sensitive provisions of this Agreement, to the extent permitted by Law. The Parties shall promptly inform each other as to the activities or inquiries of any such Regulatory Authority relating to this Agreement, and shall reasonably cooperate to respond to any request for further information therefrom on a timely basis.

15.4 Force Majeure. The occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties hereunder which is not within the reasonable control of the Party affected or any of its Affiliates, and which could not with the exercise of due diligence have been avoided ("Force Majeure Event"), including but not limited

to, war, rebellion, earthquake, fire, accident, strike, riot, civil commotion, act of God, inability to obtain raw materials, delay or errors by shipping companies or change in law, shall not excuse such Party from the performance of its obligations or duties under this Agreement, but shall merely suspend such performance during the Force Majeure Event. The Party subject to a Force Majeure Event shall promptly notify the other Party of the occurrence and particulars of such Force Majeure Event and shall provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure Event and with notice of the termination thereof. The Party so affected shall use Commercially Reasonable Efforts to avoid or remove such causes of nonperformance as soon as is reasonably practicable. Upon termination of the Force Majeure Event, the performance of any suspended obligation or duty shall promptly recommence. The Party subject to the Force Majeure Event shall not be liable to the other Party for any damages arising out of or relating to the suspension or termination of any of its obligations or duties under this Agreement by reason of the occurrence of a Force Majeure Event, provided that such Party complies in all material respects with its obligations under this Section 15.4.

15.5 Dispute Resolution.

15.5.1 Disputes. In the event of any dispute, controversy or claim arising out of or relating to the interpretation or failure to comply with the terms of this Agreement, the Parties shall try to settle their differences amicably between themselves.

15.5.2 Arbitration. Except for actions of specific performance where either Party may seek equitable or similar relief from any court of competent jurisdiction, any dispute, controversy or claim arising out of or in relation to this Agreement that cannot be settled amicably by agreement of the Parties hereto shall be finally and exclusively settled in accordance with [****], then in force by one or more arbitrators appointed in accordance with said rules. The location of arbitration shall be [****]. The proceedings shall be in English and the governing law shall be as set forth in Section 15.6.1. The monetary award and any other decision rendered shall be written in the English language only. The monetary award and any other decision rendered shall be final and binding on the Parties, and judgment on the award may be entered in any court of competent jurisdiction. The costs of any arbitration, including administrative fees and fees of the arbitrator(s), shall be shared equally by the Parties, unless otherwise specified by the arbitrator(s). Each Party shall bear the cost of its own attorneys' and expert fees; provided that the arbitrator(s) may in their discretion award to the prevailing Party the costs and expenses incurred by the prevailing Party in connection with the arbitration proceeding.

15.6 Governing Law and Venue.

15.6.1 Governing Law. This Agreement shall be construed, and the respective rights of the Parties determined, according to the substantive law of the [****] without regard to the provisions governing conflict of laws or the [****], except matters of intellectual property law which shall be determined in accordance with the intellectual property laws relevant

to the intellectual property in question. The United Nations Convention on the International Sale of Goods shall not apply to this Agreement.

15.6.2 Venue. Subject to Section 15.5, the sole jurisdiction and venue for actions related to the subject matter of this Agreement shall be the federal and state courts located in the [****]. Both Parties hereby consent to the jurisdiction of such courts and agree that process may be served in the manner provided herein for giving notices or otherwise as allowed by the [****].

15.7 Assignment. This Agreement may not be assigned by either Party without the prior written consent of the other Party; provided that either Party may assign this Agreement, in whole or in part, to any of its Affiliates if such Party guarantees the performance of this Agreement by such Affiliate; and provided further that either Party may assign this Agreement to a successor to all or substantially all of the assets or business of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or other similar transaction. Any assignment in violation of this provision is void and without effect. This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns.

15.8 Notices. All demands, notices, consents, approvals, reports, requests and other communications hereunder must be in writing, in English, and will be deemed to have been duly given only if delivered personally, by facsimile with confirmation of receipt, by mail (first class, postage prepaid), or by overnight delivery using a globally-recognized carrier, to the Parties at the following addresses:

Lilly:	**Vanda:**
Eli Lilly and Company	Vanda Pharmaceuticals Inc.
Lilly Corporate Center	2200 Pennsylvania Ave, NW
Indianapolis, IN 46285	Suite 300E
	Washington, DC 20037
[****]	[****]
[****]	[****]

or to such other address as the addressee shall have last furnished in writing in accord with this provision. All notices shall be deemed effective upon receipt by the addressee.

15.9 Severability. If any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect, that provision shall be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect and enforceable.

15.10 Headings. The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof.

15.11 Waiver. No waiver of any term or condition of this Agreement shall be effective unless set forth in a written instrument duly executed by or on behalf of the waiving

Party. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any prior, concurrent or future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by Law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

15.12 Entire Agreement. This Agreement (including the Exhibits and schedules hereto) constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof and supersedes all previous agreements and understandings between the Parties, whether written or oral, including but not limited, to all proposals, negotiations, conversations, letters of intent, memoranda of understanding or discussions, between Parties relating to the subject matter of this Agreement and all past dealing or industry custom.

15.13 Modification. This Agreement may be altered, amended or changed only by a writing making specific reference to this Agreement and the clause to be modified, which amendment is signed by duly authorized representatives of Lilly and Vanda.

15.14 No License. Nothing in this Agreement shall be deemed to constitute the grant of any license or other right in either Party, to or in respect of any Licensed Product, patent, trademark, Confidential Information, trade secret or other data or any other intellectual property of the other Party, except as expressly set forth herein.

15.15 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including but not limited to, any creditor of either Party hereto.

15.16 Counterparts. This Agreement may be executed in any two counterparts, each of which, when executed, shall be deemed to be an original and both of which together shall constitute one and the same document.

IN WITNESS WHEREOF, Lilly and Vanda, by their duly authorized officers, have executed this Agreement as of the Effective Date.

VANDA PHARMACEUTICALS INC.

By: /s/ Mihael H. Polymeropoulos

Name: M.H. Polymeropoulos MD

Title: CEO, Vanda Pharmaceuticals

ELI LILLY AND COMPANY

By: /s/ Jan M. Lundberg

Name: Jan M. Lundberg

Title: Executive Vice President, Science and Technology,
and President, Lilly Research Laboratories

EXHIBIT 1

LICENSED PATENTS

[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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****CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

[****]	**[****]**	**[****]**	**[****]**	**[****]**	**[****]**	**[****]**	**[****]**
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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****Certain information has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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****Certain information has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT 2

INITIAL DEVELOPMENT PLAN

Year	Objectives
2012	• Complete technology transfer • Trial Design
[****]	[****]
[****]	[****]
[****]	[****]

****CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

EXHIBIT 31.1

CERTIFICATION

I, Mihael H. Polymeropoulos, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vanda Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 3, 2012

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

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

EXHIBIT 31.2

CERTIFICATION

I, James P. Kelly, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vanda Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 3, 2012

/s/ James P. Kelly

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

EXHIBIT 32.1

Certification

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

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

The Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 (the Form 10-Q) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the consolidated financial condition and results of operations of the Company.

Date: August 3, 2012

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

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

Date: August 3, 2012

/s/ James P. Kelly

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

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission (SEC) or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.