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 September 30, 2010

or

o **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.)*
9605 Medical Center Drive, Suite 300 Rockville, Maryland	**20850**
(Address of principal executive offices)	*(Zip Code)*

(240) 599-4500
(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 o

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 o No o

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 o	Accelerated filer ☑	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of November 5, 2010, there were 28,041,379 shares of the registrant's common stock issued and outstanding.

Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended September 30, 2010

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Part I — FINANCIAL INFORMATION

Item 1. ***Financial Statements (Unaudited).***

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	September 30, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 102,467,982	$ 205,295,488
Marketable securities	99,592,086	—
Accounts receivable	494,028	3,163,898
Inventory	—	2,398,517
Prepaid expenses, deposits and other current assets	1,901,682	2,092,581
Deferred tax asset, current portion	1,554,099	—
Total current assets	206,009,877	212,950,484
Property and equipment, net	1,015,363	1,316,302
Intangible asset, net	9,898,976	11,017,065
Restricted cash	430,230	430,230
Total assets	$ 217,354,446	$ 225,714,081
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 295,478	$ 2,423,877
Accrued liabilities	1,776,046	2,321,301
Accrued income taxes	3,234,732	—
Deferred revenues, current portion	26,788,991	26,788,991
Total current liabilities	32,095,247	31,534,169
Deferred rent	494,370	506,852
Deferred revenues, noncurrent portion	150,605,505	170,642,202
Total liabilities	183,195,122	202,683,223
Commitments		
Stockholders' equity		
Preferred stock, $0.001 par value; 20,000,000 shares authorized and none issued and outstanding at September 30, 2010 and December 31, 2009	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized as of September 30, 2010 and December 31, 2009; and 28,011,844 and 27,568,595 shares issued and outstanding as of September 30, 2010 and December 31, 2009, respectively	28,012	27,569
Additional paid-in capital	289,919,532	283,836,642
Accumulated other comprehensive income	51,945	—
Accumulated deficit	(255,840,165)	(260,833,353)
Total stockholders' equity	34,159,324	23,030,858
Total liabilities and stockholders' equity	$ 217,354,446	$ 225,714,081

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

VANDA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Revenues:				
Licensing agreement	$ 6,752,293	$ —	$ 20,036,697	$ —
Royalty revenue	494,028	—	2,630,107	—
Product sales	—	—	5,290,150	—
Total revenues	7,246,321	—	27,956,954	—
Operating expenses:				
Cost of sales, licensing agreement	376,792	376,792	1,118,089	606,143
Cost of sales, product sales	—	—	2,890,746	—
Research and development	4,072,189	2,091,984	8,516,382	11,620,918
General and administrative	2,053,584	5,266,434	7,384,502	14,478,786
Total operating expenses	6,502,565	7,735,210	19,909,719	26,705,847
Income (loss) from operations	743,756	(7,735,210)	8,047,235	(26,705,847)
Interest income	155,739	9,842	288,574	84,391
Income (loss) before tax provision	899,495	(7,725,368)	8,335,809	(26,621,456)
Tax provision (benefit)	(2,284,987)	—	3,342,621	—
Net income (loss)	$ 3,184,482	$ (7,725,368)	$ 4,993,188	$ (26,621,456)
Net income (loss) per share:				
Basic and diluted	$ 0.11	$ (0.28)	$ 0.18	$ (0.99)
Shares used in calculation of net income (loss) per share:				
Basic	28,003,453	27,196,694	27,872,542	26,920,742
Diluted	28,466,532	27,196,694	28,429,223	26,920,742

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

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Comprehensive Income	Total
	Shares	Par Value					
Balances at December 31, 2009	27,568,595	$ 27,569	$ 283,836,642	$ —	$ (260,833,353)		$ 23,030,858
Issuance of common stock from exercised stock options/restricted stock units	443,249	443	774,373	—			774,816
Employee stock-based compensation	—	—	3,529,864	—	—		3,529,864
Non-employee stock-based compensation	—	—	116,665	—	—		116,665
Excess tax benefits from exercise of stock options	—	—	1,661,988	—	—		1,661,988
Comprehensive income:							
Net income	—	—	—	—	4,993,188	$ 4,993,188	
Net unrealized gain on marketable securities	—	—	—	51,945	—	51,945	
Comprehensive income	—	—	—	—	—	$ 5,045,133	5,045,133
Balances at September 30, 2010	28,011,844	$ 28,012	$ 289,919,532	$ 51,945	$ (255,840,165)		$ 34,159,324

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

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Nine Months Ended	
	September 30, 2010	September 30, 2009
Cash flows from operating activities		
Net income (loss)	$ 4,993,188	$ (26,621,456)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	257,903	346,785
Employee and non-employee stock-based compensation	3,646,529	8,708,726
Loss on disposal of assets	(23,185)	—
Amortization of premiums and discounts on marketable securities	(11,731)	122,963
Amortization of intangible assets	1,118,089	606,143
Deferred tax asset	(1,554,099)	—
Changes in assets and liabilities:		
Accounts receivable	2,669,870	—
Inventory	2,398,517	(1,758,427)
Prepaid expenses, deposits and other current assets	190,899	(1,345,383)
Accounts payable	(2,128,399)	833,854
Accrued liabilities	(545,255)	(852,389)
Accrued income taxes	3,234,732	—
Other liabilities	(12,482)	3,061
Deferred revenues	(20,036,697)	—
Net cash used in operating activities	(5,802,121)	(19,956,123)
Cash flows from investing activities		
Acquisition of intangible asset	—	(7,000,000)
Proceeds from sales of property and equipment	66,221	—
Purchases of marketable securities	(124,028,410)	(11,365,815)
Proceeds from sales of marketable securities	—	126,547
Maturities of marketable securities	24,500,000	15,250,000
Net cash used in investing activities	(99,462,189)	(2,989,268)
Cash flows from financing activities		
Excess tax benefits from stock-based compensation	1,661,988	—
Proceeds from exercise of stock options	774,816	1,283,734
Net cash provided by financing activities	2,436,804	1,283,734
Net change in cash and cash equivalents	(102,827,506)	(21,661,657)
Cash and cash equivalents		
Beginning of period	205,295,488	39,079,304
End of period	$ 102,467,982	$ 17,417,647
Supplemental disclosure of non-cash investing activities		
Intangible asset acquisition included in accounts payable	$ —	$ 5,000,000

The accompanying notes are an integral part of these 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 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 United States 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 will 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, 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. On February 23, 2010, the U.S. Patent and Trademark Office (PTO) issued a notice of allowance for Vanda's patent application for the microsphere long acting injectable (or depot) formulation of Fanapt®. On August 3, 2010, the PTO informed Vanda that the patent has been issued with a patent term adjustment of 605 days, extending the patent expiration date to June 27, 2023. Subsequently, on October 28, 2010, the PTO informed Vanda that it has granted an additional patent term adjustment of 59 days, making the total extension 664 days and making the patent expiration date August 25, 2023. Vanda continues to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. and Canada. On November 1, 2010, the Therapeutic Goods Administration of Australia's Department of Health and Ageing, accepted for evaluation Vanda's application for marketing approval.

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 Sleep/Wake Disorder (N24HSWD) in blind individuals with no 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. Vanda initiated two clinical trials to pursue FDA approval of tasimelteon for the treatment of N24HSWD in blind individuals with no light perception in the third quarter of 2010. The first trial is a randomized, double-blind, placebo-controlled study with a planned enrollment of approximately 160 patients with N24HSWD. 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. Vanda also initiated a one-year safety study of tasimelteon for the treatment of N24HSWD. This trial is an open-label safety study with a planned enrollment of approximately 140 patients with N24HSWD. Vanda plans to conduct additional clinical trials over the next one to two years to support the use of tasimelteon as a circadian regulator and the submission of a new drug application (NDA) to the FDA and a marketing authorization application to the European

Medicines Agency (EMA). The application for orphan designation from the EMA is pending. Tasimelteon is also ready for Phase II trials for the treatment of depression. Given the range of potential indications for tasimelteon, Vanda may pursue one or more partnerships for the development and commercialization of tasimelteon worldwide.

Throughout this quarterly report on Form 10-Q, we refer to Fanapt® within the U.S. and Canada as our partnered product and we refer to Fanapt® outside the U.S. and Canada and tasimelteon as our products. All other compounds are referred to as our product candidates. In addition, we refer to our partnered products, products and product candidates collectively as our compounds. Moreover, we refer 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, 2009 included in the Company's annual report on Form 10-K. The financial information as of September 30, 2010 and for the period of the three and nine months ended September 30, 2010 and 2009, 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, 2009 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 incorporated by reference in the Form 10-K for the year ended December 31, 2009.

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 are classified as long-term securities.

Inventory

The Company values inventories at the lower of cost or net realizable value. The Company analyzes its inventory levels quarterly and writes down inventory that has become obsolete, or has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are written off to cost of sales. Prior to FDA approval, all Fanapt® manufacturing-related costs were included in research and development expenses. Subsequent to FDA approval of Fanapt®, manufacturing costs related to this product are capitalized. Pursuant to the amended and restated sublicense agreement with Novartis, the Company sold its entire stock of finished product and the remainder of its raw materials to Novartis in the first six months of 2010.

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®, the Company met a milestone under its original sublicense agreement with Novartis which required the Company to make a milestone 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 15, 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. This term is the Company's best estimate of the life of the patent; if, however, the Hatch-Waxman or pediatric extensions are not granted, the intangible asset will be amortized over a shorter period. Amortization of the intangible asset is recorded as a component of cost of sales, licensing agreement.

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 nine months ended September 30, 2010.

Revenue Recognition

The Company's revenues are derived primarily from the amended and restated sublicense agreement with Novartis and include an up-front 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 amended and restated sublicense agreement, the Company received an upfront payment of $200.0 million in December of 2009. Pursuant to the amended and restated sublicense agreement, the Company and Novartis established a Joint Steering Committee (JSC) following the effective date of the amended and restated sublicense agreement. The Company expects to have an active role on the JSC and 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 15, 2017. This includes the Hatch-Waxman extension that provides 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. This term is the Company's best estimate of the life of the patent. Revenue 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 15, 2017). Revenue related to product sales is recognized upon delivery to Novartis. The Company recognizes revenue from Fanapt® royalties and commercial and development milestones from Novartis when realizable and earned.

Concentrations of credit risk

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company places its cash, cash equivalents and marketable securities with what the Company believes to be highly-rated financial institutions. At September 30, 2010, the Company maintained all of its cash, cash equivalents and marketable securities in three 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.

Employee stock-based compensation

The Company accounts for its stock-based compensation expenses in accordance with the FASB guidance on share-based payments which were adopted on January 1, 2006. 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.

For stock awards granted subsequent to 2006, the fair value of these awards are amortized using the accelerated attribution method. For stock awards granted prior to January 1, 2006, expenses are amortized under the accelerated attribution method for options that were modified after the original grant date and under the straight-line attribution method for all other options. 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 during 2008, 2007 and 2006, were estimated to be approximately 2% and was increased to 4% in 2009 and 2010 based on the Company's historical experience.

VANDA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) — (Continued)

Total employee stock-based compensation expense recognized during the three and nine months ended September 30, 2010 and 2009 was comprised of the following:

	Three Months Ended		Nine Months Ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Research and development	$ 428,853	$ 707,646	$ 1,982,788	$ 1,517,324
General and administrative	368,174	2,555,576	1,547,076	6,803,075
Stock-based compensation expense	$ 797,027	$ 3,263,222	$ 3,529,864	$ 8,230,399
Stock-based compensation expense per share of common stock:				
Basic	$ 0.03	$ 0.12	$ 0.13	$ 0.31
Diluted	$ 0.03	$ 0.12	$ 0.12	$ 0.31
Shares used in calculation of stock-based compensation expense per share				
Basic	28,003,453	27,196,694	27,872,542	26,920,742
Diluted	28,466,532	27,196,694	28,429,223	26,920,742

As of September 30, 2010, approximately $6.3 million of total unrecognized compensation costs related to non-vested awards are expected to be recognized over a weighted average period of 1.31 years. The total income tax benefit recognized in the unaudited consolidated statement of changes in stockholders' equity for the stock-based compensation arrangements was $1.7 million and $0 for the nine months ended September 30, 2010 and 2009, respectively.

As of September 30, 2010, 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 690,952 shares were subject to outstanding options granted under the 2004 Plan as of September 30, 2010, and no additional options will be granted under this plan. As of September 30, 2010, there are 5,619,924 shares of the Company's common stock reserved under the 2006 Plan of which 3,095,422 shares were subject to outstanding options and restricted stock units (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 September 30, 2010. 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 grant 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.

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

historical volatility of the common stock of comparable entities and other factors due to the lack of historic information of the Company's publicly traded common stock. 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 and does not plan to pay dividends in the foreseeable future.

Assumptions used in the Black-Scholes-Merton option pricing model for employee and director stock options granted during the nine months ended September 30, 2010 and 2009 were as follows:

	Nine Months Ended	
	September 30, 2010	September 30, 2009
Expected dividend yield	0%	0%
Weighted average expected volatility	68%	68%
Weighted average expected term (years)	6.03	6.03
Weighted average risk-free rate	2.38%	2.95%

A summary of option activity for the 2004 Plan as of September 30, 2010, and changes during the nine months then ended is presented below:

	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2009	732,894	$1.97		
Exercised	(41,938)	$4.65		
Forfeited	(4)	$4.73		
Cancelled	—	—		
Outstanding at September 30, 2010	690,952	$1.81	5.03	$3,363,232
Exercisable at September 30, 2010	690,952	$1.81	5.03	$3,363,232

A summary of option activity for the 2006 Plan as of September 30, 2010, and changes during the nine months then ended is presented below:

	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2009	3,484,845	$15.91		
Granted	225,000	$ 8.33		
Exercised	(112,311)	$ 5.16		
Forfeited	(269,595)	$26.83		
Cancelled	(465,767)	$13.05		
Outstanding at September 30, 2010	2,862,172	$15.18	7.87	$1,144,665
Exercisable at September 30, 2010	1,617,709	$18.49	7.25	$ 649,989

The weighted average grant-date fair value of options granted during the nine months ended September 30, 2010 was $5.21 per share. For the nine months ended September 30, 2010 and 2009, the Company received a total of $774,816 and $1,283,734, respectively, in cash from options exercised under the stock-based arrangements.

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 was based on the closing price of the Company's stock on the date of grant which equals the RSUs intrinsic value. On December 17, 2009, the Compensation Committee approved RSUs for each of the Company's employees to be awarded on January 1, 2010. These awards vest in equal annual installments over four years beginning January 1, 2011, provided that the employee remains employed with us. As of September 30, 2010, there was approximately $2,059,444 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 September 30, 2010, and changes during the nine months then ended are as follows:

	Number of Shares	Weighted Average Price/Share	Aggregate Intrinsic Value
Unvested at December 31, 2009	12,500	$ 0.80	$ 140,625
Granted	292,250	$11.35	
Vested	(2,500)	$ 0.80	
Cancelled	(69,000)	$11.67	
Unvested at September 30, 2010	233,250	$10.80	$1,541,783

Income taxes

The Company accounts for income taxes under the liability method 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.

Segment information

Management has determined that the Company operates in one business segment which is the development and commercialization of pharmaceutical products.

3. Earnings per Share

Net income (loss) is calculated in accordance with FASB guidance on earnings per share. Basic earnings per share (EPS) is calculated by dividing the net income or loss by the weighted average number of shares of common stock outstanding, reduced by the weighted average unvested shares of common stock subject to repurchase. Diluted EPS is computed by dividing the net income or loss by the weighted average number of other potential common stock outstanding for the period. Other potential common stock includes stock options, warrants and RSUs, but only to the extent that their inclusion is dilutive.

VANDA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) — (Continued)

The following schedule presents the calculation of basic and diluted net income (loss) per share of common stock for the three and nine months ended September 30, 2010 and 2009:

	Three Months Ended		Nine Months Ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Numerator:				
Net income (loss)	$ 3,184,482	$ (7,725,368)	$ 4,993,188	$ (26,621,456)
Denominator:				
Weighted average shares of common stock outstanding, basic	28,003,453	27,196,694	27,872,542	26,920,742
Stock options and restricted stock units related to the issuance of common stock	463,079	—	556,681	—
Weighted average shares of common stock outstanding, diluted	28,466,532	27,196,694	28,429,223	26,920,742
Basic and diluted net income (loss) per share applicable to common stockholders	$ 0.11	$ (0.28)	$ 0.18	$ (0.99)
Anti-dilutive securities not included in diluted net income (loss) per share calculation:				
Options to purchase common stock and restricted stock units	3,786,374	4,320,992	3,786,374	4,320,992

The Company incurred a net loss for the three and nine months ended September 30, 2009, causing inclusion of any potentially dilutive securities to have an anti-dilutive affect, resulting in diluted loss per share and basic loss per share attributable to common stockholders being equivalent.

4. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of September 30, 2010:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Short-term :				
U.S. Treasury and government agencies	$ 10,813,685	$ 368	$ (1,103)	$ 10,812,950
U.S. corporate debt	88,726,456	59,779	(7,099)	88,779,136
	$ 99,540,141	$ 60,147	$ (8,202)	$ 99,592,086

As of December 31, 2009, the Company did not hold any available-for-sale marketable securities.

5. Inventory

The carrying amounts of inventories are as follows:

	September 30, 2010	December 31, 2009
Raw materials	$ —	$ 1,094,388
Finished goods	—	1,304,129
Total inventory	$ —	$ 2,398,517

Pursuant to the amended and restated sublicense agreement with Novartis, Novartis was obligated to purchase all Fanapt® inventory following the effective date of the agreement, subject to such inventory meeting certain requirements. The Company sold its entire stock of finished product and the remainder of its raw materials to Novartis in the first six months of 2010.

6. 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 September 30, 2010 and December 31, 2009:

	September 30, 2010	December 31, 2009
Current deposits with vendors	$ 50,000	$ 150,000
Prepaid insurance	388,990	283,839
Other prepaid expenses and advances	1,341,119	1,657,521
Accrued interest income	121,573	1,221
Total prepaid expenses, deposits and other current assets	$ 1,901,682	$ 2,092,581

7. Property and Equipment, Net

The following is a summary of the Company's property and equipment-at cost, as of September 30, 2010 and December 31, 2009:

	Estimated Useful Life (Years)	September 30, 2010	December 31, 2009
Laboratory equipment	5	$ 1,281,877	$ 1,348,098
Computer equipment	3	763,894	763,894
Furniture and fixtures	7	705,784	705,784
Leasehold improvements	10	844,158	844,158
		3,595,713	3,661,934
Less—accumulated depreciation and amortization		(2,580,350)	(2,345,632)
		$ 1,015,363	$ 1,316,302

Depreciation and amortization expense for the nine months ended September 30, 2010 and 2009 were $257,903 and $346,785, respectively.

VANDA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) — (Continued)

8. Intangible Asset, Net

The intangible asset consists of the following as of September 30, 2010:

		September 30, 2010		
	Estimated Useful Lives	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	8 years	$ 12,000,000	$ 2,101,024	$ 9,898,976
		$ 12,000,000	$ 2,101,024	$ 9,898,976

The intangible asset consisted of the following as of December 31, 2009:

		December 31, 2009		
	Estimated Useful Lives	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt®	8 years	$ 12,000,000	$ 982,935	$ 11,017,065
		$ 12,000,000	$ 982,935	$ 11,017,065

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 milestone 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 15, 2017. This includes the Hatch-Waxman extension that provides 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. This term is the Company's best estimate of the life of the patent; if, however, the Hatch-Waxman or pediatric extensions are 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 $1,118,089 and $606,143 for the nine months ended September 30, 2010 and 2009, respectively. The Company capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanapt®.

9. Accrued Liabilities

The following is a summary of accrued liabilities as of September 30, 2010 and December 31, 2009:

	September 30, 2010	December 31, 2009
Accrued research and development expenses	$ 851,135	$ 1,033,339
Accrued consulting and other professional fees	264,064	1,076,111
Employee benefits	633,847	106,126
Other accrued expenses	27,000	105,725
Total accrued liabilities	$ 1,776,046	$ 2,321,301

10. Revenue Recognition

The Company's revenue consisted of the following:

	December 31, 2009 Deferred Revenue	Revenue Recognized	September 30, 2010 Deferred Revenue
Revenues:			
Licensing agreement	$ 197,431,193	$ 20,036,697	$ 177,394,496
Royalty revenue	—	2,630,107	—
Product sales	—	5,290,150	—
Total revenues	$ 197,431,193	$ 27,956,954	$ 177,394,496

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 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 15, 2017). This includes the Hatch-Waxman extension that provides 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. This term is the Company's best estimate of the life of the patent. For the nine months ended September 30, 2010, the Company recognized $20.0 million of revenue for the licensing agreement. Vanda recognized $5.3 million for product sold to Novartis for the nine months ended September 30, 2010. Vanda recognizes product revenue upon delivery of our products to Novartis. Vanda recognized royalty revenue of $2.6 million for the nine months ended September 30, 2010. 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 reliably measurable and earned.

11. Commitments and Contingencies

Operating leases

The Company has commitments totaling approximately $4.5 million under operating real estate leases for its headquarters located in Rockville, Maryland, expiring in 2016.

Income taxes

The Company has submitted a private letter ruling request and a supplemental information letter to the Internal Revenue Service (IRS) to clarify the application of certain section 382 rules in the Internal Revenue Code of 1986, as amended (Code). Section 382 of the Code imposes an annual limitation on the ability of a corporation that undergoes an "ownership change" to utilize its tax attributes, including net operating loss carryforwards and research and development credits, to reduce its tax liability. The Company has determined that due to a potential December 31, 2008 ownership change, the ability to utilize its tax attributes to offset future tax liabilities may be materially limited. An adverse ruling by the IRS could have a material adverse impact on tax expense in the current year as the Company could lose the ability to utilize up to approximately $108.7 million in net operating losses and $5.5 million in research and development credits, and a material negative effect on the Company's results of operations and cash flows.

Guarantees and indemnifications

The Company has entered into a number of standard intellectual property indemnification agreements in the ordinary course of its business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners or customers, in connection with any U.S. patent or any copyright or other intellectual

property infringement claim by any third party with respect to the Company's products. The term of these indemnification agreements is generally perpetual from the date of execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes that the fair value of the indemnification agreements is minimal, and accordingly the Company has not recognized any liabilities relating to these agreements as of September 30, 2010.

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®, previously known as 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 corresponding 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 milestone 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 with Novartis. 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.

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 amended and restated sublicense 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®. Vanda is not aware of any such breach by Novartis. 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 the 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 on April 15, 2010 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) May 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 April 15, 2010 amendment, Vanda's deadline for filing a NDA for tasimelteon was extended until June 1, 2013.

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.

Future license payments. No amounts were recorded as liabilities nor were any contractual obligations relating to the license agreements included in the condensed consolidated financial statements as of September 30, 2010, 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. The Company has transitioned all outstanding manufacturing purchase orders for the raw material supply of Fanapt® to Novartis.

12. Income Taxes

On January 1, 2007, the Company adopted the FASB guidance relating to accounting for uncertainty in income taxes. The adoption of this guidance did not have a material effect on the Company's financial position or results of operations. In addition, the Company has not recorded any liabilities due to uncertain tax positions. The Company accounts for income taxes using the asset and liability method. Deferred income taxes are recognized by applying enacted statutory tax rates applicable to future years to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The measurement of deferred tax assets is reduced, if necessary, by a valuation allowance for any tax benefits for which future realization is uncertain.

The Company recorded a tax provision of $3.3 million and $0 for the nine months ended September 30, 2010 and 2009, respectively. At December 31, 2009, the Company provided a valuation allowance for the full amount of its net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating losses could not be sufficiently assured. As a result of the Company's ability in future years to carryback reversing temporary differences which generate tax deductions to offset current year taxes payable, during the nine months ended September 30, 2010 the Company recorded approximately $1.6 million of deferred tax assets. The Company provided a valuation allowance for the remaining net deferred tax assets since realization of any future benefit from deductible temporary differences is not more likely than not at September 30, 2010. In the third quarter of 2010, the Company determined that there was an error in the calculation of reversing temporary differences which generate tax deductions. This error resulted in an understatement of the first quarter 2010 tax expense of approximately $430,000 and an understatement of the second quarter of 2010 tax benefit of approximately ($190,000). The Company corrected these errors in the third quarter of 2010 by recording a cumulative adjustment of approximately $240,000. The Company evaluated these errors in relation to the current period, which is when they were corrected, as well as the prior two periods in which they originated. The Company believes these errors are immaterial to the consolidated quarterly financial statements.

The federal net operating loss carryforwards and research and development credits may be used to reduce the Company's U.S. federal income taxes otherwise payable. Section 382 of the Internal Revenue Code of 1986, as amended (Code), imposes an annual limitation on the ability of a corporation that undergoes an "ownership change" to utilize its tax attributes, including net operating loss carryforwards and research and development credits, to reduce its tax liability. The Company has determined that it has had potential ownership changes and, as a result, the ability to utilize its tax attributes to offset future tax liabilities in any particular year may be limited. The extent of the limitation on utilization of the Company's tax attributes cannot be determined at this time due to issues in the application of certain section 382 provisions. The Company has submitted a private letter ruling request and a supplemental information letter to the IRS to clarify the application of these provisions. Upon resolution of this process, the Company will provide additional information on the limitations that will be applied to its tax attributes. However, an adverse ruling by the IRS could have a material adverse impact on tax expense in the current year, as the Company could lose the ability to utilize up to approximately $108.7 million in net operating losses and $5.5 million in research and development credits, and a material negative effect on the Company's results of operations and cash flows.

VANDA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) — (Continued)

13. 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

As of September 30, 2010, 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		
	September 30, 2010	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	$ 99,592,086	$ 10,812,950	$ 88,779,136	$ —
Total	$ 99,592,086	$ 10,812,950	$ 88,779,136	$ —

As of December 31, 2009, the Company did not hold any assets or liabilities that are required to be measured at fair value on a recurring basis.

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

Various statements in this report are "forward-looking statements" under the securities laws. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," and "could," and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in our forward-looking statements include, among others:

- the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives;
- our inability to utilize a substantial portion of our prior net operating losses and research and development credits;
- our ability to successfully commercialize Fanapt® outside of the U.S. and Canada;
- delays in the completion of our clinical trials;
- a failure of our products, product candidates or partnered products to be demonstrably safe and effective;
- our failure to obtain regulatory approval for our products or product candidates or to comply with ongoing regulatory requirements;
- 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 additional 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;
- 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, 2009 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, 2009, 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 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 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).* We have developed Fanapt®, and will continue to develop it outside the U.S. and Canada, to treat schizophrenia. On May 6, 2009, the United States Food and Drug Administration (FDA) granted U.S. marketing approval of Fanapt® for the acute treatment of schizophrenia in adults. On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis. We had originally entered into a sublicense agreement with Novartis on June 4, 2004 pursuant to which we 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. On January 11, 2010, Novartis launched Fanapt® in the U.S. 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 future 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 we have exclusive rights to use any of Novartis' data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. At Novartis' option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt® outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt® outside of the U.S. and Canada. On February 23, 2010, the U.S. Patent and Trademark Office (PTO) issued a notice of allowance for our patent application for the microsphere long acting injectable (or depot) formulation of Fanapt®. On August 3, 2010, the PTO informed us that the patent has been issued with a patent term adjustment of 605 days, extending the patent expiration date to June 27, 2023. Subsequently, on October 28, 2010, the PTO informed us that it has granted an additional patent term adjustment of 59 days, making the total extension 664 days and making the patent expiration date August 25, 2023. We continue to explore the regulatory path and commercial opportunity for Fanapt® oral formulation outside of the U.S. and Canada. On November 1, 2010, the Therapeutic Goods Administration of Australia's Department of Health and Ageing, accepted for evaluation our application for marketing approval.

  As a result of the FDA's approval of the new drug application (NDA) for Fanapt®, we met a milestone under the original sublicense agreement which required us to make a milestone 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®.

- *Tasimelteon.* Tasimelteon is an oral compound in development for sleep and mood disorders, including Circadian Rhythm Sleep Disorders (CRSD). The compound binds selectively to the brain's melatonin receptors, which are thought to govern the body's natural sleep/wake cycle. Compounds that bind selectively to these receptors are thought to be able to help treat sleep disorders, and additionally are believed to offer potential benefits in mood disorders. We announced positive top-line results from our Phase III trial of tasimelteon in transient insomnia in November 2006. In June 2008, we announced positive top-line results from the Phase III trial of tasimelteon in chronic primary insomnia. The trial was a randomized, double-blind, and placebo-controlled study with 324 patients. The trial measured time to fall asleep and sleep maintenance, as well as next-day performance. On January 19, 2010, the FDA granted orphan drug designation status for tasimelteon in a specific CRSD, Non-24-Hour Sleep/Wake Disorder (N24HSWD) in blind individuals with no 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, tax credits, waiver of FDA user fees, and up to seven years of market exclusivity upon marketing approval. We initiated two clinical trials to pursue FDA approval of tasimelteon for the treatment of N24HSWD in blind individuals with no light perception in the third quarter of 2010. The first trial is a randomized, double-blind, placebo-controlled study with a planned enrollment of approximately 160 patients with N24HSWD. 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. We also initiated a one-year safety study of tasimelteon for the treatment of N24HSWD. This trial is an open-label safety study with a planned enrollment of approximately 140 patients with N24HSWD. We plan to conduct additional clinical trials over the next one to two years to support the use of tasimelteon as a circadian regulator and the submission of a NDA to the FDA and a marketing authorization application to the European Medicines Agency (EMA). The application for orphan designation from the EMA is pending. Tasimelteon is also ready for Phase II trials for the treatment of depression. Given the range of potential indications for tasimelteon, we may pursue one or more partnerships for the development and commercialization of tasimelteon worldwide.

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 revenue and achieve profitability 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, 2009.

Revenues. Our revenues are derived primarily from our amended and restated sublicense agreement with Novartis and include an up-front 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 from 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® (May 15, 2017). Revenue related to product sales is recognized upon delivery to Novartis. We recognize revenue from Fanapt® royalties and commercial and development milestones from Novartis when realizable and earned.

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 expenses related to our research and development personnel. We expense research and development costs as incurred for compounds in development stage, including certain payments made under our license agreements prior to obtaining FDA approval. 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 pharmacogenetics and pharmacogenomics expertise. 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 products or compounds.

The following table summarizes our product development initiatives for the three and nine months ended September 30, 2010 and 2009. Included in this table are the research and development expenses recognized in

connection with our products in clinical development. Included in "Other product candidates" are the costs directly related to research initiatives for all other product candidates.

	Three Months Ended		Nine Months Ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Direct project costs(1)				
Fanapt®	$ 992,000	$ 977,000	$ 2,158,000	$ 8,444,000
Tasimelteon	2,723,000	685,000	5,349,000	1,797,000
Other product candidates	—	24,000	—	101,000
Total direct project costs	3,715,000	1,686,000	7,507,000	10,342,000
Indirect project costs(1)				
Facility	150,000	153,000	459,000	465,000
Depreciation	42,000	57,000	144,000	179,000
Other indirect overhead	165,000	196,000	406,000	635,000
Total indirect project costs	357,000	406,000	1,009,000	1,279,000
Total research and development expenses	$ 4,072,000	$ 2,092,000	$ 8,516,000	$ 11,621,000

(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 and other related costs for personnel, including stock-based compensation, serving 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. For the quarter ended September 30, 2010, we incurred general and administrative expenses in the aggregate of approximately $2.1 million, including stock-based compensation expenses of approximately $0.4 million.

Interest income. Interest income consists of interest earned on our cash and cash equivalents, marketable securities and restricted cash.

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, 2009 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) management's 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 up-front payment, product revenue and future milestone and royalty revenues. 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 amended and restated sublicense agreement, we received an upfront payment of $200.0 million in December of 2009. Pursuant to the amended and restated sublicense agreement, we established a Joint Steering Committee (JSC) with Novartis following the effective date of the amended and restated sublicense agreement. We expect to have an active role on the JSC and 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, we deem the performance period of the JSC to be the life of the U.S. patent of Fanapt®, which we expect to last until May 15, 2017. This includes the Hatch-Waxman extension that provides 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. This term is our best estimate of the life of the patent. Revenue 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 15, 2017). We recognize revenue related to Fanapt® royalties and commercial and development milestones as they are realizable and earned, and product revenue upon delivery of our products to Novartis.

Stock-based compensation

We adopted the FASB guidance on share based payments January 1, 2006 using the modified prospective transition method of implementation and adopted the accelerated attribution method.

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. Expected volatility rates are based on historical volatility of the common stock of comparable entities and other factors due to the lack of historic information of our publicly traded common stock. 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 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 the Company's stock-based awards, during the three and nine months ended September 30, 2010 and 2009 was comprised of the following:

	Three Months Ended		Nine Months Ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Research and development	$ 429,000	$ 708,000	$ 1,983,000	$ 1,517,000
General and administrative	368,000	2,555,000	1,547,000	6,803,000
Stock-based compensation expense	$ 797,000	$ 3,263,000	$ 3,530,000	$ 8,320,000

Income taxes

Our annual effective tax rate is based on expected pre-tax earnings, existing statutory tax rates, limitations on the use of tax credits and net operating loss carryforwards, evaluation of qualified expenses related to the orphan drug credit and tax planning opportunities available in the jurisdictions in which we operate. Significant judgment is required in determining our annual effective tax rate.

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. We recognize the benefit of tax positions that we have taken or expect to take on the income tax returns we file if such tax position is more likely than not of being sustained. 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.

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 licensing or collaboration agreements, progress of our research and development efforts, the timing and outcome of clinical trials and related possible regulatory approvals and our and our partners' ability to successfully commercialize our products, product candidates and partnered products. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses. As of September 30, 2010, we had a deficit accumulated of approximately $256.0 million.

Three months ended September 30, 2010 compared to three months ended September 30, 2009

Revenues. Revenues were $7.2 million for the three months ended September 30, 2010 compared to revenues of $0 for the three months ended September 30, 2009. Revenues for the three months ended September 30, 2010 included $6.7 million recognized from Novartis related to straight-line recognition of up-front license fees and $0.5 million in royalty revenue based on third quarter 2010 sales of Fanapt®. Novartis launched Fanapt® in January 2010.

Cost of sales. Cost of sales were $0.4 million for the three months ended September 30, 2010 compared to cost of sales of $0.4 million for the three months ended September 30, 2009. Cost of sales for the three months ended

September 30, 2010 and 2009 consisted of $0.4 million resulting from the amortization of the capitalized intangible asset related to the milestone payment to Novartis in May 2009.

Research and development expenses. Research and development expenses increased by approximately $2.0 million, or 95.2%, to approximately $4.1 million for the three months ended September 30, 2010 compared to approximately $2.1 million for the three months ended September 30, 2009.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the three months ended September 30, 2010 and 2009:

	Three Months Ended	
	September 30, 2010	September 30, 2009
Direct project costs:		
Clinical trials	$ 1,210,000	$ 2,000
Contract research and development, consulting, materials and other direct costs	1,343,000	512,000
Salaries, benefits and related costs	733,000	464,000
Stock-based compensation	429,000	708,000
Total direct costs	3,715,000	1,686,000
Indirect project costs	357,000	406,000
Total	$ 4,072,000	$ 2,092,000

Direct costs increased approximately $2.0 million for the three months ended September 30, 2010 compared to the three months ended September 30, 2009 as a result of increases in clinical trial costs, contract research and development, consulting and other direct costs and salaries, benefits and related costs partially offset by lower stock based compensation. Clinical trials costs increased by $1.2 million for the three months ended September 30, 2010 relative to the three months ended September 30, 2009, primarily due to costs related to the tasimelteon trials for the treatment of N24HSWD in blind individuals which began in the third quarter of 2010. Contract research and development, consulting, materials and other direct costs increased approximately $0.8 million for the three months ended September 30, 2010 relative to the three months ended September 30, 2009, primarily due to costs related to the tasimelteon trials for the treatment of N24HSWD in blind individuals which began in the third quarter of 2010.

General and administrative expenses. General and administrative expenses decreased by approximately $3.2 million, or 60.4%, to approximately $2.1 million for the three months ended September 30, 2010 from approximately $5.3 million for the three months ended September 30, 2009.

The following table discloses the components of our general and administrative expenses for the three months ended September 30, 2010 and 2009:

	Three Months Ended	
	September 30, 2010	September 30, 2009
Salaries, benefits and related costs	$ 334,000	$ 408,000
Stock-based compensation	368,000	2,555,000
Marketing, legal, accounting and other professional expenses	732,000	1,755,000
Other expenses	620,000	548,000
Total	$ 2,054,000	$ 5,266,000

Stock-based compensation expense decreased by approximately $2.2 million for the three months ended September 30, 2010, compared to the three months ended September 30, 2009, as a result of the cancellation of unvested options during the three months ending September 30, 2010. Marketing, legal, accounting and other professional costs decreased by approximately $1.0 million for the three months ended September 30, 2010 compared to the three months ended September 30, 2009 due to a decrease in marketing expenses relating to Fanapt® for the three months ending September 30, 2010.

Interest income. Interest income in the three months ended September 30, 2010 was approximately $0.2 million compared to approximately $10,000 in the three months ended September 30, 2009. Interest income was higher for the three months ended September 30, 2010, compared to the three months ended September 30, 2009, due to a higher cash balance from the receipt of the $200.0 million upfront payment from Novartis received at the end of 2009.

Nine months ended September 30, 2010 compared to nine months ended September 30, 2009

Revenues. Revenues were $28.0 million for the nine months ended September 30, 2010 compared to revenues of $0 for the nine months ended September 30, 2009. Revenues for the nine months ended September 30, 2010 included $20.0 million recognized from Novartis related to straight-line recognition of up-front license fees, $5.3 million for Fanapt® product sales to Novartis and $2.7 million in royalty revenue based on first, second and third quarter 2010 sales of Fanapt®. Novartis launched Fanapt® in January 2010.

Cost of sales. Cost of sales were $4.0 million for the nine months ended September 30, 2010 compared to cost of sales of $0.6 million for the nine months ended September 30, 2009. Cost of sales for the nine months ended September 30, 2010 consisted of $1.1 million resulting from the amortization of the capitalized intangible asset related to the $12.0 million milestone payment to Novartis and $2.9 million for the inventory sold to Novartis. Prior to approval of Fanapt® by the FDA in May 2009 all inventory costs were expensed as research and development. Cost of sales of $0.6 million for the nine months ended September 30, 2009 resulted from the amortization of 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 decreased by approximately $3.1 million, or 26.7%, to approximately $8.5 million for the nine months ended September 30, 2010 compared to approximately $11.6 million for the nine months ended September 30, 2009.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the nine months ended September 30, 2010 and 2009:

	Nine Months Ended	
	September 30, 2010	September 30, 2009
Direct project costs:		
Clinical trials	$ 1,496,000	$ 37,000
Contract research and development, consulting, materials and other direct costs	1,916,000	7,295,000
Salaries, benefits and related costs	2,112,000	1,493,000
Stock-based compensation	1,983,000	1,517,000
Total direct costs	7,507,000	10,342,000
Indirect project costs	1,009,000	1,279,000
Total	$ 8,516,000	$ 11,621,000

Direct costs decreased approximately $2.8 million for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 as a result of lower contract research and development, consulting and other direct costs combined with increases in clinical trials, salaries, benefits and related costs and stock based compensation. Clinical trials increased approximately $1.5 million for the nine months ended September 30, 2010 relative to the nine months ended September 30, 2009, primarily due to costs related to the tasimelteon trials for the treatment of N24HSWD in blind individuals which began in the third quarter of 2010. Contract research and development, consulting, materials and other direct costs decreased approximately $5.4 million for the nine months ended September 30, 2010 relative to the nine months ended September 30, 2009, primarily due to reduced expenses of $5.3 million for the regulatory consultants who assisted us during the nine months ended September 30, 2009 in our efforts to obtain FDA approval of Fanapt®.

General and administrative expenses. General and administrative expenses decreased by approximately $7.1 million, or 49.0%, to approximately $7.4 million for the nine months ended September 30, 2010 from approximately $14.5 million for the nine months ended September 30, 2009.

The following table discloses the components of our general and administrative expenses for the nine months ended September 30, 2010 and 2009:

	Nine Months Ended	
	September 30, 2010	September 30, 2009
Salaries, benefits and related costs	$ 1,346,000	$ 1,376,000
Stock-based compensation	1,547,000	6,802,000
Marketing, legal, accounting and other professional expenses	2,616,000	4,586,000
Other expenses	1,876,000	1,715,000
Total	$ 7,385,000	$ 14,479,000

Stock-based compensation expense decreased by approximately $5.3 million for the nine months ended September 30, 2010, compared to the nine months ended September 30, 2009, as a result of the cancellation of unvested options during the nine months ending September 30, 2010 combined with historic higher priced options becoming nearly fully vested in the nine months ended September 30, 2009. Marketing, legal, accounting and other professional costs decreased by approximately $2.0 million for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 due to a decrease in commercial costs related to Fanapt® expensed and a decrease in legal fees for the nine months ending September 30, 2010. The higher legal fees in the nine months ended September 30, 2009 were due to additional legal fees incurred in connection with a potential proxy contest.

Other income, net. Interest and other income in the nine months ended September 30, 2010 was approximately $0.3 million compared to approximately $84,000 in the nine months ended September 30, 2009. Interest income was higher for the nine months ended September 30, 2010, compared to the nine months ended September 30, 2009, due to a higher cash balance from the receipt of the $200.0 million upfront payment from Novartis at the end of 2009.

Liquidity and Capital Resources

As of September 30, 2010, our total cash and cash equivalents and marketable securities were approximately $202.1 million compared to approximately $205.3 million at December 31, 2009. 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 September 30, 2010, we also held a non-current deposit of $430,000 that is used to collateralize a letter of credit issued for our current office lease in Rockville, Maryland which expires in 2016.

As of September 30, 2010, we maintained all of our cash and cash equivalents in three 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.

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

As of September 30, 2010, we held certain assets that are required to be measured at fair value on a recurring basis.

		Fair Value Measurements at Reporting Date Using		
	September 30, 2010	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	$ 99,592,000	$ 10,813,000	$ 88,779,000	$ —
Total	$ 99,592,000	$ 10,813,000	$ 88,779,000	$ —

As of December 31, 2009, we did not hold any assets or liabilities that are required to be measured at fair value on a recurring basis.

We believe that our current existing cash and cash equivalents is sufficient to meet our working capital and capital expenditure needs to execute our current business plan. However, the amounts of expenditures that will be needed to carry out our business plan are subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. We have submitted a private letter ruling request and a supplemental information letter to the IRS to clarify the application of certain section 382 change of ownership rules. Section 382 of the Code imposes an annual limitation on the ability of a corporation that undergoes an “ownership change” to utilize its tax attributes, including net operating loss carryforwards and research and development credits, to reduce its tax liability. We have determined that due to a potential December 31, 2008 ownership change our ability to utilize our tax attributes to offset future tax liabilities may be materially limited. An adverse ruling by the IRS could have a material adverse impact on tax expense in the current year, as we could lose the ability to utilize up to approximately $108.7 million in net operating losses and $5.5 million in research and development credits, and a material negative effect on the Company’s results of operations and cash flows.

We entered into an amended and restated sublicense agreement in 2009 with Novartis to commercialize 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 will recognize the $200.0 million upfront payment 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 15, 2017). 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. During the nine months ended September 30, 2010, we recorded approximately $20.0 million in licensing revenue. To date, we have recognized product revenue of approximately $5.3 million from product sold to Novartis and $2.6 million in royalty revenue. We recognize product revenue on the sale of the existing Fanapt® product to Novartis upon delivery to Novartis and royalty revenue when realizable and earned. Other than participation in the JSC, we have no control over the progress of Novartis’ commercial plans. We cannot forecast with any degree of certainty the achievement of milestones and royalties under this agreement.

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 active product candidates. We initiated two clinical trials to pursue FDA approval of tasimelteon for the treatment of N24HSWD in blind individuals with no light perception beginning in the third quarter of 2010. The first trial is a randomized, double-blind, placebo-controlled study with a planned enrollment of approximately 160 patients with N24HSWD. 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 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, primarily consisting of the upfront payment received under the Novartis contract and investment income will be sufficient to fund our operations. Our future capital requirements and the adequacy of our available funds will depend on many factors, primarily including the scope and costs of our clinical development programs, the scope and costs of our manufacturing and process development activities, the magnitude of our discovery and preclinical development programs and the level of our pre-commercial launch activities. There can be no assurance that any additional financing required in the future will be available on acceptable terms, if at all.

Cash Flow

The following table summarizes our cash flows for the nine months ended September 30, 2010, and 2009:

	Nine Months Ended	
	September 30, 2010	September 30, 2009
Net cash provided by (used in)		
Operating activities	$ (5,802,000)	$ (19,956,000)
Investing activities	(99,462,000)	(2,989,000)
Financing activities	2,437,000	1,284,000
Net change in cash and cash equivalents	$ (102,827,000)	$ (21,661,000)

Net cash used in operations was approximately $5.8 million and approximately $20.0 million for the nine months ended September 30, 2010 and 2009, respectively. Net cash used in operations for the nine months ended September 30, 2010 consisted primarily of net income for the nine months ended September 30, 2010 of approximately $5.0 million, an increase in non-cash items of $3.4 million, the receipt of $2.5 million in amounts due from Novartis for the remaining finished product and royalty revenue, a decrease in inventory of $2.4 million for the final inventory sold to Novartis and an increase of $3.2 million in accrued taxes offset by a decrease of $20.0 million in the deferred revenue related to the upfront payment received from Novartis in December 2009, a decrease of $0.2 million in prepaid expenses and other current assets, a decrease of $2.7 million in accounts payable and accrued expenses. Net cash used in investing activities for the nine months ended September 30, 2010 was approximately $99.5 million and consisted primarily of net purchases of marketable securities. The $2.4 million provided by financing activities for the nine months ended September 30, 2010 relates to the $1.7 million in excess tax benefits from the exercise of stock options and $0.7 million received from the exercise of stock options.

Contractual Obligations and Commitments

Operating leases

Our commitments under operating leases shown above consist of payments relating to our real estate leases for our current headquarters located in Rockville, Maryland, expiring in 2016.

The following table summarizes our long-term contractual cash obligations as of September 30, 2010:

	Cash Payments Due by Period						
	Total	October to December 2010	2011	2012	2013	2014	After 2014
Operating leases	$ 4,458,000	$ 176,000	$ 727,000	$ 749,000	$ 771,000	$ 795,000	$ 1,240,000
Total	$ 4,458,000	$ 176,000	$ 727,000	$ 749,000	$ 771,000	$ 795,000	$ 1,240,000

Clinical research organization contracts and 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 licensing agreements with BMS and Novartis, respectively, for the exclusive rights to develop and commercialize tasimelteon and Fanapt®. On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis. We are obligated to make (in the case of tasimelteon 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 certain royalties (and in the case of Fanapt® in the U.S. and Canada, will be entitled to receive) based on net sales for each of the licensed products. Please see the notes to the consolidated financial statements included with this report for a more detailed description of these license agreements.

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 licensing agreement with BMS and subsequently paid a license fee of $1.0 million.

As a result of the acceptance by 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®, we met an additional milestone under the original sublicense agreement with Novartis which required us to make a milestone 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 15, 2017. This includes the Hatch-Waxman extension that provides 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. This term is the Company's best estimate of the life of the patent; if, however, the Hatch-Waxman or pediatric extensions are 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 September 30, 2010, 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 we will 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.

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.

Effects of Inflation

Our most liquid assets are cash and cash equivalents and marketable securities. Because of their liquidity, these assets are not directly affected by inflation. We also believe that we have intangible assets in the value of our intellectual property. In accordance with generally accepted accounting principles, we have not capitalized the value of this intellectual property on our balance sheet. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

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.

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.

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, who currently serves as our principal executive officer, principal financial officer and principal accounting 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 September 30, 2010. Based upon that evaluation, our Chief Executive Officer, who currently serves as our principal executive officer, principal financial officer and principal accounting, officer has concluded that our disclosure controls and procedures are effective as of September 30, 2010, 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, who currently serves as our principal executive officer, principal financial officer and principal accounting officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the third quarter of 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Effective August 6, 2010, our then Acting Chief Financial Officer, Secretary, Treasurer, principal financial officer and principal accounting officer resigned to pursue other opportunities. Our Board of Directors is currently identifying a replacement for the position left vacant by her resignation. We are executing changes to our key controls to mitigate segregation of duties issues related to her resignation. However, her departure and the changes did not materially affect internal control over financial reporting as of September 30, 2010. Our President and Chief Executive Officer is currently serving as our principal financial and accounting officer until a permanent replacement is identified.

PART II — OTHER INFORMATION

Item 1. ***Legal Proceedings.***

None.

Item 1A. ***Risk Factors***

Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2009 sets forth information relating to the material risks and uncertainties with respect to our business and our common stock. In addition to those risk factors, we believe the following risk factors are relevant to the understanding of our business, financial condition and operating results. These risks are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of these risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment.

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

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

We have determined that due to a potential December 31, 2008 ownership change, our ability to utilize our tax attributes to offset future tax liabilities may be materially limited. The Company has submitted a private letter ruling request and a supplemental information letter to the Internal Revenue Service (IRS) to clarify the application of certain section 382 rules in the Code. An adverse ruling by the IRS could have a material adverse impact on tax expense in the current year, as we could lose the ability to utilize up to approximately $108.7 million in net operating losses and $5.5 million in research and development credits.

An unfavorable ruling related to our request or a future “ownership change” could have a material negative effect on our results of operations and cash flows. Limitations imposed on the ability to use NOLs and tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than would otherwise be required if such limitations were not in effect and could cause such NOLs and tax credits to expire unused, in each case reducing or eliminating the benefit of such NOLs and tax credits. Similar rules and limitations may apply for state income tax purposes.

Healthcare reform could adversely affect our revenue and financial results.

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

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

In addition, Federal, state, and foreign governmental authorities are likely to continue efforts to control the price of drugs and reduce overall healthcare costs. These efforts could impact our ability to market products and generate revenues in the U.S. and foreign countries.

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

None.

Item 3. ***Defaults Upon Senior Securities.***

None.

Item 5. ***Other Information.***

None.

Item 6. ***Exhibits.***

Exhibit Number	Description
31.1	Certification of the Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer), as required by Section 906 of the Sarbanes-Oxley Act of 2002.

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.

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

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

November 8, 2010

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

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EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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: November 8, 2010

/s/ Mihael H. Polymeropoulos
Mihael H. Polymeropoulos
Chief Executive Officer
(Principal Executive 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 September 30, 2010 (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: November 8, 2010

/s/ Mihael H. Polymeropoulos

Mihael H. Polymeropoulos
Chief Executive Officer
(Principal Executive 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.