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 March 31, 2011

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 *(State or other jurisdiction of incorporation or organization)*	**03-0491827** *(I.R.S. Employer Identification No.)*
9605 Medical Center Drive, Suite 300 **Rockville, Maryland** *(Address of principal executive offices)*	**20850** *(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. (Check one):

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 May 5, 2011, there were 28,103,441 shares of the registrant's common stock issued and outstanding.

Vanda Pharmaceuticals Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended March 31, 2011

INDEX

		Page
	PART I — FINANCIAL INFORMATION	
ITEM 1.	Financial Statements (Unaudited):	3
	Condensed Consolidated Balance Sheets as of March 31, 2011 and December 31, 2010	3
	Condensed Consolidated Statements of Operations for the three months ended March 31, 2011 and 2010	4
	Condensed Consolidated Statement of Changes in Stockholders' Equity for the three months ended March 31, 2011	5
	Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2011 and 2010	6
	Notes to Condensed Consolidated Financial Statements	7
ITEM 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	21
ITEM 3.	Quantitative and Qualitative Disclosures about Market Risk	31
ITEM 4.	Controls and Procedures	31
	PART II — OTHER INFORMATION	
ITEM 1.	Legal Proceedings	31
ITEM 1A.	Risk Factors	31
ITEM 2.	Unregistered Sales of Equity Securities and Use of Proceeds	32
ITEM 3.	Defaults Upon Senior Securities	32
ITEM 4.	Removed and Reserved	32
ITEM 5.	Other Information	32
ITEM 6.	Exhibits	32
Signatures		33
Exhibits		34

Part I — FINANCIAL INFORMATION

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

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	March 31, 2011	December 31, 2010
	(In thousands, except for share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 52,520	$ 42,559
Marketable securities	142,035	155,478
Accounts receivable	895	511
Prepaid expenses, deposits and other current assets	1,619	1,843
Deferred tax asset, current portion	182	182
Total current assets	197,251	200,573
Property and equipment, net	860	937
Intangible asset, net	9,153	9,522
Deferred tax asset, non-current portion	1,639	1,639
Restricted cash	430	430
Total assets	$ 209,333	$ 213,101
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 834	$ 648
Accrued liabilities	2,141	1,324
Accrued income taxes	2,272	2,266
Deferred revenues, current portion	26,789	26,789
Total current liabilities	32,036	31,027
Deferred rent	482	490
Deferred revenues, noncurrent portion	137,247	143,853
Total liabilities	169,765	175,370
Commitments		
Stockholders' equity:		
Preferred stock, $0.001 par value; 20,000,000 shares authorized and none issued and outstanding at March 31, 2011 and December 31, 2010	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized as of March 31, 2011 and December 31, 2010; and 28,103,441 and 28,041,379 shares issued and outstanding as of March 31, 2011 and December 31, 2010, respectively	28	28
Additional paid-in capital	292,946	291,342
Accumulated other comprehensive income	99	2
Accumulated deficit	(253,505)	(253,641)
Total stockholders' equity	39,568	37,731
Total liabilities and stockholders' equity	$ 209,333	$ 213,101

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			
	March 31, 2011		March 31, 2010	
	(In thousands, except for share amounts)			
Revenues:				
Licensing agreement	$	6,606	$	6,606
Royalty revenue		895		2,067
Product sales		—		3,748
Total revenues		7,501		12,421
Operating expenses:				
Cost of sales, product		—		1,375
Research and development		4,267		2,041
General and administrative		2,858		2,489
Intangible asset amortization		369		369
Total operating expenses		7,494		6,274
Income from operations		7		6,147
Interest income		135		47
Income before tax provision		142		6,194
Tax provision		6		5,665
Net income	$	136	$	529
Net income per share:				
Basic and diluted	$	0.00	$	0.02
Shares used in calculation of net income per share:				
Basic		28,101,418		27,704,418
Diluted		28,936,835		28,318,754

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	Accumulated Other Comprehensive	Accumulated	Comprehensive	
	Shares	Par Value	Capital	Income	Deficit	Income	Total
			(In thousands, except for share amounts)				
Balances at December 31, 2010	28,041,379	$ 28	$ 291,342	$ 2	$ (253,641)		$ 37,731
Issuance of common stock from exercised stock options/restricted stock units	62,062	—	—	—	—		—
Employee and non-employee stock-based compensation	—	—	1,604	—	—		1,604
Excess tax benefits from exercise of stock options	—	—	—	—	—		—
Comprehensive income:							
Net income	—	—	—	—	136	$ 136	
Net unrealized gain on marketable securities	—	—	—	97	—	97	
Comprehensive income	—	—	—	—	—	$ 233	233
Balances at March 31, 2011	28,103,441	$ 28	$ 292,946	$ 99	$ (253,505)		$ 39,568

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

VANDA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Three Months Ended March 31, 2011	Three Months Ended March 31, 2010
	(In thousands)	
Cash flows from operating activities		
Net income	$ 136	$ 529
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	77	94
Employee and non-employee stock-based compensation	1,604	1,121
Loss on disposal of assets	—	(23)
Amortization of premiums and discounts on marketable securities	315	(4)
Amortization of intangible assets	369	369
Deferred tax benefits	—	(1,984)
Changes in assets and liabilities:		
Accounts receivable	(384)	(2,867)
Inventory	—	919
Prepaid expenses, deposits and other current assets	224	415
Accounts payable	186	(1,556)
Accrued liabilities	817	(969)
Income taxes payable	6	5,740
Other liabilities	(8)	(4)
Deferred revenues	(6,606)	(6,606)
Net cash used in operating activities	(3,264)	(4,826)
Cash flows from investing activities		
Purchases of marketable securities	(47,400)	(32,457)
Maturities of marketable securities	60,625	—
Net cash provided by (used in) investing activities	13,225	(32,457)
Cash flows from financing activities		
Excess tax benefits from stock-based compensation	—	1,910
Proceeds from exercise of stock options	—	23
Net cash provided by financing activities	—	1,933
Net change in cash and cash equivalents	9,961	(35,350)
Cash and cash equivalents		
Beginning of period	42,559	205,295
End of period	$ 52,520	$ 169,945

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

1. Business Organization and Presentation

Business organization

Vanda Pharmaceuticals Inc. (We, Vanda or the Company) is a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders. Vanda commenced its operations in 2003. The Company's lead product, Fanapt® (iloperidone), which Novartis Pharma AG (Novartis) began marketing in the U.S. in the first quarter of 2010, is a compound for the treatment of schizophrenia. On May 6, 2009, the U.S. Food and Drug Administration (FDA) granted U.S. marketing approval of Fanapt® for the acute treatment of schizophrenia in adults. On October 12, 2009, Vanda entered into an amended and restated sublicense agreement with Novartis. Vanda had originally entered into a sublicense agreement with Novartis on June 4, 2004 pursuant to which Vanda obtained certain worldwide exclusive licenses from Novartis relating to Fanapt®. Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanapt®. Pursuant to the amended and restated sublicense agreement, Vanda received an upfront payment of $200.0 million at the end of 2009 and is eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. Vanda also receives royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. In addition, Vanda is no longer required to make any future milestone payments with respect to sales of Fanapt® or any future royalty payments with respect to sales of Fanapt® in the U.S. and Canada. Vanda retains exclusive rights to Fanapt® outside the U.S. and Canada and Vanda has exclusive rights to use any of Novartis' data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. At Novartis' option, Vanda will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt® outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt® outside of the U.S. and Canada. 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 for the Fanapt® oral formulation.

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 without light perception. The FDA grants orphan drug designation to drugs that may provide significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation provides potential financial and regulatory incentives including study design assistance, waiver of FDA user fees, tax credits, and up to seven years of market exclusivity upon marketing approval. On February 23, 2011, the European Commission (EC) designated tasimelteon as an orphan medicinal product for the same indication. Vanda initiated two clinical trials to pursue FDA approval of tasimelteon for the treatment of N24HSWD in blind individuals without 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). On January 6, 2011, an end-of-Phase II meeting was held with the FDA to discuss the development plan for tasimelteon in the treatment of N24HSWD. Vanda is also evaluating tasimelteon in Major Depressive Disorder (MDD) and plans to initiate a Phase IIb/III clinical trial of tasimelteon in patients with MDD. The trial is expected to begin during the second half of 2011 and will investigate the efficacy and safety of tasimelteon versus placebo in the treatment of MDD. The study is expected to include an 8-week treatment period and an optional open-label extension. 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, Vanda refers to Fanapt® within the U.S. and Canada as its partnered product and Vanda refers to Fanapt® outside the U.S. and Canada and tasimelteon as its products. All other compounds are referred to as Vanda's product candidates. In addition, Vanda refers to its partnered products, products and product candidates collectively as its compounds. Moreover, Vanda refers to drug products generally as drugs or products.

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's consolidated financial statements for the year ended December 31, 2010 included in the Company's annual report on Form 10-K. The financial information as of March 31, 2011 and for the period of the three months ended March 31, 2011 and 2010, 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, 2010 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 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, 2010.

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.

Intangible asset, net

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

As a result of the FDA's approval of the NDA for Fanapt® in May 2009, the Company met a milestone under its original sublicense agreement with Novartis which required the Company to make a payment of $12.0 million to Novartis. The $12.0 million is being amortized on a straight line basis over the remaining life of the U.S. patent for Fanapt®, which the Company expects to last until May 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.

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 three months ended March 31, 2011.

Fair value of financial instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, marketable securities and accounts receivable, approximate their fair values due to their short nature.

Property and equipment

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

Revenue Recognition

The Company's revenues are derived primarily from the amended and restated sublicense agreement with Novartis and include an 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 March 31, 2011, 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.

Accrued expenses

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

Research and development expenses

The Company’s research and development expenses consist primarily of fees for services provided by third parties in connection with the clinical trials, costs of contract manufacturing services, milestone license fees, costs of materials used in clinical trials and research and development, cost for regulatory consultants and filings, depreciation of capital resources used to develop products, related facilities costs, and salaries, other employee related costs and stock-based compensation for the research and development personnel. The Company expenses research and development costs as they are incurred for compounds in the development stage, including certain payments made under the license agreements. Prior to FDA approval, all Fanapt® manufacturing-related and milestone costs were included in research and development expenses. Subsequent to FDA approval of Fanapt®, manufacturing and milestone costs related to this product are being capitalized. Costs related to the acquisitions of intellectual property have been expensed as incurred since the underlying technology associated with these acquisitions were made in connection with the Company’s research and development efforts and have no alternative future use. Milestone payments are accrued in accordance with the FASB guidance on accounting for contingencies which states that milestones payments be accrued when it is deemed probable that the milestone event will be achieved.

General and administrative expenses

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

Employee stock-based compensation

The Company accounts for its stock-based compensation 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.

The fair value of stock options granted is amortized using the accelerated attribution method. The fair value of restricted stock units (RSUs) awarded is amortized using the straight line method. As stock-based compensation expense recognized in the consolidated statements of operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures on the options granted prior to 2009 were estimated to be approximately 2%. The forfeiture rate was increased to 4% in 2009 based on the Company's historical experience.

Total employee stock-based compensation expense recognized during the three months ended March 31, 2011 and 2010 was comprised of the following:

	Three Months Ended	
	March 31, 2011	March 31, 2010
	(In thousands)	
Research and development	$ 720	$ 893
General and administrative	878	196
Stock-based compensation expense	$ 1,598	$ 1,089

As of March 31, 2011, $8.1 million of total unrecognized compensation costs related to non-vested awards are expected to be recognized over a weighted average period of 1.43 years.

As of March 31, 2011, 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 680,754 shares were subject to outstanding options granted under the 2004 Plan as of March 31, 2011, and no additional options will be granted under this plan. As of March 31, 2011, there were 6,741,579 shares of the Company's common stock reserved under the 2006 Plan of which 3,703,063 shares were subject to outstanding options and RSUs issued to employees and non-employees.

Options are subject to terms and conditions established by the compensation committee of the board of directors. None of the stock-based awards are classified as a liability as of March 31, 2011. 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 the Company's historical volatility of its publicly traded common stock blended with the historical volatility of the common stock of comparable entities. The expected term of options granted is based on the transition approach provided by FASB guidance as the options meet the "plain vanilla" criteria required by this guidance. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid cash 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 three months ended March 31, 2011 and 2010 were as follows:

	Three Months Ended	
	March 31, 2011	March 31, 2010
Expected dividend yield	0%	0%
Weighted average expected volatility	73%	68%
Weighted average expected term (years)	6.03	6.03
Weighted average risk-free rate	2.46%	2.80%

A summary of option activity for the 2004 Plan as of March 31, 2011, and changes during the three months then ended is presented below:

	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
		(In thousands, except for share amounts)		
Outstanding at December 31, 2010	680,754	$ 1.77		
Exercised	—	—		
Forfeited	—	—		
Cancelled	—	—		
Outstanding at March 31, 2011	680,754	$ 1.77	4.53	$ 3,754
Exercisable at March 31, 2011	680,754	$ 1.77	4.53	$ 3,754

A summary of option activity for the 2006 Plan as of March 31, 2011, and changes during the three months then ended is presented below:

	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
		(In thousands, except for share amounts)		
Outstanding at December 31, 2010	3,324,790	$ 14.07		
Granted	27,500	$ 6.88		
Exercised	—	—		
Forfeited	(9,750)	$ 8.75		
Cancelled	(2,790)	$ 11.66		
Outstanding at March 31, 2011	3,339,750	$ 14.03	7.78	$ 1,471
Exercisable at March 31, 2011	1,850,216	$ 17.67	6.92	$ 982

The weighted average grant-date fair value of options granted during the three months ended March 31, 2011 was $4.52 per share. For the three months ended March 31, 2011 and 2010, the Company received a total of $0 and $0.02 million, 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. As of March 31, 2011, there was $3.3 million of total unrecognized compensation cost related to unvested RSU awards granted under the Company's stock incentive plans.

A summary of RSU activity for the 2006 Plan as of March 31, 2011, and changes during the three months then ended are as follows:

	Number of Shares	Weighted Average Price/Share	Aggregate Intrinsic Value
	(In thousands, except for share amounts)		
Unvested at December 31, 2010	359,563	$ 9.75	$ 3,401
Granted	9,500	$ 6.88	
Vested	(2,500)	$ 0.80	
Cancelled	(3,250)	$ 8.75	
Unvested at March 31, 2011	363,313	$ 9.72	$ 2,649

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.

3. Earnings per Share

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

The following schedule presents the calculation of basic and diluted net income per share of common stock for the three months ended March 31, 2011 and 2010:

	Three Months Ended March 31, 2011	Three Months Ended March 31, 2010
	(In thousands, except for share amounts)	
Numerator:		
Net income	$ 136	$ 529
Denominator:		
Weighted average shares of common stock outstanding, basic	28,101,418	27,704,418
Stock options and restricted stock units related to the issuance of common stock	835,417	614,336
Weighted average shares of common stock outstanding, diluted	28,936,835	28,318,754
Basic and diluted net income per share	$ 0.00	$ 0.02
Anti-dilutive securities not included in diluted net income per share calculation:		
Stock options and restricted stock units related to the issuance of common stock	3,146,805	2,738,080

4. Marketable Securities

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(In thousands)			
Short-term :				
U.S. Treasury and government agencies	$ 40,236	$ 14	$ —	$ 40,250
U.S. corporate debt	101,700	85	—	101,785
	$ 141,936	$ 99	$ —	$ 142,035

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2010:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(In thousands)			
Short-term :				
U.S. Treasury and government agencies	$ 45,466	$ —	$ (11)	$ 45,455
U.S. corporate debt	110,010	27	(14)	110,023
	$ 155,476	$ 27	$ (25)	$ 155,478

5. Prepaid Expenses, Deposits and Other Current Assets

The following is a summary of the Company's prepaid expenses, deposits and other current assets, as of March 31, 2011 and December 31, 2010:

	March 31, 2011	December 31, 2010
	(In thousands)	
Prepaid insurance	$ 75	$ 244
Other prepaid expenses and vendor advances	1,255	966
Accrued interest income	289	633
Total prepaid expenses, deposits and other current assets	$ 1,619	$ 1,843

6. Property and Equipment, Net

The following is a summary of the Company's property and equipment-at cost, as of March 31, 2011 and December 31, 2010:

	Estimated Useful Life (Years)	March 31, 2011	December 31, 2010
		(In thousands)	
Laboratory equipment	5	$ 1,273	$ 1,282
Computer equipment	3	725	764
Furniture and fixtures	7	700	706
Leasehold improvements	10	844	844
		3,542	3,596
Less—accumulated depreciation and amortization		(2,682)	(2,659)
		$ 860	$ 937

Depreciation and amortization expense for the three months ended March 31, 2011 and 2010 was $0.1 million.

7. Intangible Asset, Net

The intangible asset consists of the following as of March 31, 2011:

	March 31, 2011			
	Estimated Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
		(In thousands)		
Fanapt®	8 years	$ 12,000	$ 2,847	$ 9,153
		$ 12,000	$ 2,847	$ 9,153

The intangible asset consisted of the following as of December 31, 2010:

	December 31, 2010			
	Estimated Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
		(In thousands)		
Fanapt®	8 years	$ 12,000	$ 2,478	$ 9,522
		$ 12,000	$ 2,478	$ 9,522

On May 6, 2009, the Company announced that the FDA had approved the NDA for Fanapt®. As a result of the FDA's approval of the NDA for Fanapt®, the Company met a milestone under its original sublicense agreement with Novartis which required the Company to make a payment of $12.0 million to Novartis. The $12.0 million is being amortized on a straight line basis over the remaining life of the U.S. patent for Fanapt®, which the Company expects to last until May 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 $0.4 million for the three months ended March 31, 2011 and 2010. The Company capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanapt®.

8. Accrued Liabilities

The following is a summary of accrued liabilities as of March 31, 2011 and December 31, 2010:

	March 31, 2011	December 31, 2010
	(In thousands)	
Accrued research and development expenses	$ 1,593	$ 1,061
Accrued consulting and other professional fees	189	201
Employee benefits	315	62
Other accrued expenses	44	—
Total accrued liabilities	$ 2,141	$ 1,324

9. Revenue Recognition

The Company's revenue consisted of the following:

	December 31, 2010 Deferred Revenue	Revenue Recognized	March 31, 2011 Deferred Revenue
		(In thousands)	
Revenues:			
Licensing agreement	$ 170,642	$ 6,606	$ 164,036
Royalty revenue	—	895	—
Total revenues	$ 170,642	$ 7,501	$ 164,036

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 three months ended March 31, 2011, the Company recognized $6.6 million of revenue for the licensing agreement. Vanda recognized royalty revenue of $0.9 million for the three months ended March 31, 2011. 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.

10. Commitments and Contingencies

Operating leases

The Company has commitments totaling $4.1 million under operating real estate leases for its headquarters located in Rockville, Maryland, which expires in 2016.

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 March 31, 2011.

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 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 its first Phase III clinical trial for tasimelteon. The Company is also obligated under this agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that the Company receives from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. The Company has agreed with BMS in the license agreement for tasimelteon to use commercially reasonable efforts to develop and commercialize tasimelteon and to meet certain milestones in initiating and completing certain clinical work. The license agreement with BMS was amended 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 March 31, 2011, 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.

11. 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 $0.01 million and $5.7 million for the three months ended March 31, 2011 and 2010, respectively. At March 31, 2011, the Company reflected a net deferred tax asset of $1.8 million associated with the Company's ability to carryback current taxable losses to recover income taxes paid in 2010. During the three months ended March 31, 2010, the Company released $2.0 million of valuation allowance due to the possibility of offsetting the current year tax provision through the carryback of losses generated by the future reversal of temporary differences. The remaining net deferred tax assets at March 31, 2011 and March 31, 2010 were offset by a valuation allowance since realization of any future benefit from deductible temporary differences and net operating losses could not be sufficiently assured.

12. Fair Value Measurements

FASB guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 — defined as observable inputs such as quoted prices in active markets
- Level 2 — defined as inputs other than quoted prices in active markets that are either directly or indirectly observable
- Level 3 — defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions

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

	Fair Value Measurements at Reporting Date Using			
	March 31, 2011	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	(In thousands)			
Description:				
Available-for-sale securities	$ 142,035	$ 40,250	$ 101,785	$ —
Total	$ 142,035	$ 40,250	$ 101,785	$ —

As of December 31, 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			
	December 31, 2010	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	(In thousands)			
Description:				
Available-for-sale securities	$ 155,478	$ 45,455	$ 110,023	$ —
Total	$ 155,478	$ 45,455	$ 110,023	$ —

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

Various statements in this report are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may appear throughout this report. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," and "could," or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in our forward-looking statements include, among others:

- the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives;
- our ability to successfully commercialize Fanapt® outside of the U.S. and Canada;
- delays in the completion of our 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 our research and development activities;
- our failure to identify or obtain rights to new products or product candidates;
- our failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage our growth;
- limitations on our ability to utilize some or all of our prior net operating losses and research and development credits;
- a loss of any of our key scientists or management personnel;
- losses incurred from product liability claims made against us; and
- a loss of rights to develop and commercialize our products or product candidates under our license and sublicense agreements.

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

We encourage you to read the discussion and analysis of our financial condition and our condensed consolidated financial statements contained in this quarterly report on Form 10-Q. We also encourage you to read Item 1A of Part II of this quarterly report on Form 10-Q entitled "Risk Factors" and Item 1A of Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 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, 2010, 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 the treatment of central nervous system disorders. We believe that each of our products and partnered products will address a large market with significant unmet medical needs by offering advantages over currently available therapies. Our product portfolio includes:

- *Fanapt® (iloperidone).* We have developed Fanapt®, and will continue to develop it outside the U.S. and Canada, to treat schizophrenia. 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. 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 of the Fanapt® oral formulation.

  For the three months ended March 31, 2011 we incurred $0.3 million in research and development costs directly attributable to our development of Fanapt®. As a result of the FDA's approval of the new drug application (NDA) for Fanapt® in May 2009, we met a milestone under the original sublicense agreement which required us to make a payment of $12.0 million to Novartis. The $12.0 million was capitalized and will be amortized over the remaining life of the U.S. patent for Fanapt®, which we expect to last until May 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.

- *Tasimelteon.* Tasimelteon is an oral compound in development for the treatment of 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 without light perception. The FDA grants orphan drug designation to drugs that may provide significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation provides potential financial and regulatory incentives, including study design assistance, tax credits, waiver of FDA user fees, and up to seven years of market exclusivity upon marketing approval. On February 23, 2011, the European Commission (EC) designated tasimelteon as an orphan medicinal product for the same indication. We initiated two clinical trials to pursue FDA approval of tasimelteon for the treatment of N24HSWD in blind individuals without 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). On January 6, 2011, an end-of-Phase II meeting was held with the FDA to discuss the development plan for tasimelteon in the treatment of N24HSWD. We are also evaluating tasimelteon in Major Depressive Disorder (MDD) and plan to initiate a Phase IIb/III clinical trial of tasimelteon in patients with MDD. The trial is expected to begin during the second half of 2011 and will investigate the efficacy and safety of tasimelteon versus placebo in the treatment of MDD. The study is expected to include an 8-week treatment period and an optional open-label extension. Given the range of potential indications for tasimelteon, we may pursue one or more partnerships for the development and commercialization of tasimelteon worldwide. For the three months ended March 31, 2011, we incurred $3.7 million in direct research and development costs directly attributable to our development of tasimelteon.

Since we began our operations in March 2003, we have devoted substantially all of our resources to the in-licensing and clinical development of our compounds. Our ability to generate 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, 2010.

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®, which we expect 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. We recognize revenue from Fanapt® royalties and commercial and development milestones from Novartis when realizable and earned and product revenue upon delivery of our products to Novartis.

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 FDA approval. Prior to FDA approval, all Fanapt® manufacturing-related and milestone costs were included in research and development expenses. Subsequent to FDA approval of Fanapt®, manufacturing and milestone costs related to this product are being capitalized. Costs related to the acquisition of intellectual property have been expensed as incurred since the underlying technology associated with these acquisitions were made in connection with the Company's research and development efforts and have no alternative future use. Milestone payments are accrued in accordance with the FASB guidance on accounting for contingencies which states that milestone payments be accrued when it is deemed probable that the milestone event will be achieved. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to realize the potential of our products and product candidates and pharmacogenetics and pharmacogenomics expertise. For the three months ended March 31, 2011, we incurred research and development expenses in the aggregate of $4.3 million, including stock-based compensation expenses of $0.7 million. We expect our research and development expenses to increase as we continue to develop our products and product candidates. We expect to incur licensing costs in the future that could be substantial, as we continue our efforts to develop our products, product candidates and partnered products and to evaluate potential in-license product candidates or compounds.

The following table summarizes our product development initiatives for the three months ended March 31, 2011 and 2010. Included in this table are the research and development expenses recognized in connection with the clinical development of Fanapt® and tasimelteon.

	Three Months Ended	
	March 31, 2011	March 31, 2010
	(In thousands)	
Direct project costs(1)		
Fanapt®	$ 349	$ 616
Tasimelteon	3,685	1,018
Total direct project costs	4,034	1,634
Indirect project costs(1)		
Facility	155	158
Depreciation	42	55
Other indirect overhead	36	194
Total indirect project costs	233	407
Total research and development expenses	$ 4,267	$ 2,041

(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. General and administrative expenses also include third party expenses incurred to support business development, marketing and other business activities related to Fanapt®. For the three months ended March 31, 2011, we incurred general and administrative expenses in the aggregate of $2.9 million, including stock-based compensation expenses of $0.9 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, 2010 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 will be recognized ratably from the date the amended and restated sublicense agreement became effective (November 27, 2009) through the expected life of the U.S. patent for Fanapt®, which we expect to last until May 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. 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. Our revenues are also derived from grant income which is recognized when it is received.

Stock-based compensation

We currently use the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The determination of the fair value of stock options on the date of grant using an option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the expected stock price volatility over the expected term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatility rates are based on our historical volatility of our publicly traded common stock blended with the historical volatility of the common stock of comparable entities. The expected term of options granted is based on the transition approach provided by FASB guidance as the options meet the "plain vanilla" criteria required by this 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 cash 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 our stock-based awards during the three months ended March 31, 2011 and 2010 was comprised of the following:

	Three Months Ended	
	March 31, 2011	March 31, 2010
	(In thousands)	
Research and development	$ 720	$ 893
General and administrative	878	196
Employee stock-based compensation expense	$ 1,598	$ 1,089

Income taxes

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

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

Recent Accounting Pronouncements

In September 2009, the FASB issued new accounting guidance related to the revenue recognition of multiple element arrangements. The new guidance states that if vendor-specific objective evidence or third party evidence for deliverables in an arrangement cannot be determined, companies will be required to develop a best estimate of the selling price to separate deliverables and allocate arrangement consideration using the relative selling price method. The accounting guidance will be applied prospectively and became effective during the first quarter of 2011. We adopted this guidance beginning January 1, 2011, with no material impact to our financial statements.

Results of Operations

We have a limited history of operations. We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, including any possible payments made or received pursuant to 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 March 31, 2011, we had a deficit accumulated of $253.5 million.

Three months ended March 31, 2011 compared to three months ended March 31, 2010

Revenues. Revenues were $7.5 million for the three months ended March 31, 2011 compared to revenues of $12.4 for the three months ended March 31, 2010. Revenues for the three months ended March 31, 2011 included $6.6 million recognized from Novartis related to straight-line recognition of up-front license fees and $0.9 million in royalty revenue based on first quarter 2011 sales of Fanapt®. Novartis launched Fanapt® commercially in the U.S. in January 2010.

Intangible asset amortization. Intangible asset amortization was $0.4 million for the three months ended March 31, 2011 compared to intangible amortization of $0.4 million for the three months ended March 31, 2010. Intangible amortization for the three months ended March 31, 2011 and 2010 consisted of $0.4 million resulting from the amortization of the capitalized intangible asset related to the $12.0 million payment to Novartis in May 2009.

Research and development expenses. Research and development expenses increased by $2.2 million, or 109.1%, to $4.3 million for the three months ended March 31, 2011 compared to $2.0 million for the three months ended March 31, 2010.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the three months ended March 31, 2011 and 2010:

	Three Months Ended	
	March 31, 2011	March 31, 2010
	(In thousands)	
Direct project costs:		
Clinical trials	$ 1,525	$ 2
Contract research and development, consulting, materials and other direct costs	895	50
Salaries, benefits and related costs	894	706
Stock-based compensation	720	876
Total direct costs	4,034	1,634
Indirect project costs	233	407
Total	$ 4,267	$ 2,041

Direct costs increased $2.4 million for the three months ended March 31, 2011 compared to the three months ended March 31, 2010 as a result of increases in clinical trial costs, contract research and development, consulting, materials and other direct costs and salaries, benefits and related costs partially offset by lower stock based compensation. Clinical trials costs increased by $1.5 million for the three months ended March 31, 2011 relative to the three months ended March 31, 2010, primarily due to costs related to the tasimelteon trials for the treatment of N24HSWD in blind individuals without light perception which began in the third quarter of 2010. Contract research and development, consulting, materials and other direct costs increased $0.8 million for the three months ended March 31, 2011 relative to the three months ended March 31, 2010, primarily due to costs related to the tasimelteon trials for the treatment of N24HSWD in blind individuals without light perception which began in the third quarter of 2010.

General and administrative expenses. General and administrative expenses increased by $0.4 million, or 14.8%, to $2.9 million for the three months ended March 31, 2011 from $2.5 million for the three months ended March 31, 2010.

The following table discloses the components of our general and administrative expenses for the three months ended March 31, 2011 and 2010:

	Three Months Ended	
	March 31, 2011	March 31, 2010
	(In thousands)	
Salaries, benefits and related costs	$ 529	$ 571
Stock-based compensation	878	196
Marketing, legal, accounting and other professional expenses	888	1,061
Other expenses	563	661
Total	$ 2,858	$ 2,489

Stock-based compensation expense increased by $0.7 million for the three months ended March 31, 2011 compared to the three months ended March 31, 2010, as a result of the reversal of expense related to the cancellation of unvested options due to executive departures during the first quarter of 2010. Marketing, legal, accounting and other professional costs decreased by $0.2 million for the three months ended March 31, 2011 compared to the three months ended March 31, 2010 due to a decrease in marketing expenses relating to Fanapt® for the three months ending March 31, 2011.

Interest income. Interest income in the three months ended March 31, 2011 was $0.1 million compared to $0.05 million in the three months ended March 31, 2010.

Liquidity and Capital Resources

As of March 31, 2011, our total cash and cash equivalents and marketable securities were $194.6 million compared to $198.0 million at December 31, 2010. 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 March 31, 2011, we also held a non-current deposit of $0.4 million that is used to collateralize a letter of credit issued for our current office lease in Rockville, Maryland which expires in 2016.

As of March 31, 2011, 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.

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®, 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. 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 three months ended March 31, 2011, we recorded $6.6 million in licensing revenue. Through March 31, 2011, we had recognized product revenue of $5.3 million from product sold to Novartis and $4.0 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 Joint Steering Committee established following the effective date of the amended and restated sublicense agreement with Novartis, 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 without 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 second trial is 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. 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 are also evaluating tasimelteon in MDD and plan to initiate a Phase IIb/III clinical trial of tasimelteon in patients with MDD. The trial is expected to begin during the second half of 2011 and will investigate the efficacy and safety of tasimelteon versus placebo in the treatment of MDD. The study is expected to include an 8-week treatment period and an optional open-label extension. We plan to assess the antidepressant and circadian effects of tasimelteon, as well as further characterize the safety profile of the compound.

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 planned operations. Our future capital requirements and the adequacy of our available funds will depend on many factors, primarily including the scope and costs of our clinical development programs, the scope and costs of our manufacturing and process development activities, the magnitude of our discovery and preclinical development programs and the level of our pre-commercial launch activities. There can be no assurance that any additional financing required in the future will be available on acceptable terms, if at all.

Cash Flow

The following table summarizes our cash flows for the three months ended March 31, 2011 and 2010:

	Three Months Ended	
	March 31, 2011	March 31, 2010
	(In thousands)	
Net cash provided by (used in)		
Operating activities	$ (3,264)	$ (4,826)
Investing activities	13,225	(32,457)
Financing activities	—	1,933
Net change in cash and cash equivalents	$ 9,961	$ (35,350)

Net cash used in operations was $3.3 million and $4.8 million for the three months ended March 31, 2011 and 2010, respectively. Adjustments to reconcile net income to net cash used in operating activities included non-cash charges for depreciation and amortization of $0.8 million and stock-based compensation of $1.6 million, decreases in prepaid expenses and other assets and other liabilities of $0.2 million, increases in accounts receivable, accrued expenses, accounts payable and accrued income taxes of $0.6 million, and decreases in deferred revenue of $6.6 million. Net cash provided by investing activities for the three months ended March 31, 2011 was $13.2 million and consisted primarily of net maturities of marketable securities.

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. Due to the nature of this intellectual property, we believe that these intangible assets are not affected by inflation. 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.

Off-balance sheet arrangements

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

Contractual Obligations and Commitments

Operating leases

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

The following table summarizes our long-term contractual cash obligations as of March 31, 2011:

	Cash Payments Due by Period						
	Total	April to December 2011	2012	2013	2014	2015	After 2015
	(In thousands)						
Operating leases	$ 4,100	$ 545	$ 749	$ 771	$ 795	$ 818	$ 422
Total	$ 4,100	$ 545	$ 749	$ 771	$ 795	$ 818	$ 422

Clinical research organization contracts and other contracts

Other contracts. We have entered into agreements for tasimelteon with clinical supply manufacturing organizations and other outside contractors who will be responsible for additional services supporting our ongoing clinical development processes. These contractual obligations are not reflected in the table above because we may terminate them on no more than 60 days notice without incurring additional charges (other than charges for work completed but not paid for through the effective date of termination and other costs incurred by our contractors in closing out work in progress as of the effective date of termination).

License agreements. In February 2004 and June 2004, we entered into separate 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 certain royalties) based on net sales for each of the licensed products. 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 the FDA of the NDA for Fanapt® in October 2007, we met a milestone under our original sublicense agreement with Novartis and subsequently paid a $5.0 million fee. As a result of the FDA's approval of the NDA for Fanapt® in May 2009, we met an additional milestone under the original sublicense agreement with Novartis which required us to make a payment of $12.0 million to Novartis. The $12.0 million was capitalized and will be amortized over the remaining life of the U.S. patent for Fanapt®, which we expect to last until May 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 March 31, 2011, since the amounts, timing and likelihood of these payments are unknown and will depend on the successful outcome of future clinical trials, regulatory filings, favorable regulatory approvals, growth in product sales and other factors.

Pursuant to the amended and restated sublicense agreement, Novartis has exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. Novartis is responsible for the further clinical development activities in the U.S. and Canada, including the development of a long-acting injectable (or depot) formulation of Fanapt®. Pursuant to the amended and restated sublicense agreement, we received an upfront payment of $200.0 million and are eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanapt® in the U.S. and Canada. We also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanapt® in the U.S. and Canada. In addition, we are no longer required to make any future milestone payments with respect to sales of Fanapt® or any royalty payments with respect to sales of Fanapt® in the U.S. and Canada. We retain exclusive rights to Fanapt® outside the U.S. and Canada and have exclusive rights to use any of Novartis' data for Fanapt® for developing and commercializing Fanapt® outside the U.S. and Canada. At Novartis' option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt® outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt® outside of the U.S. and Canada.

Item 3. ***Quantitative and Qualitative Disclosures about Market Risk.***

Interest Rates

Our exposure to market risk is currently confined to our cash and cash equivalents, marketable securities and restricted cash. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments.

Marketable securities

We deposit our cash with financial institutions that we consider to be of high credit quality and purchase marketable securities which are generally investment grade, liquid, short-term fixed income securities and money-market instruments denominated in U.S. dollars.

Item 4. ***Controls and Procedures.***

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2011. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of March 31, 2011, the end of the period covered by this quarterly report, to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the first quarter of 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

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

None.

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

In our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed with the SEC on March 10, 2011, we identify under Item 1A important factors which could affect our business, financial condition, results of operations and future operations and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this

Form 10-Q. There have been no material change in our risk factors subsequent to the filing of our Form 10-K for the fiscal year ended December 31, 2010.

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

None.

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

None.

Item 4. ***Removed and Reserved.***

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

None.

Item 6. ***Exhibits.***

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

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)

May 9, 2011

/s/ James P. Kelly

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

May 9, 2011

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

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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.

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.

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

Date: May 9, 2011

EXHIBIT 31.2

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

I, James P. Kelly, certify that:

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

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

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

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

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

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

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

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

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

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

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

/s/ James P. Kelly

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

Date: May 9, 2011

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 March 31, 2011 (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.

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

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

Date: May 9, 2011

/s/ James P. Kelly

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

Date: May 9, 2011

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.