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

Form 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2009

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: 000-51863

VANDA PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	**03-0491827**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
9605 Medical Center Drive, Suite 300 **Rockville, Maryland** *(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 November 3, 2009, there were 27,201,978 shares of the registrant's common stock issued and outstanding.

Vanda Pharmaceuticals Inc.
(A Development Stage Enterprise)

Form 10-Q Index

For the Three and Nine Months Ended September 30, 2009

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Part I — FINANCIAL INFORMATION

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

VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	September 30, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,417,647	$ 39,079,304
Marketable securities	3,265,175	7,378,798
Prepaid expenses, deposits and other current assets	2,632,783	1,287,400
Inventory	1,758,427	—
Total current assets	25,074,032	47,745,502
Property and equipment, net	1,411,326	1,758,111
Restricted cash	430,230	430,230
Intangible asset, net	11,393,857	—
Total assets	$ 38,309,445	$ 49,933,843
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,346,236	$ 512,382
Accrued liabilities	2,046,028	2,898,417
Total current liabilities	8,392,264	3,410,799
Deferred rent	505,831	502,770
Total liabilities	8,898,095	3,913,569
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 20,000,000 shares authorized and none issued and outstanding at September 30, 2009 and December 31, 2008	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized as of September 30, 2009 and December 31, 2008; and 27,201,978 and 26,653,478 shares issued and outstanding as of September 30, 2009 and December 31, 2008, respectively	27,202	26,653
Additional paid-in capital	280,980,068	270,988,157
Accumulated other comprehensive income (loss)	43	(20,029)
Deficit accumulated during the development stage	(251,595,963)	(224,974,507)
Total stockholders' equity	29,411,350	46,020,274
Total liabilities and stockholders' equity	$ 38,309,445	$ 49,933,843

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

VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended		Nine Months Ended		Period from March 13, 2003 (Inception) to September 30, 2009
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008	
Revenues	$ —	$ —	$ —	$ —	$ 81,545
Operating expenses:					
Cost of sales	376,792	—	606,143	—	606,143
Research and development	2,091,984	3,792,424	11,620,918	20,375,998	161,206,238
General and administrative	5,266,434	7,400,263	14,478,786	24,814,462	100,397,625
Total operating expenses	7,735,210	11,192,687	26,705,847	45,190,460	262,210,006
Loss from operations	(7,735,210)	(11,192,687)	(26,705,847)	(45,190,460)	(262,128,461)
Other income (expense):					
Interest income	9,842	323,476	84,391	1,630,238	10,564,062
Interest expense	—	—	—	—	(80,485)
Other income	—	—	—	—	71,947
Total other income, net	9,842	323,476	84,391	1,630,238	10,555,524
Loss before tax provision	(7,725,368)	(10,869,211)	(26,621,456)	(43,560,222)	(251,572,937)
Tax provision	—	—	—	—	23,026
Net loss	(7,725,368)	(10,869,211)	(26,621,456)	(43,560,222)	(251,595,963)
Beneficial conversion feature — deemed dividend to preferred stockholders	—	—	—	—	(33,486,623)
Net loss attributable to common stockholders	$ (7,725,368)	$ (10,869,211)	$ (26,621,456)	$ (43,560,222)	$ (285,082,586)
Basic and diluted net loss per share applicable to common stockholders	$ (0.28)	$ (0.41)	$ (0.99)	$ (1.63)	
Shares used in calculation of basic and diluted net loss per share applicable to common stockholders	27,196,694	26,650,534	26,920,742	26,649,439	

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

VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Comprehensive Loss	Total
	Shares	Par Value					
Balances at December 31, 2008	26,653,478	$ 26,653	$ 270,988,157	$ (20,029)	$ (224,974,507)		$ 46,020,274
Issuance of common stock from exercised stock options/restricted stock units	548,500	549	1,283,185	—	—		1,283,734
Employee stock-based compensation	—	—	8,320,399	—	—		8,320,399
Non-employee stock-based compensation	—	—	388,327	—	—		388,327
Comprehensive loss:							
Net loss	—	—	—	—	(26,621,456)	$ (26,621,456)	
Net unrealized gain on marketable securities	—	—	—	20,072	—	20,072	
Comprehensive loss						$ (26,601,384)	(26,601,384)
Balances at September 30, 2009	27,201,978	$ 27,202	$ 280,980,068	$ 43	$ (251,595,963)		$ 29,411,350

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

VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Nine Months Ended		Period from March 13, 2003 (Inception) to September 30, 2009
	September 30, 2009	September 30, 2008	
Cash flows from operating activities			
Net loss	$ (26,621,456)	$ (43,560,222)	$ (251,595,963)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	346,785	403,141	2,846,447
Employee and non-employee stock-based compensation	8,708,726	12,679,311	53,032,038
Loss on disposal of assets	—	(173)	57,458
Amortization of discounts and premiums on marketable securities	122,963	(212,664)	(2,104,357)
Amortization of intangible assets	606,143	—	606,143
Changes in assets and liabilities:			
Prepaid expenses, deposits and other current assets	(1,345,383)	(1,160,103)	(2,632,783)
Inventory	(1,758,427)	—	(1,758,427)
Accounts payable	833,854	(2,089,044)	1,346,236
Accrued expenses	(852,389)	(6,708,552)	2,046,028
Other liabilities	3,061	142,732	505,831
Net cash used in operating activities	(19,956,123)	(40,505,574)	(197,651,349)
Cash flows from investing activities			
Acquisition of intangible asset	(7,000,000)	—	(7,000,000)
Purchases of property and equipment	—	(943,659)	(4,381,391)
Proceeds from sale of property and equipment	—	—	200,179
Purchases of marketable securities	(11,365,815)	(11,491,577)	(279,184,558)
Proceeds from sales of marketable securities	126,547	10,373,251	97,100,390
Maturities of marketable securities	15,250,000	42,060,000	180,925,000
Investment in restricted cash	—	—	(430,230)
Net cash provided by (used in) investing activities	(2,989,268)	39,998,015	(12,770,610)
Cash flows from financing activities			
Proceeds from borrowings on note payable	—	—	515,147
Principal payments on obligations under capital lease	—	—	(91,797)
Principal payments on note payable	—	—	(515,147)
Proceeds from issuance of preferred stock, net of issuance costs	—	—	61,795,187
Proceeds from exercise of stock options and warrants	1,283,734	—	1,591,243
Proceeds from issuance of common stock, net of issuance costs	—	—	164,588,801
Net cash provided by financing activities	1,283,734	—	227,883,434
Effect of foreign currency translation	—	16,745	(43,828)
Net change in cash and cash equivalents	(21,661,657)	(490,814)	17,417,647
Cash and cash equivalents			
Beginning of period	39,079,304	41,929,533	—
End of period	$ 17,417,647	$ 41,438,719	$ 17,417,647
Supplemental disclosure of non-cash investing activities			
Intangible asset acquisition included in accounts payable	$ 5,000,000	$ —	$ 5,000,000

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

VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. Business Organization and Presentation

Business organization

Vanda Pharmaceuticals Inc. (Vanda or the Company) is a biopharmaceutical company focused on the development and commercialization of small molecule therapeutics for various central nervous system disorders. Vanda commenced its operations in 2003. The Company's lead product, iloperidone, which the Company expects to be marketed by Novartis Pharma AG (Novartis) under the tradename Fanaptтм in the U.S. beginning in the first quarter of 2010, is a compound for the treatment of schizophrenia. On May 6, 2009, the United States Food and Drug Administration (FDA) granted U.S. marketing approval of Fanaptтм 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 Fanaptтм. The amended and restated sublicense agreement is subject to, and will become effective upon, clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act), which is expected by the end of 2009. Pursuant to the amended and restated sublicense agreement, Novartis will have exclusive commercialization rights to all formulations of Fanaptтм in the U.S. and Canada. Except for two post-approval studies started by Vanda prior to the execution date of the amended and restated sublicense agreement, which Vanda is obligated to complete, Novartis will be 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 Fanaptтм. Pursuant to the terms of the amended and restated sublicense agreement, Vanda will be entitled to an upfront payment of $200.0 million, which it expects to receive within 30 days after the effective date of the agreement. Vanda will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptтм in the U.S. and Canada. Vanda will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptтм in the U.S. and Canada. In addition, Vanda will no longer be required to make any future milestone payments with respect to sales of Fanaptтм or any future royalty payments with respect to sales of Fanaptтм in the U.S. and Canada. Vanda retains exclusive rights to Fanaptтм outside the U.S. and Canada and Vanda will have exclusive rights to use any of Novartis' data for Fanaptтм for developing and commercializing Fanaptтм outside the U.S. and Canada. At Novartis' option, Vanda will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptтм outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptтм outside of the U.S. and Canada.

Tasimelteon is a compound 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. In November 2006, Vanda announced positive top-line results from the Phase III trial of tasimelteon in transient insomnia. In June 2008, the Company announced positive top-line results from the Phase III trial of tasimelteon in chronic primary insomnia. The Company believes that tasimelteon may be effective in the treatment of insomnia caused by jet lag. The Company met with the FDA in June 2009 in an end of Phase II meeting to discuss the clinical development plan for the insomnia of jet lag disorder indication and will continue to work with the FDA to characterize the path to a New Drug Application (NDA) for tasimelteon. Tasimelteon is also ready for Phase II trials for the treatment of depression.

Capital resources

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, market research, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, the Company is considered to be in the development stage.

VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

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

The Company's activities will necessitate significant uses of working capital throughout 2009 and beyond. Vanda is currently concentrating its efforts on the transition of the commercialization and development rights to Fanaptᵀᴹ in the U.S. and Canada to Novartis and expects to work with Novartis, including exchanging information via the joint steering committee established pursuant to the amended and restated sublicense agreement, to assist Novartis' anticipated commercial launch of Fanaptᵀᴹ in the first quarter of 2010. The transition includes all regulatory, manufacturing and certain post-marketing commitments requested by the FDA. Under the terms of the amended and restated sublicense agreement with Novartis, except for two post-approval studies started by Vanda prior to the execution date of the amended and restated sublicense agreement, which Vanda is obligated to complete, Novartis will be responsible for the further clinical development activities in the U.S. and Canada, including the development of a depot formulation of Fanaptᵀᴹ. Vanda will also continue to work closely with the FDA on the path forward for tasimelteon. The Company expects to continue to operate on a reduced spending plan with its fixed overhead costs expected to be approximately $2.5 million to $3.0 million per quarter.

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The consolidated financial statements include the accounts of the Company and its wholly-owned Singapore subsidiary that ceased operations during 2007. All inter-company balances and transactions have been eliminated.

The accompanying unaudited condensed consolidated financial statements of Vanda have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) and the rules and regulations of the Securities and Exchange Commission (SEC) for interim financial information. 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, 2008 included in the Company's annual report on Form 10-K/A. The financial information as of September 30, 2009 and for the periods of the three and nine months ended September 30, 2009 and 2008 and for the period from March 13, 2003 (inception) to September 30, 2009, is unaudited, but in the opinion of management all adjustments, consisting only of normal recurring accruals, considered necessary for a fair statement of the results of these interim periods have been included. The condensed consolidated balance sheet data as of December 31, 2008 was derived from audited financial statements but does not include all disclosures required by GAAP.

The results of the Company's operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year. The financial information included herein should be read in conjunction with the consolidated financial statements and notes in the Company's annual report incorporated by reference in the Form 10-K/A for the year ended December 31, 2008.

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.

VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

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

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.

Inventory

The Company values inventories at the lower of cost or net realizable value. The Company analyzes its inventory levels quarterly and writes down inventory that has become obsolete, or has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are written off to cost of sales. Prior to FDA approval, all Fanaptᴛᴍ manufacturing-related costs were included in research and development expenses. Subsequent to FDA approval of Fanaptᴛᴍ, manufacturing costs related to this product are capitalized.

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 collaborators 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 Fanaptᴛᴍ, the Company met a milestone under its original sublicense agreement with Novartis which required the Company to make a license payment of $12.0 million to Novartis. Of the $12.0 million milestone payment, $7.0 million was paid in May 2009 and the remaining $5.0 million was paid in October 2009. The $12.0 million is being amortized on a straight line basis over the remaining life of the U.S. patent for Fanaptᴛᴍ, 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. Amortization of the intangible asset is recorded as a component of cost of goods sold.

The carrying values of intangible assets are periodically reviewed to determine if the facts and circumstances suggest that a potential impairment may have occurred. The Company had no impairments of its intangible assets for the nine months ended September 30, 2009.

VANDA PHARMACEUTICALS INC.
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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) — (Continued)

Concentrations of credit risk

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company places its cash, cash equivalents and marketable securities with what the Company believes to be highly-rated financial institutions. At September 30, 2009, the Company maintained all of its cash, cash equivalents and marketable securities in three financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand, and the Company believes there is minimal risk of losses on such balances.

Employee stock-based compensation

The Company accounts for the stock-based compensation expenses in accordance with the FASB guidance on share-based payments adopted on January 1, 2006. Accordingly, compensation costs for all stock-based awards to employees and directors are measured based on the grant date fair value of those awards and recognized over the period during which the employee or director is required to perform service in exchange for the award. The Company generally recognizes the expense over the award's vesting period.

For stock awards subsequent to 2006, the fair value of these awards are amortized using the accelerated attribution method. For stock awards granted prior to January 1, 2006, expenses are amortized under the accelerated attribution method for options that were modified after the original grant date and under the straight-line attribution method for all other options. As stock-based compensation expense recognized in the consolidated statements of operations is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures on the options granted during 2008, 2007 and 2006, were estimated to be approximately 2% and was increased to 4% in 2009 based on the Company's historical experience. In the periods prior to January 1, 2006, the Company accounted for forfeitures as they occurred. The cumulative effect adjustment of adopting the change in estimating forfeitures was not considered material to the Company's financial statements for periods prior to January 1, 2006.

Total employee stock-based compensation expense recognized during the three and nine months ended September 30, 2009 and 2008 and the period from March 13, 2003 (inception) to September 30, 2009 was comprised of the following:

	Three Months Ended		Nine Months Ended		Period from March 13, 2003 (Inception) to September 30, 2009
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008	
Research and development	$ 707,646	$ 504,686	$ 1,517,324	$ 2,357,015	$ 9,057,513
General and administrative	2,555,576	3,115,679	6,803,075	10,349,328	43,438,413
Stock-based compensation expense	$ 3,263,222	$ 3,620,365	$ 8,320,399	$ 12,706,343	$ 52,495,926
Stock-based compensation expense per basic and diluted share of common stock	$ 0.12	$ 0.14	$ 0.31	$ 0.48	
Shares used in calculation of stock-based compensation expense per share	27,196,694	26,650,534	26,920,742	26,649,439	

VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

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

As of September 30, 2009, approximately $8.8 million of total unrecognized compensation costs related to non-vested awards are expected to be recognized over a weighted average period of 1.33 years.

As of September 30, 2009, 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 1,033,910 shares were subject to outstanding options granted under the 2004 Plan as of September 30, 2009, and no additional options will be granted under this plan. As of September 30, 2009 there are 4,061,684 shares of the Company's common stock reserved under the 2006 Plan of which 3,287,082 shares were subject to outstanding options and restricted stock units issued to employees and non-employees.

Options are subject to terms and conditions established by the compensation committee of the board of directors. None of the stock-based awards are classified as a liability as of September 30, 2009. Option awards have 10-year contractual terms and all options granted prior to December 31, 2006, options granted to new employees, and certain options granted to existing employees vest and become exercisable on the first anniversary of the grant date with respect to 25% of the shares subject to the option awards. The remaining 75% of the shares subject to the option awards vest and become exercisable monthly in equal installments thereafter over three years. Certain option awards granted to existing employees after December 31, 2006 vest and become exercisable monthly in equal installments over four years. The initial stock options granted to directors upon their election vest and become exercisable in equal monthly installments over a period of four years, while the subsequent annual stock option grants to directors vest and become exercisable in equal monthly installments over a period of one year. Certain option awards to executives and directors provide for accelerated vesting if there is a change in control of the Company. Certain option awards to employees and executives provide for accelerated vesting if the respective employee's or executive's service is terminated by the Company for any reason other than cause or permanent disability.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model that uses the assumptions noted in the following table. Expected volatility rates are based on historical volatility of the common stock of comparable entities and other factors due to the lack of historic information of the Company's publicly traded common stock. The expected term of options granted is based on the transition approach provided by FASB guidance as the options meet the "plain vanilla" criteria required by this guidance. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception and does not plan to pay dividends in the foreseeable future.

Assumptions used in the Black-Scholes-Merton option pricing model for employee and director stock options granted during the nine months ended September 30, 2009 and 2008 were as follows:

	Nine Months Ended	
	September 30, 2009	September 30, 2008
Expected dividend yield	0%	0%
Weighted average expected volatility	68%	68%
Weighted average expected term (years)	6.03	6.03
Weighted average risk-free rate	2.95%	3.29%

VANDA PHARMACEUTICALS INC.
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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) — (Continued)

A summary of option activity for the 2004 Plan is presented below:

	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	1,154,248	$ 1.74		
Exercised	(93,545)	3.48		
Forfeited	—	—		
Cancelled	(26,793)	2.71		
Outstanding at September 30, 2009	1,033,910	1.53	5.95	$ 10,451,401
Exercisable at September 30, 2009	1,016,751	1.47	5.93	$ 10,362,835

A summary of option activity for the 2006 Plan is presented below:

	Number of shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	2,631,381	$ 17.43		
Granted	965,000	12.78		
Exercised	(143,455)	6.68		
Forfeited	(196,443)	23.99		
Cancelled	(299,901)	13.70		
Outstanding at September 30, 2009	2,956,582	16.91	8.39	$ 5,569,847
Exercisable at September 30, 2009	1,276,690	20.53	7.79	$ 2,420,908

The weighted average grant-date fair value of options granted during the nine months ended September 30, 2009 was $8.07 per share. For the nine months ended September 30, 2009 and 2008, the Company received a total of $1,283,734 and $0, respectively, in cash from options exercised under the stock-based arrangements.

Restricted stock is a stock award that entitles the holder to receive shares of the Company's common stock as the award vests. The Company issued restricted stock to all employees who remained with the Company following the workforce reduction in December 2008 and key consultants retained by the Company. Of the RSUs issued in 2008 to the retained employees, 50% of the shares vested upon approval by the FDA of the NDA for Fanapt™, and 50% of the shares vest on December 31, 2009. Upon a change of control of the Company, 100% of the unvested RSUs will vest. The fair value of each restricted stock award was based on the closing price of the Company's stock on the date of grant which equals the RSUs intrinsic value. As of September 30, 2009, there was approximately $321,981 of total unrecognized compensation cost related to unvested restricted stock awards granted under the Company's stock incentive plans. The majority of the cost is expected to be recognized through December 2009.

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A summary of restricted stock activity for the 2006 Plan is presented below:

	Number of Shares	Weighted Average Price/Share	Aggregate Intrinsic Value
Unvested at December 31, 2008	623,000	0.57	$ 311,500
Granted	54,000	5.70	
Vested	(311,500)	0.58	
Cancelled	(35,000)	0.57	
Unvested at September 30, 2009	330,500	1.39	$ 3,847,020

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, fees for marketing and other commercialization activities, and severance related costs due to the Company's workforce reduction which occurred in the fourth quarter of 2008. 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.

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 development stage, including certain payments made under the license agreements. Prior to FDA approval, all Fanaptᴛᴍ manufacturing-related and milestone costs were included in research and development expenses. Post FDA approval of Fanaptᴛᴍ, 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, 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

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services. General and administrative expenses also include third party expenses incurred to support business development, marketing and other business activities related to Fanapt™.

Income taxes

The Company accounts for income taxes under the liability method in accordance with the FASB provisions on accounting for income taxes, which requires companies to account for deferred income taxes using the asset and liability method. Under the asset and liability method, current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credits and loss carryforwards. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Tax rate changes are reflected in income during the period such changes are enacted. Changes in ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

Segment information

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

Recent accounting pronouncements

In May 2009, the FASB issued guidance on subsequent events which establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. Corporate financial statements are considered issued when they are widely distributed to shareholders and other financial statement users for “general use and reliance” in a form and format that complies with GAAP. Financial statements are considered available to be issued when they are in a form and format that complies with GAAP. The FASB guidance provides that companies should recognize in the financial statements the effects of all subsequent events that provide additional evidence about conditions that existed at the date of the balance sheet, including the estimates inherent in the process of preparing financial statements. The Company has implemented this new standard with no material impact on the Company’s consolidated financial position and results of operations.

In June 2009, the FASB issued the accounting standards codification and the hierarchy of generally accepted accounting principles. This guidance identifies the source of accounting principles and the framework for selecting the principles used in the preparation of financial statements. The guidance is effective for interim and annual periods ending after September 15, 2009. The Company has updated its financial statement disclosures as appropriate upon adoption of this standard in the third quarter of 2009.

3. Earnings per Share

Net loss attributable to common stockholders per share is calculated in accordance with FASB guidance on earnings per share. Basic earnings per share (EPS) is calculated by dividing the net income or loss attributable to common stockholders by the weighted average number of shares of common stock outstanding, reduced by the weighted average unvested shares of common stock subject to repurchase.

Diluted EPS is computed by dividing the net income or loss attributable to common stockholders by the weighted average number of other potential common stock outstanding for the period. Other potential common stock includes stock options, warrants and restricted stock units, but only to the extent that their inclusion is

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dilutive. The Company incurred a net loss in all periods presented, causing inclusion of any potentially dilutive securities to have an anti-dilutive affect, resulting in dilutive loss per share attributable to common stockholders and basic loss per share attributable to common stockholders being equivalent. The Company did not have any common shares issued for nominal consideration as defined under the FASB terms, which would be included in EPS calculations.

	Three Months Ended		Nine Months Ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Numerator:				
Net loss	$ (7,725,368)	$ (10,869,211)	$ (26,621,456)	$ (43,560,222)
Denominator:				
Weighted average shares of common stock outstanding	27,196,694	26,652,728	26,920,742	26,652,728
Weighted average unvested shares of common stock subject to repurchase	—	(2,194)	—	(3,289)
Denominator for basic and diluted net loss per share	27,196,694	26,650,534	26,920,742	26,649,439
Basic and diluted net loss per share applicable to common stockholders	$ (0.28)	$ (0.41)	$ (0.99)	$ (1.63)
Anti-dilutive securities not included in diluted net loss per share calculation:				
Options to purchase common stock and restricted stock units	4,320,992	4,255,488	4,320,992	4,255,488

4. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of September 30, 2009:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Short-term:				
U.S. Treasury and government agencies	$ 3,265,132	$ 129	$ (86)	$ 3,265,175
	$ 3,265,132	$ 129	$ (86)	$ 3,265,175

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The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2008:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Short-term:				
U.S. Treasury and government agencies	$ 1,992,452	$ 7,408	$ —	$ 1,999,860
U.S. corporate debt	5,279,828	2,336	(29,818)	5,252,346
U.S. asset-based securities	126,547	45	—	126,592
	$ 7,398,827	$ 9,789	$ (29,818)	$ 7,378,798

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 September 30, 2009, and December 31, 2008:

	September 30, 2009	December 31, 2008
Current deposits with vendors	$ 150,000	$ 210,000
Prepaid insurance	438,564	282,391
Accrued interest income	49,614	53,378
Other prepaid expenses and advances	1,934,605	326,201
Other receivables	60,000	415,430
	$ 2,632,783	$ 1,287,400

6. Inventory

Inventory, net consisted of the following:

	September 30, 2009
Raw materials	$ —
Work-in-process	439,607
Finished goods	1,318,820
Total inventory, net	$ 1,758,427

Pursuant to the amended and restated sublicense agreement with Novartis, Novartis will be obligated to purchase all Fanapt™ inventory following the effective date of the agreement, subject to such inventory meeting certain requirements.

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7. Property and Equipment

The following is a summary of the Company's property and equipment — at cost, as of September 30, 2009 and December 31, 2008:

	Estimated Useful Life (Years)	September 30, 2009	December 31, 2008
Laboratory equipment	5	$ 1,348,098	$ 1,348,098
Computer equipment	3	776,921	776,921
Furniture and fixtures	7	705,784	705,784
Leasehold improvements	10	844,158	844,158
		3,674,961	3,674,961
Less — accumulated depreciation and amortization		(2,263,635)	(1,916,850)
		$ 1,411,326	$ 1,758,111

Depreciation and amortization expense for the nine months ended September 30, 2009 and 2008 were $346,785 and $403,141, respectively, and for the period from March 13, 2003 (inception) to September 30, 2009 was $2,846,447.

8. Intangible Asset, Net

The intangible asset consists of the following:

		September 30, 2009		
	Estimated Useful Lives	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt™	8 years	$ 12,000,000	$ 606,143	$ 11,393,857
		$ 12,000,000	$ 606,143	$ 11,393,857

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™, it met a milestone under its original sublicense agreement with Novartis which required the Company to make a license payment of $12.0 million to Novartis. Of the $12.0 million milestone payment, $7.0 million was paid in May 2009 and the remaining $5.0 million was paid in October 2009. 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 $606,143 for the nine months ended September 30, 2009. The estimated annual amortization expense for intangible assets is approximately $1.0 million in 2009, $1.5 million in 2010, $1.5 million in 2011, $1.5 million in 2012 and $6.5 from 2013 through 2017. The Company capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanapt™.

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9. Accrued Liabilities

The following is a summary of accrued liabilities, as of September 30, 2009, and December 31, 2008:

	September 30, 2009	December 31, 2008
Accrued research and development expenses	$ 612,584	$ 925,124
Accrued consulting and other professional fees	1,008,139	233,829
Employee benefits	196,466	126,816
Accrued severance	228,839	1,612,648
	$ 2,046,028	$ 2,898,417

10. Commitments and Contingencies

Operating leases

The Company has commitments totaling approximately $5.2 million under operating real estate leases for its headquarters located in Rockville, Maryland, expiring in 2016.

Severance payments

On December 16, 2008, the Company committed to a plan of termination that resulted in a work force reduction of 17 employees, including two officers, in order to reduce operating costs. The Company commenced notification of employees affected by the workforce reduction on December 17, 2008. The following table summarizes the activity in the nine months ended September 30, 2009 for the liability for the cash portion of severance costs related to the reductions-in-force:

	Nine Months Ended September 30, 2009			
	Beginning Balance	Charge	Cash Paid	Ending Balance
Workforce Reduction:				
Research Development	$ 571,391	$ —	$ 483,988	$ 87,403
General & Administrative	1,041,257	—	899,821	141,436
Total	$ 1,612,648	$ —	$ 1,383,809	$ 228,839

Consulting fees

The Company engaged a regulatory consultant to assist in the Company's efforts to obtain FDA approval of the Fanapt™ NDA. The Company committed to initial consulting expenses in the aggregate amount of $2.0 million pursuant to this engagement, which was expensed in 2008. In addition, the Company retained the services of the consultant on a monthly basis at a retainer fee of $250,000 per month effective as of January 1, 2009. The Company was obligated to pay the consultant a success fee of $6.0 million as a result of the approval by the FDA of its NDA for Fanapt™, which was fully expensed in May 2009 and was offset by the aggregate amount of all monthly retainer fees previously paid to the consultant (Success Fee). Through September 30, 2009, the Company paid $5.0 million to the consultant. The Success Fee was paid monthly in $1.0 million increments with the last payment occurring in October 2009. In addition to these fees, the Company reimbursed the consultant for its ordinary and necessary business expenses incurred in connection with its engagement.

The Company also engaged financial advisors and consultants to act as strategic advisors to the Company in connection with a proposed transaction or partnership involving the possible sale, partnership, or other

business combination of the Company. Pursuant to agreements with such strategic advisors, Vanda is obligated to pay an aggregate success fee of approximately $3.5 million following the effective date of the amended and restated sublicense agreement with Novartis, which is expected to occur by the end of 2009.

Guarantees and indemnifications

The Company has entered into a number of standard intellectual property indemnification agreements in the ordinary course of its business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company's products. The term of these indemnification agreements is generally perpetual from the date of execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes that the fair value of the indemnification agreements is minimal, and accordingly the Company has not recognized any liabilities relating to these agreements as of September 30, 2009.

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 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 iloperidone and completed early clinical work on the compound. In 1996, following a review of its product portfolio, HMRI licensed its rights to the iloperidone patents to Titan Pharmaceuticals, Inc. (Titan) on an exclusive basis. In 1997, soon after it had acquired its rights, Titan sublicensed its rights to iloperidone on an exclusive basis to Novartis. In June 2004, the Company acquired exclusive worldwide rights to these patents as well as certain Novartis patents to develop and commercialize iloperidone through a sublicense agreement with Novartis. In partial consideration for this sublicense, the Company paid Novartis an initial license fee of $500,000 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™, the Company met an additional milestone under this sublicense agreement which required the Company to make a license payment of $12.0 million to Novartis. Of the $12.0 million milestone payment, $7.0 million was paid in May 2009 and the remaining $5.0 million was paid in October 2009.

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. The amended and restated sublicense agreement is subject to, and will become effective upon, clearance under the HSR Act, which is expected by the end of 2009. Pursuant to the amended and restated sublicense agreement, Novartis will have exclusive commercialization rights to all formulations of Fanapt™ in the U.S. and Canada. Except for two post-approval studies started by Vanda prior to the execution date of the amended and restated sublicense agreement, which Vanda is obligated to complete, Novartis will be 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 Fanaptᵀᴹ. Pursuant to the terms of the amended and restated sublicense agreement, Vanda will be entitled to an upfront payment of $200.0 million, which Vanda expects to receive within 30 days after the effective date of the agreement. Vanda will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵀᴹ in the U.S. and Canada. Vanda will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵀᴹ in the U.S. and Canada. In addition, Vanda will no longer be required to make any future milestone payments with respect to sales of Fanaptᵀᴹ or any future royalty payments with respect to sales of Fanaptᵀᴹ in the U.S. and Canada. Vanda retains exclusive rights to Fanaptᵀᴹ outside the U.S. and Canada and Vanda will have exclusive rights to use any of Novartis' data for Fanaptᵀᴹ for developing and commercializing Fanaptᵀᴹ outside the U.S. and Canada. At Novartis' option, Vanda will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵀᴹ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵀᴹ outside of the U.S. and Canada.

Vanda may lose its rights to develop and commercialize Fanaptᵀᴹ 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 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 Fanaptᵀᴹ 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 Fanaptᵀᴹ. 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 $500,000 and is obligated to make future milestone payments to BMS of less than $40.0 million in the aggregate (the majority of which are tied to sales milestones) as well as royalty payments based on the net sales of tasimelteon at a rate which, as a percentage of net sales, is in the low teens. The Company made a milestone payment to BMS of $1.0 million under this license agreement in 2006 relating to the initiation of the Phase III clinical trial for tasimelteon. The Company is also obligated under this agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that the Company receives from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. The Company has agreed with BMS in the license agreement for tasimelteon to use commercially reasonable efforts to develop and commercialize tasimelteon and to meet certain milestones in initiating and completing certain clinical work.

BMS holds certain rights with respect to tasimelteon in the license agreement. If the Company has not agreed to one or more partnering arrangements to develop and commercialize tasimelteon in certain significant markets with one or more third parties after the completion of the Phase III program, BMS has the option to exclusively develop and commercialize tasimelteon on its own on pre-determined financial terms, including milestone and royalty payments.

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.

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Future license payments. No amounts were recorded as liabilities other than the $5.0 million milestone payment due to Novartis with respect to the FDA approval of Fanapt™ which was paid in October 2009, nor were any contractual obligations relating to the license agreements included in the condensed consolidated financial statements as of September 30, 2009, 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 currently is committed to $5.7 million in outstanding manufacturing purchase orders for the commercial supply of Fanapt™. These commitments will be assumed by Novartis upon the effective date of the amended and restated sublicense agreement with Novartis, which is expected to occur by the end of 2009.

Pursuant to the amended and restated sublicense agreement with Novartis, we are obligated to continue work on two post-approval studies, which we started prior to the execution date of such agreement. The cash obligation with respect to these two studies is approximately $728,000.

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, there are no uncertain tax positions whose resolution in the next twelve months is expected to materially affect operating results. 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 has not recorded any tax provision or benefit for the nine months ended September 30, 2009 or 2008. The Company has provided a valuation allowance for the full amount of its net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss cannot be sufficiently assured at September 30, 2009 and December 31, 2008.

Under the Tax Reform Act of 1986, the amounts of and benefits from the operating loss carryforwards may be impaired in certain circumstances. Events which cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, over a three year period. Trading in shares of the Company's common stock has resulted in "ownership changes" as defined in Section 382 of the Internal Revenue Code of 1986, as amended (the Code). As a result, the Company's net operating loss carry forwards totaling $123.7 million at December 31, 2008 are subject to an annual limitation pursuant to the provisions of Section 382 of the Code, which the Company estimates to be significant.

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12. Fair Value Measurements

In September 2006, the FASB issued guidance on fair value measurements which defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements. In February 2008, the FASB agreed to delay the effective date of this guidance for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, to fiscal years beginning after November 15, 2008. The Company has adopted the provisions of the guidance as of January 1, 2008 and January 1, 2009, for financial instruments and non financial instruments, respectively. Although the adoption of this guidance did not materially impact its financial condition, results of operations, or cash flow, the Company is now required to provide additional disclosures as part of its financial statements.

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

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

As of September 30, 2009, the Company held certain assets that are required to be measured at fair value on a recurring basis. The Company makes use of observable market based inputs to calculate fair value, in which case the measurements are classified within Level 1. The Company currently does not have non-financial assets and non-financial liabilities that are required to be measured at fair value on a recurring basis. The following is a summary of the Company's assets that are required to be measured at fair value as of September 30, 2009:

		Fair Value Measurements at Reporting Date Using		
	September 30, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Description:				
Available-for-sale securities	$ 3,265,175	$ 3,265,175	$ —	$ —
Total	$ 3,265,175	$ 3,265,175	$ —	$ —

The following is a summary of the Company's assets that are required to be measured at fair value as of December 31, 2008:

		Fair Value Measurements at Reporting Date Using		
	December 31, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Description:				
Available-for-sale securities	$ 7,378,798	$ 1,999,860	$ 5,378,938	$ —
Total	$ 7,378,798	$ 1,999,860	$ 5,378,938	$ —

13. Subsequent Events

The Company has performed an evaluation of subsequent events through November 4, 2009, which is the date the financial statements were issued.

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

Various statements in this report are "forward-looking statements" under the securities laws. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," and "could," and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Vanda Pharmaceuticals Inc. (We, Vanda or the Company) is at an early stage of development and may not ever have any products that generate significant revenue. 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 or our partners clinical trials for our products, product candidates or partnered products;
- a failure of our products, product candidates or partnered products to be demonstrably safe and effective;
- our or our partners' failure to obtain regulatory approval for our products, product candidates or partnered products or to comply with ongoing regulatory requirements for our products or partnered products;
- a lack of acceptance of our products 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 commercial, research and development activities;
- our failure to identify or obtain rights to new products or product candidates;
- our failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage our growth;
- a loss of any of our key scientists or management personnel;
- losses incurred from product liability claims made against us or our partners related to our products, product candidates or partnered products; and
- a loss of rights to develop and commercialize our products, product candidates or partnered products 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", which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of Part II of this report, other unknown or unpredictable factors also could affect our results. 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 clinical-stage products for central nervous system disorders. We believe that each of our products and partnered products will address a large market with significant unmet medical needs by offering advantages over currently available therapies. Our product portfolio includes:

- Fanaptᵀᴹ (iloperidone), a compound for the treatment of 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 Fanaptᵀᴹ. The amended and restated sublicense agreement is subject to, and will become effective upon, clearance under the HSR Act, which is expected by the end of 2009. Pursuant to the amended and restated sublicense agreement, Novartis will have exclusive commercialization rights to all formulations of Fanaptᵀᴹ in the U.S. and Canada. We currently expect that Novartis will begin selling Fanaptᵀᴹ in the U.S. during the first quarter of 2010. Except for two post-approval studies started by us prior to the execution date of the amended and restated sublicense agreement, which we are obligated to complete, Novartis will be 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 Fanaptᵀᴹ. Pursuant to the terms of the amended and restated sublicense agreement, we will be entitled to an upfront payment of $200.0 million, which we expect to receive within 30 days after the effective date of the agreement. We will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵀᴹ in the U.S. and Canada. We will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵀᴹ in the U.S. and Canada. In addition, we will no longer be required to make any future milestone payments with respect to sales of Fanaptᵀᴹ or any future royalty payments with respect to sales of Fanaptᵀᴹ in the U.S. and Canada. We retain exclusive rights to Fanaptᵀᴹ outside the U.S. and Canada and we will have exclusive rights to use any of Novartis' data for Fanaptᵀᴹ for developing and commercializing Fanaptᵀᴹ outside the U.S. and Canada. At Novartis' option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵀᴹ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵀᴹ outside of the U.S. and Canada.
- Tasimelteon, a compound for the treatment of sleep and mood disorders, including Circadian Rhythm Sleep Disorders. In November 2006, we announced positive top-line results from the Phase III trial of tasimelteon in transient insomnia. In June 2008, we announced positive top-line results from the Phase III trial of tasimelteon in chronic primary insomnia. In addition, we believe that tasimelteon may be effective in the treatment of insomnia caused by jet lag. We met with the FDA in June 2009 for an end of Phase II meeting to discuss the clinical development plan. We will continue to work with the FDA to characterize the path to a NDA for tasimelteon. Tasimelteon is also ready for Phase II trials for the treatment of depression. Given the range of potential indications for tasimelteon, we intend to pursue one or more partnerships for the development and commercialization of tasimelteon worldwide.

We are a development stage enterprise and have accumulated net losses of approximately $251.6 million since the inception of our operations through September 30, 2009. Pursuant to the terms of the amended and restated sublicense agreement with Novartis, we will be entitled to an upfront payment of $200.0 million, which we expect to receive within 30 days after the effective date of the agreement. We have no product revenues to date and, other than Fanaptᵀᴹ in the United States, have no products or partnered products approved for sale. 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 products. Our ability to generate revenue and achieve profitability largely depends on Novartis' ability to successfully commercialize Fanaptᵀᴹ in the U.S. and to successfully develop and commercialize Fanaptᵀᴹ 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, product candidates and partnered products. 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”.

Our activities will necessitate significant uses of working capital throughout 2009 and beyond. We are currently concentrating our efforts on the transition of the commercialization and development rights to Fanaptᵀᴹ in the U.S. and Canada to Novartis and expect to work with Novartis, including exchanging information via the joint steering committee established pursuant to the amended and restated sublicense agreement, to assist Novartis’ anticipated commercial launch of Fanaptᵀᴹ in the first quarter of 2010. The transition includes all regulatory, manufacturing and certain post-marketing commitments requested by the FDA. Under the terms of the amended and restated sublicense agreement with Novartis, except for two post-approval studies we started prior to the execution date of the amended and restated sublicense agreement, which we are obligated to complete, Novartis will be responsible for the further clinical development activities in the U.S. and Canada, including the development of a depot formulation of Fanaptᵀᴹ. We will also continue to work closely with the FDA on the path forward for tasimelteon. We expect to continue to operate on a reduced spending plan with our fixed overhead costs expected to be approximately $2.5 million to $3.0 million per quarter.

Fanaptᵀᴹ. We have developed Fanaptᵀᴹ, and will continue to develop it outside the U.S. and Canada, to treat schizophrenia. We submitted an NDA for Fanaptᵀᴹ for the treatment of schizophrenia to the FDA on September 27, 2007 and on November 27, 2007, the FDA accepted the NDA. The application included data from 35 clinical trials and more than 3,000 patients treated with Fanaptᵀᴹ and also contained pharmacogenetic data aimed to further improve the benefit/risk profile of Fanaptᵀᴹ in the treatment of patients with schizophrenia. On May 6, 2009, we announced that the FDA had approved the NDA for Fanaptᵀᴹ. On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis relating to Fanaptᵀᴹ. 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 Fanaptᵀᴹ. The amended and restated sublicense agreement is subject to, and will become effective upon, clearance under the HSR Act, which is expected by the end of 2009. Pursuant to the amended and restated sublicense agreement, Novartis will have exclusive commercialization rights to all formulations of Fanaptᵀᴹ in the U.S. and Canada. Except for two post-approval studies started by us prior to the execution date of the amended and restated sublicense agreement, which we are obligated to complete, Novartis will be 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 Fanaptᵀᴹ. Pursuant to the terms of the amended and restated sublicense agreement, we will be entitled to an upfront payment of $200.0 million, which we expect to receive within 30 days after the effective date of the agreement. We will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵀᴹ in the U.S. and Canada. We will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵀᴹ in the U.S. and Canada. In addition, we will no longer be required to make any future milestone payments with respect to sales of Fanaptᵀᴹ or any future royalty payments with respect to sales of Fanaptᵀᴹ in the U.S. and Canada. We retain exclusive rights to Fanaptᵀᴹ outside the U.S. and Canada and we will have exclusive rights to use any of Novartis’ data for Fanaptᵀᴹ for developing and commercializing Fanaptᵀᴹ outside the U.S. and Canada. At Novartis’ option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵀᴹ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵀᴹ outside of the U.S. and Canada.

From inception to September 30, 2009 we incurred approximately $83.0 million in research and development costs directly attributable to our development of Fanaptᵀᴹ, including a $5.0 million milestone payment paid to Novartis in 2007 upon the acceptance of the NDA. As a result of the FDA’s approval of the NDA for Fanaptᵀᴹ, we met an additional milestone under the original sublicense agreement which required us to make a license 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 Fanaptᵀᴹ. Of the $12.0 million milestone payment, $7.0 million was paid in May 2009 and the remaining $5.0 million was paid in October 2009.

Tasimelteon. Tasimelteon is our product under development to treat sleep and mood disorders. Tasimelteon is a melatonin receptor agonist that works by adjusting the human “body clock” of circadian

rhythm. Tasimelteon has successfully completed a Phase III trial for the treatment of 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. In addition, we believe that tasimelteon may be effective in the treatment of insomnia caused by jet lag. We met with the FDA in June 2009 in an end of Phase II meeting to discuss this potential jet lag indication. We will continue to work with the FDA to characterize the path to an NDA for tasimelteon. Tasimelteon is also ready for Phase II trials for the treatment of depression.

From inception to September 30, 2009, we incurred approximately $53.1 million in direct research and development costs directly attributable to our development of tasimelteon, including a $1.0 million milestone license fee paid to BMS in 2006 upon the initiation of our Phase III program.

VSF-173. On November 3, 2008, we received written notice from Novartis that our license agreement with respect to VSF-173 had terminated in accordance with its terms as a result of our failure to satisfy a specific development milestone within the time period specified in the license agreement. As a result, we no longer have any rights with respect to VSF-173 and Novartis has a non-exclusive worldwide license to all information and intellectual property generated by us or on our behalf related to our development of VSF-173. We are currently evaluating any options that we may have with respect to VSF-173, which may include the possibility of entering into a new license agreement or other arrangement with Novartis to allow us to resume our development of VSF-173; however, there can be no assurance that we will be able to enter into such an agreement or arrangement on acceptable terms, or at all.

From inception to September 30, 2009, we incurred approximately $6.7 million in research and development costs directly attributable to our development of VSF-173, including a milestone license fee of $1.0 million paid to Novartis upon the initiation of our first Phase II clinical trial in March of 2007.

Research and development expenses

Our research and development expenses consist primarily of fees paid to third-party professional service providers in connection with the services they provide for our clinical trials, costs of contract manufacturing services, costs of materials used in clinical trials and research and development, costs for regulatory consultants and filings, depreciation of capital resources used to develop our products, all related facilities costs, and salaries, benefits and stock-based compensation expenses related to our research and development personnel. We expense research and development costs as incurred for compounds in development stage, including certain payments made under our license agreements prior to obtaining FDA approval. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to realize the potential of our products and pharmacogenetics and pharmacogenomics expertise. From inception through September 30, 2009 we incurred research and development expenses in the aggregate of approximately $161.2 million, including stock-based compensation expenses of approximately $9.1 million. We expect to incur licensing costs in the future that could be substantial, as we continue our efforts to develop our products, product candidates and partnered products and to evaluate potential in-license products or compounds.

The following table summarizes our product development initiatives for the three and nine months ended September 30, 2009 and 2008 and for the period from March 13, 2003 (inception) to September 30, 2009. Included in this table are the research and development expenses recognized in connection with our products

in clinical development. Included in “Other product candidates” are the costs directly related to research initiatives for all other product candidates.

	Three Months Ended		Nine Months Ended		Period from March 13, 2003 (Inception) to September 30, 2009
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008	
Direct project costs(1)					
Fanapt™	$ 977,000	$ 993,000	$ 8,444,000	$ 5,410,000	$ 82,973,000
Tasimelteon	685,000	1,513,000	1,797,000	11,277,000	53,107,000
VSF-173	—	216,000	—	774,000	6,711,000
Other product candidates	24,000	355,000	101,000	1,300,000	6,672,000
Total direct product costs	1,686,000	3,077,000	10,342,000	18,761,000	149,463,000
Indirect project costs(1)					
Facility	153,000	163,000	465,000	532,000	2,727,000
Depreciation	57,000	84,000	179,000	262,000	2,195,000
Other indirect overhead	196,000	468,000	635,000	821,000	6,821,000
Total indirect expenses	406,000	715,000	1,279,000	1,615,000	11,743,000
Total research and development expenses	$ 2,092,000	$ 3,792,000	$ 11,621,000	$ 20,376,000	$ 161,206,000

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

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel, including stock-based compensation, serving executive, finance, accounting, information technology, marketing and human resource functions. Other costs include facility costs not otherwise included in research and development expenses and fees for legal, accounting and other professional services. From inception through September 30, 2009, we incurred general and administrative expenses in the aggregate of approximately $100.4 million, including stock-based compensation expenses of approximately $43.4 million.

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, 2008 included in our annual report on Form 10-K/A. 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.

Inventory

We value our inventories at the lower of cost or net realizable value. We analyze our inventory levels quarterly and write down inventory that has become obsolete, or has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are written off to cost of sales. Prior to FDA approval, all Fanaptтм manufacturing-related costs were included in research and development expenses. Subsequent to FDA approval of Fanaptтм, manufacturing costs related to this product are capitalized.

Intangible asset, net

Costs incurred for 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 candidate has been approved by the FDA or an alternative future use exists for a product candidate, patent and license costs are capitalized and amortized over the expected patent life of the related product candidate. Milestone payments to the Company's collaborators 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 Fanaptтм, we met a milestone under our original sublicense agreement with Novartis which required us to make a payment of $12.0 million to Novartis. Of the $12.0 million milestone payment, $7.0 million was paid in May 2009 and the remaining $5.0 million was paid in October 2009. The $12.0 million is being amortized on a straight line basis over the remaining life of the U.S. patent for Fanaptтм, 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. This term is our best estimate of the life of the patent; if, however, the Hatch-Waxman or pediatric extensions are not granted, the intangible asset will be amortized over a shorter period. Amortization of the intangible asset is recorded as a component of cost of goods sold.

The carrying values of intangible assets are periodically reviewed to determine if the facts and circumstances suggest that a potential impairment may have occurred. We had no impairments of our intangible assets for nine months ended September 30, 2009.

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.

Stock-based compensation

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

We currently use the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The determination of the fair value of stock options on the date of grant using an option pricing

model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the expected stock price volatility over the expected term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatility rates are based on historical volatility of the common stock of comparable entities and other factors due to the lack of historic information of our publicly traded common stock. The expected term of options granted is based on the transition approach provided by FASB guidance as the options meet the "plain vanilla" criteria required by this method. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have not paid dividends to our stockholders since our inception and do not plan to pay dividends in the foreseeable future. The stock-based compensation expense for a period is also affected by expected forfeiture rate for the respective option grants. If our estimates of the fair value of these equity instruments or expected forfeitures are too high or too low, it would have the effect of overstating or understating expenses.

Total stock-based compensation expense, related to all of the Company's stock-based awards, during the three and nine months ended September 30, 2009 and 2008 was comprised of the following:

	Three Months Ended		Nine Months Ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Research and development	$ 708,000	$ 505,000	$ 1,517,000	$ 2,357,000
General and administrative	2,555,000	3,115,000	6,803,000	10,349,000
Stock-based compensation expense	$ 3,263,000	$ 3,620,000	$ 8,320,000	$ 12,706,000

Recent accounting pronouncements

In May 2009, the FASB issued guidance on subsequent events which establishes general standards of accounting for and the disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. Corporate financial statements are considered issued when they are widely distributed to shareholders and other financial statement users for "general use and reliance" in a form and format that complies with GAAP. Financial statements are considered available to be issued when they are in a form and format that complies with GAAP. The guidance provides that companies should recognize in the financial statements the effects of all subsequent events that provide additional evidence about conditions that existed at the date of the balance sheet, including the estimates inherent in the process of preparing financial statements. The implementation of this new standard did not have a material impact on our consolidated financial position and results of operations.

In June 2009, the FASB issued guidance on accounting standards codification and the hierarchy of generally accepted accounting principles. The guidance identifies the source of accounting principles and the framework for selecting the principles used in the preparation of financial statements. The guidance is effective for interim and annual periods ending after September 15, 2009. We have updated our financial statement disclosures as appropriate upon adoption of this standard in the third quarter of 2009.

Results of Operations

We have a limited history of operations. We anticipate that our results of operations will fluctuate for the foreseeable future due to several factors, including any possible payments made or received pursuant to licensing or collaboration agreements, progress of our research and development efforts, the timing and outcome of clinical trials and related possible regulatory approvals and our and our partners' ability to successfully commercialize our products, product candidates and partnered products. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses. As of September 30, 2009, we had a deficit accumulated during the development stage of approximately $251.6 million. Pursuant to the terms of the amended and restated sublicense agreement with Novartis, we will be entitled to an upfront payment of $200.0 million, which we expect to receive within 30 days after the effective date of the agreement.

Three months ended September 30, 2009 compared to three months ended September 30, 2008

Research and development expenses. Research and development expenses decreased by approximately $1.7 million, or 44.8%, to approximately $2.1 million for the three months ended September 30, 2009 compared to approximately $3.8 million for the three months ended September 30, 2008.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the three months ended September 30, 2009 and 2008:

	Three Months Ended	
	September 30, 2009	September 30, 2008
Direct project costs:		
Clinical trials	$ 2,000	$ 578,000
Contract research and development, consulting, materials and other direct costs	512,000	857,000
Salaries, benefits and related costs	464,000	1,138,000
Stock-based compensation	708,000	504,000
Total direct costs	1,686,000	3,077,000
Indirect project costs	406,000	715,000
Total	$ 2,092,000	$ 3,792,000

Direct costs decreased approximately $1.4 million for the three months ended September 30, 2009 compared to the three months ended September 30, 2008 as a result of lower clinical trial costs due to the completion of the Phase III clinical trial for tasimelteon in chronic primary insomnia which was completed in 2008, combined with lower manufacturing expenses for Fanaptᵀᴹ and tasimelteon as manufacturing costs for Fanaptᵀᴹ were capitalized upon its FDA approval on May 6, 2009, as well as lower salary and benefit expenses netted with increases in stock based compensation. Clinical trials expense decreased approximately $576,000 for the three months ended September 30, 2009 compared to the three months ended September 30, 2008 due to lower clinical trial costs relating to the Phase III clinical trial for tasimelteon in chronic primary insomnia which was completed in 2008. Contract research and development, consulting, materials and other direct costs decreased approximately $345,000 for the three months ended September 30, 2009 relative to the three months ended September 30, 2008, primarily as a result of decreased manufacturing costs related to Fanaptᵀᴹ and tasimelteon as manufacturing costs related to Fanaptᵀᴹ are now capitalized. Salaries, benefits and related costs decreased approximately $674,000 for the three months ended September 30, 2009 relative to the three months ended September 30, 2008 primarily due to our workforce reduction which occurred in the fourth quarter of 2008. Stock-based compensation expense for the three months ended September 30, 2009 increased by approximately $204,000 compared to the three months ended September 30, 2008 as a result of the expense generated by options granted to employees in the second quarter of 2009.

General and administrative expenses. General and administrative expenses decreased by approximately $2.1 million, or 28.8%, to approximately $5.3 million for the three months ended September 30, 2009 from approximately $7.4 million for the three months ended September 30, 2008.

The following table discloses the components of our general and administrative expenses for the three months ended September 30, 2009 and 2008:

	Three Months Ended	
	September 30, 2009	September 30, 2008
Salaries, benefits and related costs	$ 408,000	$ 1,306,000
Stock-based compensation	2,555,000	3,116,000
Marketing, legal, accounting and other professional expenses	1,755,000	2,316,000
Other expenses	548,000	662,000
Total	$ 5,266,000	$ 7,400,000

Salaries, benefits and related costs decreased by approximately $898,000 for the three months ended September 30, 2009 compared to the three months ended September 30, 2008 primarily due to our workforce reduction which occurred in the fourth quarter of 2008. Stock-based compensation expense decreased by approximately $561,000 for the three months ended September 30, 2009, compared to the three months ended September 30, 2008, as a result of the expense generated by options granted to employees in the second quarter of 2009 netted with the smaller expense generated by the reduced workforce. Marketing, legal, accounting and other professional costs decreased by approximately $561,000 for the three months ended September 30, 2009 compared to the three months ended September 30, 2008 due primarily to reduced commercial costs related to Fanaptᵀᴹ.

Other income, net. Interest and other income in the three months ended September 30, 2009 was approximately $10,000 compared to approximately $323,000 in the three months ended September 30, 2008. Interest income was lower for the three months ended September 30, 2009, compared to the three months ended September 30, 2008, due to lower average cash balances for the three months ended September 30, 2009.

Nine months ended September 30, 2009 compared to nine months ended September 30, 2008

Research and development expenses. Research and development expenses decreased by approximately $8.8 million, or 43.0%, to approximately $11.6 million for the nine months ended September 30, 2009 compared to approximately $20.4 million for the nine months ended September 30, 2008.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the nine months ended September 30, 2009 and 2008:

	Nine Months Ended	
	September 30, 2009	September 30, 2008
Direct project costs:		
Clinical trials	$ 37,000	$ 7,775,000
Contract research and development, consulting, materials and other direct costs	7,295,000	5,277,000
Salaries, benefits and related costs	1,493,000	3,352,000
Stock-based compensation	1,517,000	2,357,000
Total direct costs	10,342,000	18,761,000
Indirect project costs	1,279,000	1,615,000
Total	$ 11,621,000	$ 20,376,000

Direct costs decreased approximately $8.4 million for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008 primarily as a result of lower clinical trial expenses relating to tasimelteon. Clinical trials expense decreased approximately $7.7 million for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008 primarily due to our Phase III

clinical trial of tasimelteon in primary insomnia being completed in 2008. Contract research and development, consulting, materials and other direct costs increased approximately $2.0 million for the nine months ended September 30, 2009 relative to the nine months ended September, 2008, primarily as a result of increased consulting fees including a $5.2 million Success Fee due to our regulatory consultants upon approval of Fanaptᵀᴹ by the FDA in conjunction with lower manufacturing costs related to Fanaptᵀᴹ and tasimelteon. Salaries, benefits and related costs decreased approximately $1.9 million for the nine months ended September 30, 2009 relative to the nine months ended September 30, 2008 primarily due to our workforce reduction which occurred in the fourth quarter of 2008. Stock-based compensation expense decreased by approximately $840,000 for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008 as a result of the expense generated by options granted to employees in the second quarter of 2009 netted with the smaller expense generated by the reduced workforce.

General and administrative expenses. General and administrative expenses decreased by approximately $10.3 million, or 41.7% to approximately $14.5 million for the nine months ended September 30, 2009 from approximately $24.8 million for the nine months ended September 30, 2008.

The following table discloses the components of our general and administrative expenses for the nine months ended September 30, 2009 and 2008:

	Nine Months Ended	
	September 30, 2009	September 30, 2008
Salaries, benefits and related costs	$ 1,376,000	$ 3,394,000
Stock-based compensation	6,802,000	10,349,000
Marketing, legal, accounting and other professional services	4,586,000	8,834,000
Other expenses	1,715,000	2,237,000
Total	$ 14,479,000	$ 24,814,000

Salaries, benefits and related costs decreased by approximately $2.0 million for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008 primarily due to our workforce reduction which occurred in the fourth quarter of 2008. Stock-based compensation expense decreased by approximately $3.5 million for the nine months ended September 30, 2009, compared to the nine months ended September 30, 2008, as a result of the expense generated by options granted to employees in the second quarter of 2009 netted with the smaller expense generated by the reduced workforce. Marketing, legal, accounting and other professional services decreased by approximately $4.2 million for the nine months ended September 30, 2009, relative to the nine months ended September 30, 2008, due primarily to reduced commercial costs related to Fanaptᵀᴹ.

Other income, net. Interest and other income in the nine months ended September 30, 2009 was approximately $84,000 compared to approximately $1.6 million in the nine months ended September 30, 2008. Interest income was lower for the nine months ended September 30, 2009, compared to the nine months ended September 30, 2008, due to lower average cash balances for the nine months ended September 30, 2009.

Intangible Asset, Net

The intangible asset consisted of the following:

		September 30, 2009		
	Estimated Useful Lives	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Fanapt™	8 years	$ 12,000,000	$ 606,000	$ 11,394,000
		$ 12,000,000	$ 606,000	$ 11,394,000

On May 6, 2009, we announced that the FDA had approved the NDA for Fanaptᵀᴹ. As a result of the FDA's approval of the NDA, we met a milestone under our original sublicense agreement with Novartis which required us to make a payment of $12.0 million to Novartis. Of the $12.0 million milestone payment, $7.0 million was paid in May 2009 and the remaining $5.0 million was paid in October 2009. The $12.0 million was capitalized and will be amortized over the remaining life of the U.S. patent for Fanaptᵀᴹ. We expect the patent for Fanaptᵀᴹ to be in effect until May 15, 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of up to five years to compensate for time spent in development and a six-month pediatric term extension. This term is our best estimate of the life of the patent; 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 approximately $606,000 for the nine months ended September 30, 2009. The estimated annual amortization expense for intangible assets is approximately $1.0 million in 2009, $1.5 million in 2010, $1.5 million in 2011, $1.5 million in 2012 and $6.5 million from 2013 through 2017. We capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanaptᵀᴹ.

Inventory

Inventory consisted of the following:

	September 30, 2009
Raw materials	$ —
Work-in-process	439,000
Finished goods	1,319,000
Total inventory, net	$ 1,758,000

Pursuant to the amended and restated sublicense agreement with Novartis, Novartis will be obligated to purchase all Fanaptᵀᴹ inventory following the effective date of the agreement, subject to such inventory meeting certain requirements.

Liquidity and Capital Resources

We have funded our operations through September 30, 2009 principally with the net proceeds from private preferred stock offerings totaling approximately $62.0 million, with net proceeds from our April 2006 initial public offering of approximately $53.3 million and with net proceeds from our January 2007 follow-on offering of approximately $111.3 million.

As of September 30, 2009, our total cash and cash equivalents and marketable securities were approximately $20.7 million compared to approximately $46.5 million at December 31, 2008. 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. As of September 30, 2009, we also held a non-current deposit of $430,000 that is used to collateralize a letter of credit issued for our current office lease expiring in 2016.

As of September 30, 2009 and December 31, 2008, our liquidity resources are summarized as follows:

	September 30, 2009	December 31, 2008
Cash and cash equivalents	$ 17,418,000	$ 39,079,000
U.S. Treasury and government agencies	3,265,000	2,000,000
U.S. corporate debt	—	5,252,000
U.S. asset-backed securities	—	127,000
Marketable securities, short-term	3,265,000	7,379,000
Total	$ 20,683,000	$ 46,458,000
Restricted cash	$ 430,000	$ 430,000

As of September 30, 2009, we maintained all of our 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, but we do not anticipate any losses with respect to such deposits.

In September 2006, the FASB issued guidance on fair value measurements which defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements. In February 2008, the FASB agreed to delay the effective date of this guidance for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, to fiscal years beginning after November 15, 2008. We have adopted the provisions of the guidance as of January 1, 2008 and January 1, 2009, for financial instruments and non financial instruments, respectively. Although the adoption of this guidance did not materially impact our financial condition, results of operations, or cash flow, we are now required to provide additional disclosures as part of our financial statements.

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 September 30, 2009, we held certain assets that are required to be measured at fair value on a recurring basis. We make use of observable market-based inputs to calculate fair value, in which case the measurements are classified within Level 2. We currently do not have non-financial assets and non-financial liabilities that are required to be measured at fair value on a recurring basis.

The following is a summary of our assets that are required to be measured at fair value as of September 30, 2009:

		Fair Value Measurements at Reporting Date Using		
	September 30, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Description :				
Available-for-sale securities	$ 3,265,000	$ 3,265,000	$ —	$ —
Total	$ 3,265,000	$ 3,265,000	$ —	$ —

The following is a summary of our assets that are required to be measured at fair value as of December 31, 2008:

		Fair Value Measurements at Reporting Date Using		
	December 31, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Description :				
Available-for-sale securities	$ 7,379,000	$ 2,000,000	$ 5,379,000	$ —
Total	$ 7,379,000	$ 2,000,000	$ 5,379,000	$ —

Our activities will necessitate significant uses of working capital throughout 2009 and beyond. Pursuant to our amended and restated sublicense agreement with Novartis, we will be entitled to an upfront payment of $200.0 million, which we expect to receive within 30 days after the effective date of the agreement. We are currently concentrating our efforts on the transition of the commercialization and development rights to Fanaptᵀᴹ in the U.S. and Canada to Novartis and expect to work with Novartis, including exchanging information via the joint steering committee established pursuant to the amended and restated sublicense agreement, to assist Novartis' anticipated commercial launch of Fanaptᵀᴹ in the first quarter of 2010. The transition includes all regulatory, manufacturing and certain post-marketing commitments requested by the FDA. Under the terms of the amended and restated sublicense agreement with Novartis, except for two post-approval studies we started prior to the execution date of the amended and restated sublicense agreement, which we are obligated to complete, Novartis will be responsible for the further clinical development activities in the U.S. and Canada, including the development of a depot formulation of Fanaptᵀᴹ. We will also continue to work closely with the FDA on the path forward for tasimelteon. We expect to continue to operate on a reduced spending plan with our fixed overhead costs expected to be approximately $2.5 million to $3.0 million per quarter.

Cash Flow

The following table summarizes our cash flows for the nine months ended September 30, 2009, and September 30, 2008:

	Nine Months Ended	
	September 30, 2009	September 30, 2008
Net cash provided by (used in)		
Operating activities	$ (19,956,000)	$ (40,506,000)
Investing activities	(2,989,000)	39,998,000
Financing activities	1,284,000	—
Exchange rate effect on cash and equivalents	—	17,000
Net change in cash and cash equivalents	$ (21,661,000)	$ (491,000)

Net cash used in operations was approximately $20.0 million and approximately $40.5 million for the nine months ended September 30, 2009 and 2008, respectively. The net loss for the nine months ended September 30, 2009 of approximately $26.6 million was offset by increases in prepaid expenses and advances of $1.3 million, increases in inventory of $1.8 million, $9.8 million in non-cash depreciation, amortization, and stock-based compensation expenses, and $100,000 changes in net working capital outflows. Net cash used in investing activities for the nine months ended September 30, 2009 was approximately $3.0 million and consisted primarily of net maturities of marketable securities of $4.0 million netted with a $7.0 million milestone payment to Novartis. There was $1.3 million provided by financing activities for the nine months ended September 30, 2009 from the exercise of employee stock options.

Contractual Obligations and Commitments

The following table summarizes our long-term contractual cash obligations as of September 30, 2009:

	Cash payments due by period						
	Total	October to December 2009	2010	2011	2012	2013	After 2013
Severance payments	$ 229,000	$ 216,000	$ 13,000	$ —	$ —	$ —	$ —
Operating leases	5,159,000	171,000	706,000	727,000	749,000	771,000	2,035,000
Total	$ 5,388,000	$ 387,000	$ 719,000	$ 727,000	$ 749,000	$ 771,000	$ 2,035,000

Severance payments

On December 16, 2008, we committed to a plan of termination that resulted in a work force reduction of 17 employees, including two officers, in order to reduce operating costs. We commenced notification of employees affected by the workforce reduction on December 17, 2008.

The following table summarizes the activity in the nine months ended September 30, 2009 for the liability for the cash portion of severance costs related to the reductions-in-force:

	Nine Months Ended September 30, 2009			
	Beginning Balance	Charge	Cash Paid	Ending Balance
Workforce Reduction:				
Research Development	$ 571,000	$ —	$ 484,000	$ 87,000
General & Administrative	1,041,000	—	899,000	142,000
Total	$ 1,612,000	$ —	$ 1,383,000	$ 229,000

Operating leases

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

Consulting fees

We had engaged a regulatory consultant to us assist in our efforts to obtain FDA approval of the Fanaptᵀᴹ NDA. We had committed to initial consulting expenses in the aggregate amount of $2.0 million pursuant to this engagement, which was expensed in 2008. In addition, we retained the services of the consultant on a monthly basis at a retainer fee of $250,000 per month effective as of January 1, 2009. We became obligated to pay the consultant a success fee of $6.0 million as a result of the approval by the FDA of the NDA for Fanaptᵀᴹ which was fully expensed in May 2009 and, was offset by the aggregate amount of all monthly retainer fees previously paid to the consultant (Success Fee). Through September 30, 2009, we paid $5.0 million to the consultant. The Success Fee paid in monthly $1.0 million increments, with the last payment occurring in October 1, 2009. In addition to these fees, we reimbursed the consultant for its ordinary and necessary business expenses incurred in connection with its engagement.

We also engaged financial advisors and consultants to act as our strategic advisors in connection with a proposed transaction or partnership involving the possible sale, partnership, or other business combination of the Company. Pursuant to agreements with such strategic advisors, we are obligated to pay an aggregate success fee of approximately $3.5 million following the effective date of the amended and restated sublicense agreement with Novartis, which is expected to occur by the end of 2009.

Clinical research organization contracts and other contracts

We have entered into agreements with clinical research organizations responsible for conducting and monitoring our clinical trials for Fanaptᵀᴹ and tasimelteon, and have also entered into agreements 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).

We are currently committed to $5.7 million in outstanding manufacturing purchase orders for the commercial supply of Fanaptᵀᴹ. These commitments will be assumed by Novartis upon the effective date of the amended and restated sublicense agreement with Novartis, which is expected to occur by the end of 2009.

Pursuant to the amended and restated sublicense agreement with Novartis, we are obligated to continue work on two post-approval studies which we started prior to the execution date of such agreement. The cash obligation with respect to these two studies is approximately $728,000.

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 Fanaptᵀᴹ. On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis which is subject to, and will become effective upon, clearance under the HSR Act. We are obligated to make (in the case of tasimelteon and, in the case of Fanaptᵀᴹ 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 Fanaptᵀᴹ in the U.S. and Canada, will be entitled to receive) based on net sales for each of the licensed products. Please see the notes to the condensed consolidated financial statements included with this report for a more detailed description of these license agreements.

As a result of the successful commencement of the Phase III clinical study of tasimelteon in March 2006, we met the first milestone specified in our licensing agreement with BMS and subsequently paid a license fee of $1.0 million.

As a result of the acceptance by FDA of the NDA for Fanaptᵀᴹ in October 2007, we met a milestone under our original sublicense agreement with Novartis and subsequently paid a $5.0 million milestone fee. No amounts were recorded as liabilities relating to the license agreements included in the consolidated financial statements as of December 31, 2008, 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. As a result of the FDA's approval of the NDA for Fanaptᵀᴹ, 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. Of the $12.0 million milestone payment, $7.0 million was paid in May 2009 and the remaining $5.0 million was paid in October 2009.

The amended and restated sublicense agreement is subject to, and will become effective upon, clearance under the HSR Act, which is expected by the end of 2009. Pursuant to the amended and restated sublicense agreement, Novartis will have exclusive commercialization rights to all formulations of Fanaptᵀᴹ in the U.S. and Canada. Except for two post-approval studies started by us prior to the execution date of the amended and restated sublicense agreement, which we are obligated to complete, Novartis will be 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 Fanaptᵀᴹ. Pursuant to the terms of the amended and restated sublicense agreement, we will be entitled to an upfront payment of $200.0 million, which we expect to receive within 30 days after the effective date of the agreement. We will be eligible for additional payments totaling up to $265.0 million upon the achievement of certain commercial and development milestones for Fanaptᵀᴹ in the U.S. and Canada. We will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵀᴹ in the U.S. and Canada. In addition, we will no longer be required to make any future milestone payments with respect to sales of Fanaptᵀᴹ or any royalty payments with respect to sales of Fanaptᵀᴹ in the U.S. and Canada. We retain exclusive rights to Fanaptᵀᴹ outside the U.S. and Canada and we will have exclusive rights to use any of Novartis' data for Fanaptᵀᴹ for developing and commercializing Fanaptᵀᴹ outside the U.S. and Canada. At Novartis' option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanaptᵀᴹ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanaptᵀᴹ outside of the U.S. and Canada.

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

Interest Rates

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

Effects of Inflation

Our most liquid assets are cash and cash equivalents and marketable securities. Because of their liquidity, these assets are not directly affected by inflation. We also believe that we have intangible assets in the value of our intellectual property. In accordance with generally accepted accounting principles, we have not capitalized the value of this intellectual property on our balance sheet. 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.

Marketable securities

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

Off-balance sheet arrangements

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

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

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of the our management, including the Chief Executive Officer and Acting 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 September 30, 2009. Based upon that evaluation, our Chief Executive Officer and Acting Chief Financial Officer concluded that our disclosure controls and procedures are effective as of September 30, 2009, 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 Acting Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the third quarter of 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. In December 2008, we executed a work force reduction which included our active Chief Financial Officer. We executed changes to our key controls to mitigate segregation of duties issues related to a reduced accounting and finance department. However, the changes did not materially affect internal control over financial reporting as of September 30, 2009.

PART II — OTHER INFORMATION

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

None.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this report and our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2008, including the consolidated financial statements and the related notes appearing herein and therein, with respect to any investment in shares of our common stock. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment.

Risks related to our business and industry

We expect Novartis to begin selling, marketing and distributing our first approved product, Fanaptᵀᴹ, in the U.S. in the first quarter of 2010 and we will depend heavily on the success of this product in the marketplace.

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

- the ability of patients to be able to afford Fanaptᵀᴹ or obtain health care coverage that covers Fanaptᵀᴹ in the current uncertain economic climate
- acceptance of, and ongoing satisfaction, with Fanaptᵀᴹ by the medical community, patients receiving therapy and third party payers
- a satisfactory efficacy and safety profile as demonstrated in a broad patient population
- the size of the market for Fanaptᵀᴹ
- successfully expanding and sustaining manufacturing capacity to meet demand
- cost and availability of raw materials
- the extent and effectiveness of the sales and marketing and distribution support Fanaptᵀᴹ receives
- safety concerns in the marketplace for schizophrenia therapies generally
- regulatory developments relating to the manufacture or continued use of Fanaptᵀᴹ
- decisions as to the timing of product launches, pricing and discounts
- the competitive landscape for approved and developing therapies that will compete with Fanaptᵀᴹ
- Novartis' ability to successfully develop and commercialize a long — acting injectable (or depot) formulation of Fanaptᵀᴹ in the U.S. and Canada
- Novartis' ability to expand the indications for which Fanaptᵀᴹ can be marketed in the U.S.
- Novartis' ability to obtain regulatory approval in Canada for Fanaptᵀᴹ and our ability to obtain regulatory approval for Fanaptᵀᴹ in countries outside the U.S. and Canada
- our ability to successfully develop and commercialize Fanaptᵀᴹ, including a long — acting injectable (or depot) formulation of Fanaptᵀᴹ, outside of the U.S. and Canada
- the unfavorable outcome of any potential litigation relating to Fanaptᵀᴹ

We have entered into an amended and restated sublicense agreement with Novartis to commercialize Fanaptᵀᴹ in the U.S. and Canada and to further develop and commercialize a long-acting injectable (or depot) formulation of Fanaptᵀᴹ in the U.S. and Canada. As such, we will not be involved in the marketing or sales efforts for Fanaptᵀᴹ in the U.S. and Canada. Our future revenues depend substantially on royalties and milestone payments we may receive from Novartis. Pursuant to the terms of the amended and restated sublicense agreement with Novartis, which is subject to, and will become effective upon, clearance under the HSR Act, we will be entitled to an upfront payment of $200.0 million, which we expect to receive within 30 days after the effective date of the agreement. We will be eligible for additional payments totaling up to $265.0 million upon Novartis' achievement of certain commercial and development milestones for Fanaptᵀᴹ in the U.S. and Canada, which may or may not be achieved or met. We will also receive royalties, which, as a percentage of net sales, are in the low double-digits, on net sales of Fanaptᵀᴹ in the U.S. and Canada. Such royalties may not be significant and will depend on numerous factors. We cannot control the amount and timing of resources that Novartis may devote to Fanaptᵀᴹ or the depot formulation of Fanaptᵀᴹ. If Novartis fails to successfully commercialize Fanaptᵀᴹ in the U.S., fails to develop and commercialize Fanaptᵀᴹ in Canada or further develop a long-acting injectable (or depot) formulation of Fanaptᵀᴹ, if Novartis' efforts are not effective, or if Novartis focuses its efforts on other schizophrenia therapies or schizophrenia drug candidates, our business will be negatively affected. If Novartis does not successfully commercialize Fanaptᵀᴹ in the U.S. or Canada, we will receive limited revenues from them.

Although we have developed and continue to develop additional products and product candidates for commercial introduction, we expect to be substantially dependent on sales from Fanaptᵀᴹ for the foreseeable future. For reasons outside of our control, including those mentioned above, sales of Fanaptᵀᴹ may not meet our expectations. Any significant negative developments relating to Fanaptᵀᴹ, such as safety or efficacy issues, the introduction or greater acceptance of competing products or adverse regulatory or legislative developments, will have a material adverse effect on our results of operations.

If our products or partnered products are determined to be unsafe or ineffective in humans, whether commercially or in clinical trials, our business will be materially harmed.

Despite the FDA's approval of the NDA for Fanaptᵀᴹ and the positive results of our completed trials for Fanaptᵀᴹ and tasimelteon, we are uncertain whether either of these products will ultimately prove to be effective and safe in humans. Frequently, products that have shown promising results in clinical trials have suffered significant setbacks in later clinical trials or even after they are approved for commercial sale. Future uses of our products or our partnered products, whether in clinical trials or commercially, may reveal that the product is ineffective, unacceptably toxic, has other undesirable side effects, is difficult to manufacture on a large scale, is uneconomical, infringes on proprietary rights of another party or is otherwise not fit for further use. If our products or partnered products are determined to be unsafe or ineffective in humans, our business will be materially harmed.

Clinical trials for our products, product candidates and partnered products are expensive and their outcomes are uncertain. Any failure or delay in completing clinical trials for our products, product candidates or partnered products could severely harm our business.

Pre-clinical studies and clinical trials required to demonstrate the safety and efficacy of our products, product candidates or partnered products are time-consuming and expensive and together take several years to complete. Before obtaining regulatory approvals for the commercial sale of any products or product candidates, we or our partners must demonstrate through preclinical testing and clinical trials that such product or product candidate is safe and effective for use in humans. We have incurred, and we will continue to incur, substantial expense for, and devote a significant amount of time to, preclinical testing and clinical trials.

Historically, the results from preclinical testing and early clinical trials often have not predicted results of later clinical trials. A number of new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Clinical trials conducted by us, by our partners or by third parties on our or our partners' behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for our products, product candidates

or our partnered products. Regulatory authorities may not permit us or our partners to undertake any additional clinical trials for our products, product candidates or partnered product, and it may be difficult to design efficacy studies for products or product candidates in new indications.

Clinical development efforts performed by us or our partners may not be successfully completed. Completion of clinical trials may take several years or more. The length of time can vary substantially with the type, complexity, novelty and intended use of the product or product candidate. The commencement and rate of completion of clinical trials for our products, product candidates and partnered products may be delayed by many factors, including:

- the inability to manufacture or obtain from third parties materials sufficient for use in pre-clinical studies and clinical trials
- delays in beginning a clinical trial
- delays in patient enrollment and variability in the number and types of patients available for clinical trials
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data
- poor effectiveness of products or product candidates during clinical trials
- unforeseen safety issues or side effects and
- governmental or regulatory delays and changes in regulatory requirements and guidelines

If we or our partners fail to complete successfully one or more clinical trials for our products, product candidates or partnered products, we or they may not receive the regulatory approvals needed to market that product or product candidate. Therefore, any failure or delay in commencing or completing these clinical trials would harm our business materially.

We and our partners face heavy government regulation. FDA regulatory approval of products, product candidates or partnered products is uncertain and we and our partners are continually at risk of the FDA requiring us or them to discontinue marketing any products that have obtained, or in the future may obtain, regulatory approval.

The research, testing, manufacturing and marketing of products such as those that we have developed or we or in regard to partnered products, our partners, are developing are subject to extensive regulation by federal, state and local government authorities, including the FDA. To obtain regulatory approval of such products, we or our partners must demonstrate to the satisfaction of the applicable regulatory agency that, among other things, the product is safe and effective for its intended use. In addition, we or our partners must show that the manufacturing facilities used to produce such products are in compliance with current Good Manufacturing Practices regulations or cGMP.

The process of obtaining FDA and other required regulatory approvals and clearances can take many years and will require us and, in the case of partnered products, our partners to expend substantial time and capital. Despite the time and expense expended, regulatory approval is never guaranteed. The number of pre-clinical and clinical trials that will be required for FDA approval varies depending on the product or product candidate, the disease or condition that the product or product candidate is in development for, and the requirements applicable to that particular product or product candidate. The FDA can delay, limit or deny approval of a product, product candidate or partnered product for many reasons, including that:

- a product or product candidate may not be shown to be safe or effective
- the FDA may interpret data from pre-clinical and clinical trials in different ways than we do
- the FDA may not approve our or our partners' manufacturing processes or facilities
- a product or product candidate may not be approved for all the indications we or our partners request
- the FDA may change its approval policies or adopt new regulations

- the FDA may not meet, or may extend, the Prescription Drug User Fee Act (PDUFA) date with respect to a particular NDA and
- the FDA may not agree with our or our partners' regulatory approval strategies or components of the regulatory filings, such as clinical trial designs

For example, if certain of our or our partners' methods for analyzing trial data are not accepted by the FDA, we or our partners may fail to obtain regulatory approval for our products, product candidates or partnered products.

Moreover, the marketing, distribution and manufacture of approved products remain subject to extensive ongoing regulatory requirements. Failure to comply with applicable regulatory requirements could result in, among other things:

- warning letters
- fines
- civil penalties
- injunctions
- recall or seizure of products
- total or partial suspension of production
- refusal of the government to grant future approvals
- withdrawal of approvals and
- criminal prosecution

Any delay or failure to obtain regulatory approvals for our products, product candidates or partnered products will result in increased costs, could diminish competitive advantages that we may attain and would adversely affect the marketing of our products. Other than Fanapt™ in the U.S., which will be marketed and sold by Novartis, we have not received regulatory approval to market any product in any jurisdiction.

Even following regulatory approval of our or our partnered products, the FDA may impose limitations on the indicated uses for which such products may be marketed, subsequently withdraw approval or take other actions against us, our partners or such products that are adverse to our business. The FDA generally approves products for particular indications. An approval for a more limited indication reduces the size of the potential market for the product. Product approvals, once granted, may be withdrawn if problems occur after initial marketing.

We and our partners also are subject to numerous federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the environment and the use and disposal of hazardous substances used in connection with discovery, research and development work. In addition, we cannot predict the extent to which new governmental regulations might significantly impede the discovery, development, production and marketing of our or our partnered products. We or our partners may be required to incur significant costs to comply with current or future laws or regulations, and we may be adversely affected by the cost of such compliance.

We intend to seek regulatory approvals for our products, product candidates and partnered products in foreign jurisdictions, but we may not obtain any such approvals.

Pursuant to our amended and restated sublicense agreement with Novartis, we retained the right to develop and commercialize Fanapt™ outside the U.S. and Canada. We intend to market our products and partnered products outside the U.S. and Canada with one or more commercial partners. In order to market our products and partnered products in foreign jurisdictions, we may be required to obtain separate regulatory approvals and to comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional trials, and the time required to obtain approval

may differ from that required to obtain FDA approval. We have no experience with obtaining any such foreign approvals. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products or partnered products in any market. The failure to obtain these approvals could harm our business materially.

Our products, product candidates or partnered products may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit their marketability.

Undesirable side effects caused by our products, product candidates or partnered products could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us or our partners from commercializing or continuing the commercialization of such products and generating revenues from their sale. We and our partners, as applicable, will continue to assess the side effect profile of our products, product candidates and partnered products in our ongoing clinical development program. However, we cannot predict whether the commercial use of products (or products or product candidates in development, if and when they are approved for commercial use) will produce undesirable or unintended side effects that have not been evident in the use of, or in clinical trials conducted for, such products (and product candidates) to date. Additionally, incidents of product misuse may occur. These events, among others, could result in product recalls, product liability actions or withdrawals or additional regulatory controls, all of which could have a material adverse effect on our business, results of operations and financial condition.

In addition, if after receiving marketing approval of a product, we, our partners or others later identify undesirable side effects caused by such product, we or our partners could face one or more of the following:

- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication
- regulatory authorities may withdraw their approval of the product
- we or our partners may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product and
- our reputation may suffer

Any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from its sale.

Even after we or our partners obtain regulatory approvals of a product, acceptance of such product in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues.

Even after obtaining regulatory approvals for the sale of our products or partnered products, the commercial success of these products will depend, among other things, on their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. The degree of market acceptance of any product will depend on a number of factors, including the demonstration of its safety and efficacy, its cost-effectiveness, its potential advantages over other therapies, the reimbursement policies of government and third-party payors with respect to such product, our ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our products, receipt of regulatory clearance of marketing claims for the uses that we or our partners are developing and the effectiveness of our and our partners’ marketing and distribution capabilities. If our products or partnered products fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. If our products or partnered products do not become widely

accepted by physicians, patients, third-party payors and other members of the medical community, it is unlikely that we will ever become profitable.

If we fail to obtain the capital necessary to fund our research and development activities and commercialization efforts, we may be unable to continue operations or we may be forced to share our rights to commercialize our products with third parties on terms that may not be attractive to us.

Our activities will necessitate significant uses of working capital throughout 2009 and beyond. To date, we have relied almost entirely on external financing to fund our operations. Such financings have historically involved the sale of common and preferred stock. As of September 30, 2009, we had cash of approximately $20.7 million. Pursuant to the terms of the amended and restated sublicense agreement with Novartis, we will be entitled to an upfront payment of $200.0 million, which we expect to receive within 30 days after the effective date of the agreement. Our long term capital requirements are expected to depend on many factors, including, among others:

- the amount of royalty and milestone payments received from our commercial partners
- our ability to commercialize Fanaptᵀᴹ outside the U.S. and Canada
- costs of developing sales, marketing and distribution channels and our ability to sell our products
- costs involved in establishing manufacturing capabilities for commercial quantities of our products
- the number of potential formulations, products and product candidates in development
- progress with pre-clinical studies and clinical trials
- time and costs involved in obtaining regulatory (including FDA) clearance
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent, trademark and other intellectual property claims
- competing technological and market developments
- market acceptance of our products
- costs for recruiting and retaining employees and consultants
- costs for training physicians and
- legal, accounting, insurance and other professional and business related costs

We expect to receive royalty payments and hope to receive milestone payments relating to Fanaptᵀᴹ in connection with our amended and restated sublicense agreement with Novartis. However, if Fanaptᵀᴹ is not as commercially successful as we expect and we do not receive such payments, and given that our current cash on hand will not fully fund all development costs of our current products and product candidates, we may need to raise additional capital to fund our anticipated operating expenses and execute on our business plans. In our capital-raising efforts, we may seek to sell debt securities or additional equity securities or obtain a bank credit facility, or enter into partnerships or other collaboration agreements. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders and may also result in a lower price for our common stock. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that could restrict our operations. However, given the current global economic climate, we may have more difficulty raising funds than we would during a period of economic stability, and we may not be able to raise additional funds on acceptable terms, or at all. If we are unable to secure sufficient capital to fund our activities, we may not be able to continue operations, or we may have to enter into partnerships or other collaboration agreements that could require us to share commercial rights to our products to a greater extent or at earlier stages in the drug development process than is currently intended. These partnerships or collaborations, if consummated prior to proof-of-efficacy or safety of a given product, could impair our ability to realize value from that product. If additional financing is not available when required or is not available on acceptable terms, we may be unable to fund our operations and planned growth,

develop or enhance our technologies or products, take advantage of business opportunities or respond to competitive market pressures, any of which would materially harm our business, financial condition and results of operations.

We have a history of operating losses, anticipate future losses and may never become profitable on a sustained basis.

We have a limited operating history. As of September 30, 2009, we have accumulated net losses of approximately $251.6 million. Our ability to generate revenue and achieve profitability largely depends on Novartis' ability to successfully commercialize Fanaptᵀᴹ in the U.S. and Canada and upon our ability, alone or with others, to complete the development of our products or product candidates, obtain the regulatory approvals and manufacture, market and sell our products, product candidates and partnered products. We and our partners may be unable to achieve these goals.

Although we have generated some licensing-related and other revenue to date and expect to receive an upfront payment of $200.0 million within 30 days after the effective date of our amended and restated sublicense agreement with Novartis, we have not generated any revenue from the commercial sale of products and we cannot estimate with precision the extent of our future losses. We have been engaged in identifying and developing compounds since March 2003, which has required, and will continue to require, significant research and development expenditures. This relatively limited operating history may not be adequate to enable you to fully assess our ability to develop and commercialize our technologies and products, product candidates or partnered products, obtain FDA or other regulatory approvals and achieve market acceptance of products, product candidates or partnered products and respond to competition.

A major component of our revenue for the foreseeable future will depend on Novartis' and our ability to sell Fanaptᵀᴹ. Fanaptᵀᴹ may not be as commercially successful as we expect, Novartis may not succeed in commercializing Fanaptᵀᴹ in the U.S., developing and commercializing Fanaptᵀᴹ in Canada and we may not succeed in commercializing Fanaptᵀᴹ outside of the U.S. and Canada. In addition, we may not succeed in commercializing any other products or product candidates. We cannot assure you that we will be profitable even if our products or partnered products are successfully commercialized. We may be unable to fully develop, obtain regulatory approval for, commercialize, manufacture, market, sell and derive revenue from our products, product candidates or partnered products in the timeframes we project, if at all, and our inability to do so would materially and adversely impact the market price of our common stock and our ability to raise capital and continue operations.

There can be no assurance that we will achieve sustained profitability. Our ability to achieve sustained profitability in the future depends, in part, upon:

- our and our partners' ability to obtain and maintain regulatory approval for our products, product candidates and partnered products, both in the U.S. and in foreign countries
- Novartis' ability to successfully market and sell Fanaptᵀᴹ in the U.S. and Canada and achieve certain product development and sales milestones
- our ability to successfully commercialize Fanaptᵀᴹ outside the U.S. and Canada
- our ability to enter into agreements to develop and commercialize our products and product candidates
- our ability to develop, have manufactured and market our products and product candidates
- our ability to obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third party payors
- our ability to obtain additional research and development funding from collaborative partners or funding for our products and product candidates

In addition, the amount we spend will impact our profitability. Our spending will depend, in part, upon:

- the progress of our research and development programs for our products and product candidates, including clinical trials
- the time and expense that will be required to pursue FDA and/or foreign regulatory approvals for our products and product candidates and whether such approvals are obtained
- the time and expense required to prosecute, enforce and/or challenge patent and other intellectual property rights
- the cost of operating and maintaining development and research facilities
- the cost of third party manufacturers
- the number of product candidates we pursue
- how competing technological and market developments affect our products and product candidates
- the cost of possible acquisitions of technologies, compounds, product rights or companies
- the cost of obtaining licenses to use technology owned by others for proprietary products and otherwise
- the costs of potential litigation and
- the costs associated with recruiting and compensating a highly skilled workforce in an environment where competition for such employees may be intense

We may not achieve all or any of these goals and, thus, we cannot provide assurances that we will ever be profitable on a sustained basis or achieve significant revenues. Even if we do achieve some or all of these goals, we may not achieve significant or sustained commercial success.

If our contract research organizations do not successfully carry out their duties or if we lose our relationships with contract research organizations, our drug development efforts could be delayed.

Our arrangements with contract research organizations are critical to our success in bringing our products and product candidates to the market and promoting such marketed products profitably. We are dependent on contract research organizations, third-party vendors and investigators for pre-clinical testing and clinical trials related to our drug discovery and development efforts and we will likely continue to depend on them to assist in our future discovery and development efforts. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. As such, they may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The parties with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. If they fail to devote sufficient time and resources to our drug development programs or if their performance is substandard, it will delay the development, approval and commercialization of our products and product candidates. Moreover, these parties may also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors, it could harm our competitive position.

Our contract research organizations could merge with or be acquired by other companies or experience financial or other setbacks unrelated to our collaboration that could, nevertheless, materially adversely affect our business, results of operations and financial condition.

If we lose our relationship with any one or more of these parties, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to current Good Laboratory Practices or cGLP, and similar foreign standards and we do not have control over compliance

with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our products could be delayed.

We rely on a limited number of third party manufacturers to formulate and manufacture our products, product candidates and partnered products and our business will be seriously harmed if these manufacturers are not able to satisfy our demand and alternative sources are not available.

Our expertise is primarily in the research and development and pre-clinical and clinical trial phases of product development. We do not have an in-house manufacturing capability and depend completely on a small number of third-party manufacturers and active pharmaceutical ingredient formulators for the manufacture of our products, product candidates and partnered products. Therefore, we are dependent on third parties for our formulation development and manufacturing of our products, product candidates and partnered products. This may expose us to the risk of not being able to directly oversee the production and quality of the manufacturing process and provide ample commercial supplies to successfully launch and maintain the marketing of our products. Furthermore, these third party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or other unforeseeable events that may delay or limit production. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes would have a material adverse effect on our ability to develop and commercialize our products, product candidates and partnered products.

We do not have long-term agreements with any of these third parties, and if they are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers or formulators or enter into favorable agreements with them. Any inability to acquire sufficient quantities of our products or partnered products in a timely manner from these third parties could adversely affect sales of our product, delay clinical trials and prevent us from developing our products, product candidates and partnered products in a cost-effective manner or on a timely basis. In addition, manufacturers of our products and partnered products are subject to cGMP and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers. If one of our contract manufacturers fails to maintain compliance, the production of our products or partnered products could be interrupted, resulting in delays and additional costs. In addition, if the facilities of such manufacturers do not pass a pre-approval or post-approval plant inspection, the FDA will not grant approval and may institute restrictions on the marketing or sale of our products or partnered products.

Our manufacturing strategy presents the following additional risks:

- because most of our third-party manufacturers and formulators are located outside of the U.S., there may be difficulties in importing our compounds or their components into the U.S. as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging
- because of the complex nature of our products and product candidates, our manufacturers may not be able to successfully manufacture our products and product candidates in a cost-effective and/or timely manner.

Materials necessary to manufacture our products, product candidates and partnered products may not be available on commercially reasonable terms, or at all, which may delay the development, regulatory approval and commercialization of our products.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our products, product candidates and partnered products for our clinical trials and commercialization. Suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, product testing, potential regulatory approval of our products, product candidates and partnered products and commercial scale manufacturing could be delayed, significantly affecting our ability to further develop and commercialize our

products, product candidates and partnered products. If we, our manufacturers or, in the case of our partnered products, our partners are unable to purchase these materials for our products or partnered products, as applicable, there would be a shortage in supply or the commercial launch of such products would be delayed, which would materially affect our or our partners' ability to generate revenues from the sale of such products.

We face substantial competition which may result in others developing or commercializing products before or more successfully than we do.

Our future success will depend on our or our partners' ability to demonstrate and maintain a competitive advantage with respect to our products or partnered products and our ability to identify and develop additional products or product candidates through the application of our pharmacogenetics and pharmacogenomics expertise. Large, fully integrated pharmaceutical companies, either alone or together with collaborative partners, have substantially greater financial resources and have significantly greater experience than we do in:

- developing products and product candidates
- undertaking pre-clinical testing and clinical trials
- obtaining FDA and other regulatory approvals of products and product candidates and
- manufacturing, marketing and selling products

These companies may invest heavily and quickly to discover and develop novel products that could make our products or product candidates obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing superior products or other competing products before we do. Technological developments or the FDA's approval of new therapeutic indications for existing products may make our existing products or partnered products, or those product candidates we are developing, obsolete or may make them more difficult to market successfully, any of which could have a material adverse effect on our business, results of operations and financial condition.

Our products, product candidates or partnered products, if successfully developed and approved for commercial sale, will compete with a number of drugs and therapies currently manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products, product candidates and partnered products may also compete with new products currently under development by others or with products which may cost less than our products, product candidates or partnered products. Physicians, patients, third party payors and the medical community may not accept or utilize any of our products or partnered products that may be approved. If our products or partnered products (and our product candidates, if and when approved) do not achieve significant market acceptance, our business, results of operations and financial condition would be materially adversely affected. We believe the primary competitors for each of our products and partnered products are as follows:

- For Fanapt™ in the treatment of schizophrenia, the atypical antipsychotics risperidone, including the depot formulation Risperdal® Consta®, and Invega® (paliperidone) Sustenna® as well as oral Invega®, all by Ortho-McNeil-Janssen Pharmaceuticals, Inc., Zyprexa® (olanzapine) by Eli Lilly and Company, Seroquel® (quetiapine) by AstraZeneca PLC, Abilify® (aripiprazole) by Bristol-Myers Squibb Company/Otsuka Pharmaceutical Co., Ltd., Geodon® (ziprasidone) by Pfizer Inc., Saphris® (asenapine) by Merck Schering and generic risperidone and clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are generic). In addition to the approved products, compounds in Phase III trials (or for which an NDA has been recently filed) for the treatment of schizophrenia include lurasidone (Dainippon Sumitomo).
- For tasimelteon in the treatment of insomnia, Rozerem™ (ramelteon) by Takeda Pharmaceuticals Company Limited, hypnotics such as Ambien® CR (zolpidem) by sanofi-aventis, Lunesta® (eszopiclone) by Sepracor Inc. and Sonata® (zaleplon) by King Pharmaceuticals, Inc., generic compounds such as zolpidem, trazodone and doxepin, and over-the-counter remedies such as Benadryl® and Tylenol PM®. In addition to the approved products, compounds in Phase III trials for insomnia (or for which an NDA has been recently filed) include indiplon (Neurocrine Biosciences, Inc.), low-dose doxepin

(Silenor™) by Somaxon Pharmaceuticals, Inc. and Intermezzo® (zolpidem tartarate sublingual lozenge) by Transcept Pharmaceuticals, Inc.

- For tasimelteon in the treatment of depression, generic antidepressants such as paroxetine, sertraline, fluoxetine and buproprion, Lexapro® (escitalopram) by Lundbeck A/S /Forest Pharmaceuticals Inc., and Effexor® (venlafaxine) by Wyeth as well as other compounds such as Cymbalta® (duloxetine) by Eli Lilly and Valdoxan (agomelatine) by Novartis and Les Laboratories Servier.

Additionally, our ability to compete may be affected because insurers and other third-party payors in some cases seek to encourage the use of cheaper, generic products, which could make our products or partnered products less attractive.

We have no experience selling, marketing or distributing products and no internal capability to do so, which may make commercializing our products and product candidates difficult.

At present, we have no marketing experience and sales capabilities. Therefore, in order for us to commercialize Fanapt™, outside the U.S. and Canada, or other products or product candidates, we must either acquire or internally develop sales, marketing and distribution capabilities, or enter into collaborations with partners to perform these services for us. We may, in some instances, rely significantly on sales, marketing and distribution arrangements with our collaborative partners and other third parties. For example, we rely completely on Novartis to market, sell and distribute Fanapt™ in the U.S. and Canada and our future revenues are materially dependent on the success of the efforts of Novartis.

For the commercialization of Fanapt™ outside the U.S. and Canada or our other products or product candidates, we may not be able to establish sales and distribution partnerships on acceptable terms or at all, and if we do enter into a distribution arrangement, our success will be materially dependent upon the performance of our partner. In the event that we attempt to acquire or develop our own in-house sales, marketing and distribution capabilities, factors that may inhibit our efforts to commercialize our products without partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products
- the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage against companies with broader product lines and
- unforeseen costs associated with creating our own sales and marketing team or with entering into a partnering agreement with an independent sales and marketing organization

The cost of establishing and maintaining a sales, marketing and distribution organization may exceed its cost effectiveness. If we fail to develop sales and marketing capabilities, if sales efforts are not effective or if costs of developing sales and marketing capabilities exceed their cost effectiveness, our business, results of operations and financial condition could be materially adversely affected.

If we cannot identify, or enter into licensing arrangements for, new products or product candidates, our ability to develop a diverse product portfolio may be limited.

A component of our business strategy is acquiring rights to develop and commercialize compounds discovered or developed by other pharmaceutical and biotechnology companies for which we may find effective uses and markets through our unique pharmacogenetics and pharmacogenomics expertise. Competition for the acquisition of these compounds is intense. If we are not able to identify opportunities to acquire rights to commercialize additional products, we may not be able to develop a diverse portfolio of products and product candidates and our business may be harmed. Additionally, it may take substantial human and financial resources to secure commercial rights to promising products or product candidates. Moreover, if other firms develop pharmacogenetics and pharmacogenomics capabilities, we may face increased competition in identifying and acquiring additional products or product candidates.

We may not be successful in the development of products for our own account.

In addition to our business strategy of acquiring rights to develop and commercialize products and product candidates, we may develop products and product candidates for our own account by applying our technologies to off-patent drugs as well as developing our own proprietary molecules. Because we will be funding the development of such programs, there is a risk that we may not be able to continue to fund all such programs to completion or to provide the support necessary to perform the clinical trials, obtain regulatory approvals or market any approved products on a worldwide basis. We expect the development of products for our own account to consume substantial resources. If we are able to develop commercial products on our own, the risks associated with these programs may be greater than those associated with our programs with collaborative partners.

If we lose key scientists or management personnel, or if we fail to recruit additional highly skilled personnel, it will impair our ability to identify, develop and commercialize products.

We are highly dependent on principal members of our management team and scientific staff, including our Chief Executive Officer, Mihael H. Polymeropoulos, M.D. These executives each have significant pharmaceutical industry experience. The loss of any such executives, including Dr. Polymeropoulos, or any other principal member of our management team or scientific staff, would impair our ability to identify, develop and market new products. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of these or other key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to development or approval, loss of sales and diversion of management resources. In addition, we depend on our ability to attract and retain other highly skilled personnel, including research scientists. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all, which would negatively impact our development and commercialization programs.

Additionally, we do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products or partnered products.

The risk that we may be sued on product liability claims is inherent in the development and sale of pharmaceutical products. For example, we face a risk of product liability exposure related to the testing of our products in clinical trials and will face even greater risks upon commercialization by us or our partners of our products and partnered products. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because our products and partnered products are intended to treat behavioral disorders, and it is possible that we may be held liable for the behavior and actions of patients who use our products or partnered products. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and we or our partners may be forced to limit or forego further commercialization of one or more of our products or partnered products. Although we maintain product liability insurance, our aggregate coverage limit under this insurance is $5.0 million, and while we believe this amount of insurance is sufficient to cover our product liability exposure, these limits may not be high enough to fully cover potential liabilities. As our development activities and commercialization efforts progress and we and our partners sell our products or partnered products, this coverage may be inadequate, we may be unable to obtain adequate coverage at an acceptable cost or we may be unable to get adequate coverage at all or our insurer may disclaim coverage as to a future claim. This could prevent or limit the commercialization of our product candidates or commercial sales of our products or partnered products. Even if we are able to maintain insurance that we believe is adequate, our results of operations and financial condition may be materially adversely affected by a product liability claim. Uncertainties resulting from the initiation and continuation of products liability litigation or other proceedings could have a material adverse effect on our ability to compete

in the marketplace. Product liability litigation and other related proceedings may also require significant management time.

Legislative or regulatory reform of the healthcare system in the U.S. and foreign jurisdictions may affect our or our partners' ability to sell our products or partnered products profitably.

The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our or our partners' ability to set prices for our products or partnered products which we or our partners believe are fair, and our ability to generate revenues and achieve and maintain profitability.

Specifically, in both the U.S. and some foreign jurisdictions there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our or our partners' ability to sell our products or partnered products profitably. In the U.S., the Medicare Prescription Drug Improvement and Modernization Act of 2003 reforms the way Medicare will cover and provide reimburse for pharmaceutical products. This legislation could decrease the coverage and price that we or our partners may receive for our products or partnered products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time-consuming and expensive for us or our partners to go through the process of seeking reimbursement from Medicare and private payors. Our products or partnered products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow the sale of such products on a competitive and profitable basis. Further federal and state proposals and healthcare reforms are likely which could limit the prices that can be charged for the drugs we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the Medicare prescription drug coverage legislation, by the possible effect of this legislation on amounts that private insurers will pay and by other healthcare reforms that may be enacted or adopted in the future.

In some foreign countries, including major markets in the European Union and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take nine to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. Our business could be materially harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Our business is subject to extensive governmental regulation and oversight and changes in laws could adversely affect our revenues and profitability.

Our business is subject to extensive government regulation and oversight. As a result, we may become subject to governmental actions which could materially adversely affect our business, results of operations and financial condition, including:

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to patent protection and enforcement, health care availability, method of delivery and payment for health care products and services or our business operations generally
- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity
- new laws, regulations and judicial decisions affecting pricing or marketing and
- changes in the tax laws relating to our operations

In addition, the Food and Drug Administration Amendments Act of 2007 or the FDAAA included new authorization for the FDA to require post-market safety monitoring, along with a clinical trials registry, and expanded authority for the FDA to impose civil monetary penalties on companies that fail to meet certain commitments. The recently enacted amendments will among other things, require some new drug applicants to

submit risk evaluation and minimization strategies to monitor and address potential safety issues for products upon approval, grant the FDA the authority to impose risk management measures for marketed products and to mandate labeling changes in certain circumstances, and establish new requirements for disclosing the results of clinical trials. Companies that violate the new law are subject to substantial civil monetary penalties. Additional measures have also been enacted to address the perceived shortcomings in the FDA's handling of drug safety issues, and to limit pharmaceutical company sales and promotional practices. While we expect the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry as well as our business will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute existing products. Our and our partners' ability to commercialize approved products successfully may be hindered, and our business may be harmed as a result.

Failure to comply with government regulations regarding the sale and marketing of our products or partnered products could harm our business.

Our and our partners' activities, including the sale and marketing of our products or partnered products, are subject to extensive government regulation and oversight, including regulation under the federal Food, Drug and Cosmetic Act and other federal and state statutes. We are also subject to the provisions of the Federal Anti-Kickback Statute and several similar state laws, which prohibit payments intended to induce physicians or others either to purchase or arrange for or recommend the purchase of healthcare products or services. While the federal law applies only to products or services for which payment may be made by a federal healthcare program, state laws may apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of drugs and biologicals, such as us, by limiting the kinds of financial arrangements, including sales programs, with hospitals, physicians, and other potential purchasers of drugs and biologicals. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance that can be substantial, including the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid).

Pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting antitrust violations, violations of the Federal False Claim Act, the Anti-Kickback Statute, the Prescription Drug Marketing Act and other violations in connection with off-label promotion of products and Medicare and/or Medicaid reimbursement or related to environmental matters and claims under state laws, including state anti-kickback and fraud laws.

While we continually strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing practices are ever evolving. If any such actions are instituted against us or our partners and we or they are not successful in defending such actions or asserting our rights, those actions could have a significant and material impact on our business, including the imposition of significant fines or other sanctions. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition.

Future transactions may harm our business or the market price of our stock.

We regularly review potential transactions related to technologies, products or product rights and businesses complementary to our business. These transactions could include:

- mergers
- acquisitions
- strategic alliances

- licensing agreements and
- co-promotion and similar agreements

We may choose to enter into one or more of these transactions at any time, which may cause substantial fluctuations in the market price of our stock. Moreover, depending upon the nature of any transaction, we may experience a charge to earnings, which could also materially adversely affect our results of operations and could harm the market price of our stock.

We may undertake strategic acquisitions in the future, and difficulties integrating such acquisitions could damage our ability to sustain profitability.

Although we have no experience in acquiring businesses, we may acquire businesses that complement or augment our existing business. If we acquire businesses with promising product candidates or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to move one or more products or product candidates through preclinical and/or clinical development to regulatory approval and commercialization. Integrating any newly acquired businesses or technologies could be expensive and time-consuming, resulting in the diversion of resources from our current business. We may not be able to integrate any acquired business successfully. We cannot assure you that, following an acquisition, we will achieve revenues, specific net income or loss levels that justify the acquisition or that the acquisition will result in increased earnings, or reduced losses, for the combined company in any future period. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, which would result in dilution for stockholders or the incurrence of indebtedness. We may not be able to operate acquired businesses profitably or otherwise implement our growth strategy successfully.

Our quarterly operating results may fluctuate significantly.

Our operating results will continue to be subject to quarterly fluctuations. The revenues we generate, if any, and our operating results will be affected by numerous factors, including:

- our addition or termination of development programs
- variations in the level of expenses related to our products, product candidates or future development programs
- our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements
- the timing of royalties or milestone payments, if any, from the sales of Fanapt™
- regulatory developments affecting our products, product candidates and partnered products or those of our competitors
- product sales
- cost of product sales
- marketing and other expenses and
- manufacturing or supply issues
- any intellectual property infringement lawsuit in which we may become involved

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Risks related to intellectual property and other legal matters

Our rights to develop and commercialize our products, product candidates and partnered products are subject in part to the terms and conditions of licenses or sublicenses granted to us by other pharmaceutical companies. With respect to tasimelteon, these terms and conditions include an option in favor of the licensor to reacquire rights to commercialize and develop this product in certain circumstances.

Fanaptᵀᴹ (iloperidone) is based in part on patents and other intellectual property owned by sanofi-aventis and Novartis. Titan Pharmaceuticals, Inc. (Titan) holds an exclusive license from sanofi-aventis to the intellectual property owned by sanofi-aventis, and Titan has sublicensed its rights under such license on an exclusive basis to Novartis. We acquired exclusive rights to this and other intellectual property through a further sublicense from Novartis. The sublicense with Novartis was amended and restated in October of 2009 to provide Novartis with exclusive rights to commercialize Fanaptᵀᴹ in the U.S. and Canada and further develop and commercialize a long — acting injectable or depot formulation of Fanaptᵀᴹ in the U.S. and Canada. We retained exclusive rights to Fanaptᵀᴹ outside the U.S. and Canada, subject to, at Novartis' option, Novartis' right to co-commercialize Fanaptᵀᴹ and the depot formulation of Fanaptᵀᴹ in any country outside the U.S. and Canada on terms to be agreed to by Novartis and us at such time or to receive a royalty on sales outside the U.S. and Canada. We may lose our rights to develop and commercialize Fanaptᵀᴹ outside the U.S. and Canada if we fail to comply with certain requirements in the amended and restated sublicense agreement regarding our financial condition, or if we fail to comply with certain diligence obligations regarding our development activities or if we otherwise breach the amended and restated sublicense agreement and fail to cure such breach. Our rights to develop and commercialize Fanaptᵀᴹ outside the U.S. and Canada may be impaired if we do not cure breaches by Novartis of similar obligations contained in its sublicense agreement with Titan, although we are not aware of any such breach by Novartis. Our loss of rights in Fanaptᵀᴹ to Novartis would have a material adverse effect on our business. In addition, if Novartis breaches the amended and restated sublicense agreement with respect to its commercialization activities in the U.S. or Canada, we may terminate Novartis' commercialization rights in the applicable country. We would no longer receive royalty payments from Novartis in connection with such country in the event of such termination.

Tasimelteon is based in part on patents that we have licensed on an exclusive basis and other intellectual property licensed from Bristol-Myers Squibb Company (BMS). BMS holds certain rights with respect to tasimelteon in the license agreement. If we have not agreed to one or more partnering arrangements to develop and commercialize tasimelteon in certain significant markets with one or more third parties after the completion of the Phase III program, BMS has the option to exclusively develop and commercialize tasimelteon on its own on pre-determined financial terms, including milestone and royalty payments. BMS may terminate our license if we fail to meet certain milestones or if we otherwise breach our royalty or other obligations in the agreement. In the event that we terminate our license, or if BMS terminates our license due to our breach, all of our rights to tasimelteon (including any intellectual property we develop with respect to tasimelteon) will revert back to BMS or otherwise be licensed back to BMS on an exclusive basis. Any termination or reversion of our rights to develop or commercialize tasimelteon, including any reacquisition by BMS of our rights, may have a material adverse effect on our business.

If our efforts to protect the proprietary nature of the intellectual property related to our products, product candidates and partnered products are not adequate, we may not be able to compete effectively in our markets.

In addition to the rights we have licensed from Novartis and BMS relating to our products and partnered products, we rely upon intellectual property we own relating to these products, including patents, patent applications and trade secrets. As of September 30, 2009 we had seven pending provisional patent applications in the U.S., eight U.S. national stage applications under U.S.C. 371 and eight pending Patent Cooperation Treaty applications, which permit the pursuit of patents outside of the U.S., relating to our products in clinical development. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around these patents. In addition, we rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other

elements of our drug development processes that involve proprietary know-how, information and technology that is not covered by patent applications. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to protect or defend the intellectual property related to our technologies, we will not be able to establish or maintain a competitive advantage in our market.

If we do not obtain protection under the Hatch-Waxman Act and similar foreign legislation to extend our patents and to obtain market exclusivity for our products, our business will be materially harmed.

The United States Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the "Hatch-Waxman Act," provides for an extension of patent protection for drug compounds for a period of up to five years to compensate for time spent in development. Assuming we gain a five-year extension for tasimelteon, and that we continue to have rights under our license agreement with respect to this product, we would have exclusive rights to tasimelteon's U.S. "new chemical entity" patent (the primary patent covering the compound as a new composition of matter) until 2022. During the second quarter of 2009, we submitted to the U.S. Patent and Trademark Office our application to extend the term of its patent relating to Fanaptтм under the Hatch-Waxman Act. Assuming we gain a five-year extension for Fanaptтм, pursuant to the terms and conditions of our amended and restated sublicense agreement Novartis would have the benefit of exclusive rights to Fanaptтм's U.S. new chemical entity patent until 2016. A directive in the European Union provides that companies who receive regulatory approval for a new compound will have a 10-year period of market exclusivity for that compound (with the possibility of a further one-year extension) in most countries in Europe, beginning on the date of such European regulatory approval, regardless of when the European new chemical entity patent covering such compound expires. A generic version of the approved drug may not be marketed or sold in Europe during such market exclusivity period. This directive may be of particular importance with respect to Fanaptтм, since the European new chemical entity patent for Fanaptтм will expire prior to the end of this 10-year period of market exclusivity. However, there is no assurance that we will receive the extensions of our patents or other exclusive rights available under the Hatch-Waxman Act or similar foreign legislation. If we fail to receive such extensions and exclusive rights, our ability or our partners' ability to prevent competitors from manufacturing, marketing and selling generic versions of our products or partnered products will be materially impaired.

Litigation or third-party claims of intellectual property infringement could require us to divert resources and may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our not infringing the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to develop and commercialize one or more of our products. Defense of these claims, regardless of their merit, would divert substantial financial and employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain additional licenses from third parties to advance our research or allow commercialization of our products. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to develop and commercialize further one or more of our products.

In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties. Prosecution of these claims to enforce our rights against others could

divert substantial financial and employee resources from our business. If we fail to enforce our proprietary rights against others, our business will be harmed.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research, development and commercialization activities involve the controlled use of potentially hazardous substances, including toxic chemical and biological materials. Although we believe that our safety procedures for handling and disposing of such materials comply with state and federal standards, there will always be the risk of contamination, injury or other damages resulting from these hazardous substances. If we were to become liable for an accident, or if we or our partners were to suffer an extended facility shutdown, we could incur significant costs, damages and penalties that could materially harm our business, results of operations and financial condition.

In addition, our operations produce hazardous waste products. While third parties are responsible for disposal of our hazardous waste, we could be liable under environmental laws for any required cleanup of sites at which our waste is disposed. Federal, state, foreign and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials. If we fail to comply with these laws and regulations at any time, or if they change, we may be subject to criminal sanctions and substantial civil liabilities, which may adversely affect our business.

Even if we continue to comply with all applicable laws and regulations regarding hazardous materials, we cannot eliminate the risk of accidental contamination or discharge and our resultant liability for any injuries or other damages caused by these accidents. Although we maintain pollution liability insurance, our coverage limit under this insurance is $2.0 million, and while we believe this amount and type of insurance is sufficient to cover risks typically associated with our handling of materials, the insurance may not cover all environmental liabilities, and these limits may not be high enough to cover potential liabilities for these damages fully. The amount of uninsured liabilities may exceed our financial resources and materially harm our business.

Risks related to our common stock

Our stock price has been highly volatile and may be volatile in the future, and purchasers of our common stock could incur substantial losses.

The realization of any of the risks described in these risk factors or other unforeseen risks could have a dramatic and adverse effect on the market price of our common stock. Between September 30, 2008 and September 30, 2009, the high and low sale prices of our common stock as reported on the NASDAQ Global Market varied between $16.65 and $0.45. Additionally, market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons that were unrelated to the operating performance of any one company.

The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our common stock:

- publicity regarding actual or potential testing or trial results relating to products under development by us or our competitors
- the outcome of regulatory review relating to products under development by us or our competitors
- regulatory developments in the U.S. and foreign countries
- developments concerning any collaboration or other strategic transaction we may undertake
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors
- termination or delay of development or commercialization program(s) by our corporate partners

- safety issues with our products or those of our competitors
- our partners' ability to successfully commercialize our partnered products
- our ability to successfully execute our commercialization strategies
- announcements of technological innovations or new therapeutic products or methods by us or others
- actual or anticipated variations in our quarterly operating results
- changes in estimates of our financial results or recommendations by securities analysts or failure to meet such financial expectations
- changes in government regulations or policies or patent decisions
- changes in patent legislation or adverse changes to patent law
- additions or departures of key personnel or members of our board of directors
- publicity regarding actual or potential transactions involving us or
- economic and other external factors beyond our control

As a result of these factors, holders of our common stock might be unable to sell their shares at or above the price they paid for such shares.

If there are substantial sales of our common stock, our stock price could decline.

A small number of institutional investors and private equity funds hold a significant number of shares of our common stock. Sales by these stockholders of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock. Additionally, a small number of early investors in our company have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

In addition to our outstanding common stock, as of September 30, 2009, there were a total of 4,320,992 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options and restricted stock units granted under our Second Amended and Restated Management Equity Plan and 2006 Equity Incentive Plan. Upon the exercise or settlement of these options or restricted stock units, as the case may be, in accordance with their respective terms, these shares may be resold freely, subject to restrictions imposed on our affiliates under Rule 144. If significant sales of these shares occur in short periods of time, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms.

If securities or industry analysts do not publish research or reports or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers the Company downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, interest in the purchase of our stock could decrease, which could cause our stock price or trading volume to decline.

Our business could be negatively affected as a result of the actions of activist stockholders.

Proxy contests have been waged against many companies in the biopharmaceutical industry, including us, over the last few years. If faced with another proxy contest, we may not be able to respond successfully to the

contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest involving us or our partners because:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees;
- perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to a board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

These actions could cause our stock price to experience periods of volatility.

Anti-takeover provisions in our charter and bylaws, and in Delaware law, and our rights plan could prevent or delay a change in control of our company.

We are a Delaware corporation and the anti-takeover provisions of Section 203 of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our amended and restated certificate of incorporation and bylaws:

- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to thwart a takeover attempt
- do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of the stock to elect some directors
- establish a classified board of directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting following their election
- require that directors only be removed from office for cause
- provide that vacancies on the board of directors, including newly-created directorships, may be filled only by a majority vote of directors then in office
- limit who may call special meetings of stockholders
- prohibit stockholder action by written consent, requiring all actions to be taken at a meeting of the stockholders
- establish advance notice requirements for nominating candidates for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings

Moreover, on September 25, 2008, our board of directors adopted a rights agreement, the provisions of which could result in significant dilution of the proportionate ownership of a potential acquirer and, accordingly, could discourage, delay or prevent a change in our management or control over us.

Our investment portfolio may become impaired by further deterioration of the capital markets.

We engage one or more third parties to manage some of our cash consistent with an investment policy that allows a range of investments and maturities. The investments are intended to preserve principal while providing liquidity adequate to meet projected cash requirements. Risks of principal loss are intended to be minimized through diversified short and medium term investments of high quality, but the investments are not,

in every case, guaranteed or fully insured. In light of recent changes in the credit market, some high quality short-term investment securities, similar to the types of securities that we invest in, have suffered illiquidity or events of default. From time to time, we may suffer losses on our marketable securities, which could have a material adverse impact on our operations.

As a result of current adverse financial market conditions, investments in some financial instruments, such as auction rate securities and asset backed debt securities, may pose risks arising from liquidity and credit concerns. We have limited holdings of these investments in our portfolio, however, the current disruptions in the credit and financial markets have negatively affected investments in many industries, including those in which we invest. The current global economic crisis has had, and may continue to have, a negative impact on the market values of the investments in our investment portfolio. We cannot predict future market conditions or market liquidity and there can be no assurance that the markets for these securities will not deteriorate further or that the institutions that these investments are with will be able to meet their debt obligations at the time we may need to liquidate such investments or until such time as the investments mature.

Unstable market, credit and financial conditions may exacerbate certain risks affecting our business and have serious adverse consequences on our business.

The recent economic downturn and market instability has made the business climate more volatile and more costly. Our general business strategy may be adversely affected by unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, a lingering economic downturn or significant increase in our expenses could require additional financing on less than attractive rates or on terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our stock price and could require us to delay or abandon clinical development plans.

Sales of our products and partnered products will be dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. As a result of the current credit and financial market conditions, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our or our partners' product sales and revenue. Customers may also reduce spending during times of economic uncertainty.

In addition, we rely on third parties for several important aspects of our business. For example, we depend upon collaborators for both manufacturing and royalty revenue and the clinical development of collaboration products, we use third party contract research organizations for many of our clinical trials, and we rely upon several single source providers of raw materials and contract manufacturers for the manufacture of our products and product candidates. Due to the recent tightening of global credit and the continued deterioration in the financial markets, there may be a disruption or delay in the performance of our third party contractors, suppliers or collaborators. If such third parties are unable to satisfy their commitments to us, our business would be adversely affected.

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

None.

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

None.

Item 4. ***Submission of Matters to a Vote of Security Holders.***

On August 27, 2009, we held our 2009 Annual Meeting of Stockholders. At the meeting, the following matters were approved by the votes specified below:

1. Mihael H. Polymeropoulos, M.D. and Argeris N. Karabelas, Ph.D were elected to serve as directors of Vanda until the 2012 annual meeting or until their successors are duly elected and qualified. With respect to Dr. Polymeropoulos, 14,672,549 shares of common stock were voted in favor of his election and 6,827,304 shares of common stock were withheld. With respect to Dr. Karabelas, 13,766,149 shares of common stock were voted in favor of his election and 7,733,704 shares were withheld. There were no abstentions or broker non-votes. The terms of Messrs. Dugan, Pien, Ramsay and Watkins and Dr. Halak continued after the meeting.

2. The ratification of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the year ending December 31, 2009 was approved. The votes were cast as follows: 21,337,659 shares of common stock were voted for the ratification, 143,210 shares of common stock were voted against the ratification and 18,983 shares of common stock abstained from the vote. There were no broker non-votes.

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

None.

Item 6. ***Exhibits***

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

November 4, 2009

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

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

November 4, 2009

/s/ Stephanie R. Irish

Stephanie R. Irish
Acting Chief Financial Officer and Treasurer
(Principal financial and accounting officer)

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

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EXHIBIT 31.1

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

I, Mihael H. Polymeropoulos, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 4, 2009

/s/ Mihael H. Polymeropoulos

Mihael H. Polymeropoulos
Chairman and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

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

I, Stephanie R. Irish, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 4, 2009

/s/ Stephanie R. Irish

Stephanie R. Irish
Acting Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

Certification

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

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

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

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2009 (the Form 10-Q) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the consolidated financial condition and results of operations of the Company.

Date: November 4, 2009

/s/ Mihael H. Polymeropoulos

Mihael H. Polymeropoulos
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: November 4, 2009

/s/ Stephanie R. Irish

Stephanie R. Irish
Acting Chief Financial Officer
(Principal Financial and Accounting Officer)

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