Vanda Pharmaceuticals Inc.
Form 10-Q
November 04, 2009

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

Form 10-Q

(Mark One)

þ **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	**20850**
(Address of principal executive offices)	*(Zip Code)*

(240) 599-4500
(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ 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 þ	Non-accelerated filer o	Smaller reporting company o
	(Do not check if a smaller reporting company)		

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

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)

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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.

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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, 2008	September 30, 2009	September 30, 2008	September 30, 2009
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	$ (0.28)	$ (0.41)	$ (0.99)	$ (1.63)	

to common stockholders				
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.

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VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS EQUITY
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development	Comprehensive	
	Shares	Par Value	Capital	(Loss)	Stage	Loss	Total
alances at ecember 31, 2008	26,653,478	$ 26,653	$ 270,988,157	$ (20,029)	$ (224,974,507)		$ 46,020,274
suance of common ock from exercised ock ptions/restricted ock units	548,500	549	1,283,185				1,283,734
mployee ock-based ompensation			8,320,399				8,320,399
on-employee ock-based ompensation			388,327				388,327
omprehensive loss: et loss					(26,621,456)	$ (26,621,456)	
et unrealized gain n marketable curities				20,072		20,072	
omprehensive loss						$ (26,601,384)	(26,601,384)
alances at eptember 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.

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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, 2008	September 30, 2009
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.

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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 Fanapt[tm] 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 Fanapt[tm] for the acute treatment of schizophrenia in adults. On October 12, 2009, Vanda entered into an amended and restated sublicense agreement with Novartis. Vanda had originally entered into a sublicense agreement with Novartis on June 4, 2004 pursuant to which Vanda obtained certain worldwide exclusive licenses from Novartis relating to Fanapt[tm]. 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 Fanapt[tm] 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 Fanapt[tm]. 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 Fanapt[tm] 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 Fanapt[tm] 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 Fanapt[tm] or any future royalty payments with respect to sales of Fanapt[tm] in the U.S. and Canada. Vanda retains exclusive rights to Fanapt[tm] outside the U.S. and Canada and Vanda will have exclusive rights to use any of Novartis data for Fanapt[tm] for developing and commercializing Fanapt[tm] outside the U.S. and Canada. At Novartis option, Vanda will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt[tm] outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt[tm] 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.

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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 Fanapt[tm] 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 Fanapt[tm] 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 Fanapt[tm]. 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.

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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 Fanapt[tm] manufacturing-related costs were included in research and development expenses. Subsequent to FDA approval of Fanapt[tm], 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 Fanapt[tm], 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 Fanapt[tm], 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.

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VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

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, 2008	September 30, 2009	September 30, 2008	September 30, 2009
	$ 707,646	$ 504,686	$ 1,517,324	$ 2,357,015	$ 9,057,513

Research and development					
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	

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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%

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VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

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[tm], 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 Fanapt[tm] manufacturing-related and milestone costs were included in research and development expenses. Post FDA approval of Fanapt[tm], 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[tm].

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[tm] 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[tm]	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[tm]. As a result of the FDA s approval of the NDA for Fanapt[tm], 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[tm], 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[tm].

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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[tm] 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[tm], 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

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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[tm] 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

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depot) formulation of Fanapt[tm]. 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 Fanapt[tm] 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 Fanapt[tm] 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 Fanapt[tm] or any future royalty payments with respect to sales of Fanapt[tm] in the U.S. and Canada. Vanda retains exclusive rights to Fanapt[tm] outside the U.S. and Canada and Vanda will have exclusive rights to use any of Novartis data for Fanapt[tm] for developing and commercializing Fanapt[tm] outside the U.S. and Canada. At Novartis option, Vanda will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt[tm] outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt[tm] outside of the U.S. and Canada.

Vanda may lose its rights to develop and commercialize Fanapt[tm] 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 Fanapt[tm] outside the U.S. and Canada may be impaired if it does not cure breaches by Novartis of similar obligations contained its sublicense agreement with Titan for Fanapt[tm]. 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[tm] 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[tm]. 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.

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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 cou 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[tm] receives;
- our ability to successfully commercialize Fanapt[tm] 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.

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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:

Fanapt™ (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 Fanapt™. 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. We currently expect that Novartis will begin selling Fanapt™ 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 Fanapt™. 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 Fanapt™ 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 Fanapt™ 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 Fanapt™ or any future royalty payments with respect to sales of Fanapt™ in the U.S. and Canada. We retain exclusive rights to Fanapt™ outside the U.S. and Canada and we will have exclusive rights to use any of Novartis data for Fanapt™ for developing and commercializing Fanapt™ outside the U.S. and Canada. At Novartis option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt™ outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt™ outside of the U.S. and Canada.

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 Fanapt™ 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 Fanapt™ in the U.S. and to successfully develop and commercialize Fanapt™ in Canada and upon our

ability, alone or with others, to complete the development of our products or product candidates, and to obtain the regulatory approvals for and manufacture, market and sell our products, 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

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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 Fanapt[tm] 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 Fanapt[tm] 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 Fanapt[tm]. 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.

Fanapt[tm]. We have developed Fanapt[tm], and will continue to develop it outside the U.S. and Canada, to treat schizophrenia. We submitted an NDA for Fanapt[tm] 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 Fanapt[tm] and also contained pharmacogenetic data aimed to further improve the benefit/risk profile of Fanapt[tm] in the treatment of patients with schizophrenia. On May 6, 2009, we announced that the FDA had approved the NDA for Fanapt[tm]. On October 12, 2009, we entered into an amended and restated sublicense agreement with Novartis relating to Fanapt[tm]. We had originally entered into a sublicense agreement with Novartis on June 4, 2004 pursuant to which we obtained certain worldwide exclusive licenses from Novartis relating to Fanapt[tm]. 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[tm] 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 Fanapt[tm]. 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 Fanapt[tm] 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 Fanapt[tm] 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 Fanapt[tm] or any future royalty payments with respect to sales of Fanapt[tm] in the U.S. and Canada. We retain exclusive rights to Fanapt[tm] outside the U.S. and Canada and we will have exclusive rights to use any of Novartis data for Fanapt[tm] for developing and commercializing Fanapt[tm] outside the U.S. and Canada. At Novartis option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt[tm] outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt[tm] 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 Fanapt[tm], 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 Fanapt[tm], 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 Fanapt[tm]. 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

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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

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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, 2008	September 30, 2009	September 30, 2008	September 30, 2009
Direct project costs(1)					
Fanapt[tm]	$ 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.

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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 Fanapt[tm] manufacturing-related costs were included in research and development expenses. Subsequent to FDA approval of Fanapt[tm], 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 Fanapt[tm], 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 Fanapt[tm], 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

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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.

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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 Fanapt[tm] and tasimelteon as manufacturing costs for Fanapt[tm] 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 Fanapt[tm] and tasimelteon as manufacturing costs related to Fanapt[tm] 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.

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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 Fanapt[tm].

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

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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 Fanapt[tm] by the FDA in conjunction with lower manufacturing costs related to Fanapt[tm] 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 Fanapt[tm].

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[tm]	8 years	$ 12,000,000	$ 606,000	$ 11,394,000
		$ 12,000,000	$ 606,000	$ 11,394,000

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On May 6, 2009, we announced that the FDA had approved the NDA for Fanapt[tm]. 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 Fanapt[tm]. We expect the patent for Fanapt[tm] 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 Fanapt[tm].

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 Fanapt[tm] 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.

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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	$	$

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

	December 31, 2008	Fair Value Measurements at Reporting Date Using 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 Fanapt[tm] 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 Fanapt[tm] 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 Fanapt[tm]. 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.

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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 Fanapt[tm] 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 Fanapt[tm] 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 Fanapt[tm] 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

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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 Fanapt[tm]. 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 Fanapt[tm]. 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 Fanapt[tm] in the U.S. and Canada, are entitled to receive) payments under the conditions in the agreements upon the achievement of specified clinical, regulatory and commercial milestones. If the products are successfully commercialized we will be required to pay certain royalties (and in the case of Fanapt[tm] 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 Fanapt[tm] 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 Fanapt[tm], 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 Fanapt[tm] 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 Fanapt[tm]. 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 Fanapt[tm] 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 Fanapt[tm] 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 Fanapt[tm] or any royalty payments with

respect to sales of Fanapt[tm] in the U.S. and Canada. We retain exclusive rights to Fanapt[tm] outside the U.S. and Canada and we will have exclusive rights to use any of Novartis data for Fanapt[tm] for developing and commercializing Fanapt[tm] outside the U.S. and Canada. At Novartis option, we will enter into good faith discussions with Novartis relating to the co-commercialization of Fanapt[tm] outside of the U.S. and Canada or, alternatively, Novartis will receive a royalty on net sales of Fanapt[tm] outside of the U.S. and Canada.

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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.

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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, Fanapt[tm], 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 Fanapt[tm] and the sales of this product by Novartis in the U.S. and Canada. The ability of Fanapt[tm] 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 Fanapt[tm] or obtain health care coverage that covers Fanapt[tm] in the current uncertain economic climate
- acceptance of, and ongoing satisfaction, with Fanapt[tm] by the medical community, patients receiving therapy and third party payers
- a satisfactory efficacy and safety profile as demonstrated in a broad patient population
- the size of the market for Fanapt[tm]
- 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 Fanapt[tm] receives
- safety concerns in the marketplace for schizophrenia therapies generally
- regulatory developments relating to the manufacture or continued use of Fanapt[tm]
- decisions as to the timing of product launches, pricing and discounts

the competitive landscape for approved and developing therapies that will compete with Fanapt[tm]

Novartis ability to successfully develop and commercialize a long acting injectable (or depot) formulation of Fanapt[tm] in the U.S. and Canada

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

Novartis ability to obtain regulatory approval in Canada for Fanapt[tm] and our ability to obtain regulatory approval for Fanapt[tm] in countries outside the U.S. and Canada

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

the unfavorable outcome of any potential litigation relating to Fanapt[tm]

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We have entered into an amended and restated sublicense agreement with Novartis to commercialize Fanapt[tm] in the U.S. and Canada and to further develop and commercialize a long-acting injectable (or depot) formulation of Fanapt[tm] in the U.S. and Canada. As such, we will not be involved in the marketing or sales efforts for Fanapt[tm] 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 Fanapt[tm] 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 Fanapt[tm] in the U.S. and Canada. Such royalties may not be significant and will depend on numerous factors. We cannot control the amount and timing of resources that Novartis may devote to Fanapt[tm] or the depot formulation of Fanapt[tm]. If Novartis fails to successfully commercialize Fanapt[tm] in the U.S., fails to develop and commercialize Fanapt[tm] in Canada or further develop a long-acting injectable (or depot) formulation of Fanapt[tm], if Novartis efforts are not effective, or if Novartis focuses its efforts on other schizophrenia therapies or schizophrenia drug candidates, our business will be negatively affected. If Novartis does not successfully commercialize Fanapt[tm] in the U.S. or Canada, we will receive limited revenues from them.

Although we have developed and continue to develop additional products and product candidates for commercial introduction, we expect to be substantially dependent on sales from Fanapt[tm] for the foreseeable future. For reasons outside of our control, including those mentioned above, sales of Fanapt[tm] may not meet our expectations. Any significant negative developments relating to Fanapt[tm], 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 Fanapt[tm] and the positive results of our completed trials for Fanapt[tm] 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

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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

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