

Vanda Pharmaceuticals Inc.  
Form 10-Q  
August 10, 2009

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

**Form 10-Q**

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended June 30, 2009**
- OR**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934  
For the transition period from        to**

**Commission File Number: 000-51863**

**VANDA PHARMACEUTICALS INC.**  
*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**03-0491827**  
*(I.R.S. Employer  
Identification No.)*

**9605 Medical Center Drive, Suite 300**  
**Rockville, Maryland**  
*(Address of principal executive offices)*

**20850**  
*(Zip Code)*

**(240) 599-4500**

*(Registrant's telephone number, including area code)*

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

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

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(§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(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  No

As of August 6, 2009, there were 27,198,409 shares of the registrant's common stock issued and outstanding.

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**Vanda Pharmaceuticals Inc.**  
**(A Development Stage Enterprise)**

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**For the Three and Six Months Ended June 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)**

	<b>June 30, 2009</b>	<b>December 31, 2008</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 24,014,203	\$ 39,079,304
Marketable securities	5,008,623	7,378,798
Prepaid expenses, deposits and other current assets	1,129,194	1,287,400
Inventory	1,272,240	
Total current assets	31,424,260	47,745,502
Property and equipment, net	1,518,442	1,758,111
Restricted cash	430,230	430,230
Intangible asset, net	11,770,648	
Total assets	\$ 45,143,580	\$ 49,933,843
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,916,901	\$ 512,382
Accrued liabilities	4,415,231	2,898,417
Total current liabilities	11,332,132	3,410,799
Deferred rent	504,811	502,770
Total liabilities	11,836,943	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 June 30, 2009 and December 31, 2008		
Common stock, \$0.001 par value; 150,000,000 shares authorized as of June 30, 2009 and December 31, 2008; and 27,140,136 and 26,653,478 shares issued and outstanding as of June 30, 2009 and December 31, 2008, respectively	27,140	26,653
Additional paid-in capital	277,149,879	270,988,157

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Accumulated other comprehensive income (loss)	213	(20,029)
Deficit accumulated during the development stage	(243,870,595)	(224,974,507)
Total stockholders' equity	33,306,637	46,020,274
Total liabilities and stockholders' equity	\$ 45,143,580	\$ 49,933,843

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

**VANDA PHARMACEUTICALS INC.**  
**(A Development Stage Enterprise)**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)**

	<b>Three Months Ended</b>		<b>Six Months Ended</b>		<b>Period from</b>
	<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>	<b>March 13,</b>
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>	<b>2003</b>
					<b>(Inception) to</b>
					<b>June 30,</b>
					<b>2009</b>
Revenues	\$	\$	\$	\$	\$ 81,545
Operating expenses:					
Cost of sales	229,352		229,352		229,352
Research and development	7,195,595	5,480,909	9,528,934	16,583,574	159,114,253
General and administrative	4,988,317	8,454,985	9,212,351	17,414,199	95,131,191
Total operating expenses	12,413,264	13,935,894	18,970,637	33,997,773	254,474,796
Loss from operations	(12,413,264)	(13,935,894)	(18,970,637)	(33,997,773)	(254,393,251)
Other income (expense):					
Interest income	21,163	441,012	74,549	1,306,762	10,554,220
Interest expense					(80,485)
Other income					71,947
Total other income, net	21,163	441,012	74,549	1,306,762	10,545,682
Loss before tax provision	(12,392,101)	(13,494,882)	(18,896,088)	(32,691,011)	(243,847,569)
Tax provision					23,026
Net loss	(12,392,101)	(13,494,882)	(18,896,088)	(32,691,011)	(243,870,595)
Beneficial conversion feature deemed dividend to preferred stockholders					(33,486,623)
Net loss attributable to common stockholders	\$ (12,392,101)	\$ (13,494,882)	\$ (18,896,088)	\$ (32,691,011)	\$ (277,357,218)
Basic and diluted net loss per share applicable to common stockholders	\$ (0.46)	\$ (0.51)	\$ (0.71)	\$ (1.23)	
Shares used in calculation of basic and	26,900,841	26,649,439	26,777,159	26,648,892	

diluted net loss per share  
applicable to common  
stockholders

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

**VANDA PHARMACEUTICALS INC.**  
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**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**  
**(Unaudited)**

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Comprehensive Loss	Total
<b>Balances at December 31, 2008</b>	26,653,478	\$ 26,653	\$ 270,988,157	\$ (20,029)	\$ (224,974,507)		\$ 46,020,274
Issuance of common stock from exercised stock							
Options/restricted stock units	486,658	487	882,356				882,843
Employee stock-based compensation			5,057,177				5,057,177
Non-employee stock-based compensation			222,189				222,189
Comprehensive loss:							
Net loss					(18,896,088)	\$ (18,896,088)	
Net unrealized gain on marketable securities				20,242		20,242	
Comprehensive loss						\$ (18,875,846)	(18,875,846)
<b>Balances at June 30, 2009</b>	27,140,136	\$ 27,140	\$ 277,149,879	\$ 213	\$ (243,870,595)		\$ 33,306,637

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



**VANDA PHARMACEUTICALS INC.**  
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**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)**

	<b>Six Months Ended</b>		<b>Period from</b>
	<b>June 30,</b>	<b>June 30,</b>	<b>March 13,</b>
	<b>2009</b>	<b>2008</b>	<b>2003</b>
			<b>(Inception) to</b>
			<b>June 30,</b>
			<b>2009</b>
<b>Cash flows from operating activities</b>			
Net loss	\$ (18,896,088)	\$ (32,691,011)	\$ (243,870,595)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	239,669	259,707	2,739,331
Employee and non-employee stock-based compensation	5,279,366	9,074,594	49,602,678
Loss on disposal of assets		211	57,458
Amortization of net discounts on short-term investments	96,599	(195,911)	(2,130,721)
Amortization of intangible assets	229,352		229,352
Changes in assets and liabilities:			
Prepaid expenses, deposits and other current assets	158,206	(247,729)	(1,129,194)
Inventory	(1,272,240)		(1,272,240)
Accounts payable	1,404,519	2,425,921	1,916,901
Accrued expenses	1,516,814	(5,979,353)	4,415,231
Other liabilities	2,041	136,734	504,811
Net cash used in operating activities	(11,241,762)	(27,216,837)	(188,936,988)
<b>Cash flows from investing activities</b>			
Acquisition of intangible asset	(7,000,000)		(7,000,000)
Purchases of property and equipment		(479,581)	(4,381,391)
Proceeds from sale of property and equipment			200,179
Purchases of marketable securities	(8,082,729)	(2,081,121)	(275,901,472)
Proceeds from sales of marketable securities	126,547	4,875,076	97,100,390
Maturities of marketable securities	10,250,000	39,460,000	175,925,000
Investment in restricted cash			(430,230)
Net cash provided by (used in) investing activities	(4,706,182)	41,774,374	(14,487,524)
<b>Cash flows from financing activities</b>			
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	882,843		1,190,352

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Proceeds from issuance of common stock, net of issuance costs			164,588,801
Net cash provided by financing activities	882,843		227,482,543
Effect of foreign currency translation		16,745	(43,828)
Net change in cash and cash equivalents	(15,065,101)	14,574,282	24,014,203
<b>Cash and cash equivalents</b>			
Beginning of period	39,079,304	41,929,533	
End of period	\$ 24,014,203	\$ 56,503,815	\$ 24,014,203
<b>Supplemental disclosure of non-cash investing activities</b>			
Intangible asset acquisition included in accounts payable	\$ 5,000,000		\$ 5,000,000

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

**VANDA PHARMACEUTICALS INC.**  
**(A Development Stage Enterprise)**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**1. Business Organization and Presentation**

***Business organization***

Vanda Pharmaceuticals Inc. (Vanda or the Company) is a biopharmaceutical company focused on the development and commercialization of clinical stage products, with exclusive worldwide commercial rights to two products in clinical development for various central nervous system disorders. Vanda commenced its operations in 2003. The Company's lead product, iloperidone, which the Company intends to market under the tradename Fanapt<sup>®</sup>, 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<sup>™</sup> for the acute treatment of schizophrenia in adults. Holders of a New Drug Application (NDA) have 60 days after approval to file for patent term restoration under the Hatch-Waxman Act. Vanda submitted its application for patent term restoration with respect to Fanapt<sup>™</sup> on June 9, 2009. Vanda expects to make Fanapt<sup>™</sup> available in U.S. pharmacies later this year. Tasimelteon is a compound for the treatment of sleep and 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 and 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.

***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 as defined in Statement of Financial Accounting Standards (SFAS) No. 7, *Accounting and Reporting by Development Stage Enterprises*.

The Company's activities will necessitate significant uses of working capital throughout 2009 and beyond. Based on its current operating plans, the Company believes that its existing cash, cash equivalents and marketable securities, will be sufficient to meet the Company's anticipated operating needs through 2009. However, given the recent approval by the FDA of the Company's NDA for Fanapt<sup>®</sup>, the Company is currently evaluating alternative commercial strategies for the product. These strategies include, in addition to the Company launching Fanapt<sup>™</sup> on its own, entering into one or more partnerships, other collaboration agreements or strategic transactions that may provide capital to support the Company's operations. If, however, the Company needs to raise additional funds in order to execute on its operating plans, it may seek to sell debt securities or additional equity securities or obtain a bank credit facility. The sale of additional equity or debt securities, if convertible, could result in dilution to the Company's stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict the Company's operations. However, given the current global economic climate, the Company may have more difficulty raising funds than it would during a period of economic stability, and the Company may not be able to raise additional funds or enter into partnerships, other collaboration agreements or strategic transactions on acceptable terms, or at all. If the Company is unable to secure sufficient capital to fund its commercial and research and development activities, or attract a strategic partner, it may not be able to continue operations.

***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

**VANDA PHARMACEUTICALS INC.**  
**(A Development Stage Enterprise)**

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

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 the Form 10-K/A. The financial information as of June 30, 2009 and for the periods of the three and six months ended June 30, 2009 and 2008 and for the period from March 13, 2003 (inception) to June 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.

*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

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

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<sup>™</sup> manufacturing-related costs were included in research and development expenses. Subsequent to FDA approval of Fanapt<sup>™</sup>, 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 the underlying requirement is met.

As a result of the FDA's approval of the Company's NDA for Fanapt, the Company met a milestone under its license agreement with Novartis which required the Company to make a license payment of \$12 million to Novartis. The \$12 million is being amortized on a straight line basis over the remaining life of the patent for Fanapt<sup>™</sup>, 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 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. The Company had no impairments of its intangible assets for the six months ended June 30, 2009.

***Concentrations of credit risk***

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company places its cash, cash equivalents and marketable securities with what the Company believes to be highly-rated financial institutions. At June 30, 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 Financial Accounting Standards Board (FASB) revised SFAS No. 123, *Share-Based Payment* (SFAS 123(R)) 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



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

estimated forfeitures. SFAS 123(R) requires forfeitures 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 pro forma information required under SFAS 123 for 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 upon implementation of SFAS 123(R).

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

	<b>Three Months Ended</b>		<b>Six Months Ended</b>		<b>Period from</b>
	<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>	<b>March 13,</b>
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>	<b>2003</b>
					<b>(Inception) to</b>
					<b>June 30, 2009</b>
Research and development	\$ 582,558	\$ 696,937	\$ 809,678	\$ 1,852,330	\$ 8,349,867
General and administrative	2,171,824	3,270,503	4,247,499	7,233,648	40,882,837
Stock-based compensation expense	\$ 2,754,382	\$ 3,967,440	\$ 5,057,177	\$ 9,085,978	\$ 49,232,704
Stock-based compensation expense per basic and diluted share of common stock	\$ 0.10	\$ 0.15	\$ 0.19	\$ 0.34	
Shares used in calculation of stock-based compensation expense per share	26,900,841	26,649,439	26,777,159	26,648,892	

As of June 30, 2009, approximately \$11.3 million of total unrecognized compensation costs related to non-vested awards are expected to be recognized over a weighted average period of 1.41 years.

As of June 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 1,034,271 shares were subject to outstanding options granted under the 2004 Plan as of June 30, 2009, and no additional options will be granted under this plan. As of June 30, 2009 there are 4,105,194 shares of the Company's common stock reserved under the 2006 Plan of which 3,345,249 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 June 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

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

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 Staff Accounting Bulletin (SAB) No. 107 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 six months ended June 30, 2009 and 2008 were as follows:

	<b>Six Months Ended</b>	
	<b>June 30, 2009</b>	<b>June 30, 2008</b>
Expected dividend yield	0%	0%
Weighted average expected volatility	68%	68%
Weighted average expected term (years)	6.03	6.05
Weighted average risk-free rate	2.96%	3.28%

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

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price at Grant Date</b>	<b>Weighted Average Remaining Term (Years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2008	1,154,248	\$ 1.74		
Exercised	(93,184)	3.48		
Forfeited				
Cancelled	(26,793)	2.71		
Outstanding at June 30, 2009	1,034,271	1.53	6.20	\$ 10,588,389
Exercisable at June 30, 2009	960,592	1.46	6.18	\$ 9,926,801

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

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price at Grant Date</b>	<b>Weighted Average Remaining Term (Years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2008	2,631,381	\$ 17.43		
Granted	875,000	12.57		
Exercised	(102,445)	6.53		
Forfeited	(82,786)	16.43		
Cancelled	(299,901)	13.70		
Outstanding at June 30, 2009	3,021,249	17.31	8.54	\$ 5,872,450
Exercisable at June 30, 2009	1,226,109	21.88	7.87	\$ 2,020,732

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

The weighted average grant-date fair value of options granted during the six months ended June 30, 2009 was \$7.94 per share. For the six months ended June 30, 2009 and 2008, the Company received a total of \$882,843 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 one employee in 2007 and restricted stock units (RSUs) to all employees who remained with the Company following the workforce reduction in December 2008 and key consultants retained by the Company. The Company also issued RSUs to one consultant in the second quarter of 2009. The restricted stock issued in 2007 vested annually with respect to 25% of the shares each year after the grant. For the RSUs issued in 2008 to the retained employees, 50% of such shares vested upon approval by the FDA of the NDA for Fanapt™, and 50% of such shares vest on December 31, 2009. Pursuant to the FDA approval, the Company recognized \$163,000 in expense relating to the RSUs granted to all employees. For the RSUs issued to the consultant in the second quarter of 2009, 100% of the shares vest on August 31, 2009, provided that the consultant has continually provided services to the Company through such date. Upon a change of control of the Company, 100% of the unvested restricted stock units 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 June 30, 2009, there was approximately \$194,755 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.

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

	<b>Number of Shares</b>	<b>Weighted Average Price/Share</b>	<b>Aggregate Intrinsic Value</b>
Unvested at December 31, 2008	623,000	0.57	\$ 311,500
Granted	45,000	3.88	
Vested	(309,000)	0.57	
Cancelled	(35,000)	0.57	
Unvested at June 30, 2009	324,000	1.02	\$ 3,813,480

***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.

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***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<sup>™</sup> manufacturing-related and milestone costs were included in research and development expenses. Post FDA approval of Fanapt<sup>™</sup>, manufacturing and milestone costs related to this product will be 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 SFAS No. 5, *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 services. General and administrative expenses also include third party expenses incurred to support business development, marketing and other business activities related to Fanapt<sup>™</sup>.

***Income taxes***

The Company accounts for income taxes under the liability method in accordance with the provisions of SFAS No. 109, *Accounting for Income Taxes* (SFAS 109), 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 will 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 Statement No. 165, Subsequent Events (SFAS 165). SFAS 165 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



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available to be issued when they are in a form and format that complies with GAAP. SFAS 165 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 Statement No. 168, "The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles" (SFAS 168). SFAS 168 identifies the source of accounting principles and the framework for selecting the principles used in the preparation of financial statements. SFAS 168 is effective for interim and annual periods ending after September 15, 2009. The Company will update 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 SFAS No. 128, *Earnings per Share* and SAB No. 98. 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 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 terms of SAB No. 98, which would be included in EPS calculations.

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30, 2009</b>	<b>June 30, 2008</b>	<b>June 30, 2009</b>	<b>June 30, 2008</b>
Numerator:				
Net loss	\$ (12,392,101)	\$ (13,494,882)	\$ (18,896,088)	\$ (32,691,011)
Denominator:				
Weighted average shares of common stock outstanding	26,900,841	26,652,728	26,777,159	26,652,728
Weighted average unvested shares of common stock subject to repurchase		(3,289)		(3,836)
Denominator for basic and diluted net loss per share	26,900,841	26,649,439	26,777,159	26,648,892

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Basic and diluted net loss per share applicable to common stockholders	\$	(0.46)	\$	(0.51)	\$	(0.71)	\$	(1.23)
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Anti-dilutive securities not included in diluted net loss per share calculation:

Options to purchase common stock and restricted stock units	4,379,520	3,998,499	4,379,520	3,998,499
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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) (Continued)**

**4. Marketable Securities**

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

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Market Value</b>
Short-term:				
U.S. Treasury and government agencies	\$ 4,008,716	\$ 181	\$ (34)	\$ 4,008,863
U.S. corporate debt	999,694	66		999,760
	\$ 5,008,410	\$ 247	\$ (34)	\$ 5,008,623

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

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Market Value</b>
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 June 30, 2009, and December 31, 2008:

	<b>June 30, 2009</b>	<b>December 31, 2008</b>
Current deposits with vendors	\$ 210,000	\$ 210,000
Prepaid insurance	615,340	282,391

Accrued interest income	49,343	53,378
Other prepaid expenses	254,511	326,201
Other receivables		415,430
	\$ 1,129,194	\$ 1,287,400

**6. Inventory**

Inventory, net consisted of the following:

	<b>June 30,</b>
	<b>2009</b>
Raw materials	\$
Work-in-process	1,272,240
Finished goods	
Total inventory, net	\$ 1,272,240

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

**7. Property and Equipment**

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

	<b>Estimated Useful Life (Years)</b>	<b>June 30, 2009</b>	<b>December 31, 2008</b>
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		(2,156,519)	(1,916,850)
		<b>\$ 1,518,442</b>	<b>\$ 1,758,111</b>

Depreciation and amortization expense for the six months ended June 30, 2009 and 2008 were \$239,669 and \$259,707, respectively, and for the period from March 13, 2003 (inception) to June 30, 2009 was \$2,739,331.

**8. Intangible Asset, Net**

The intangible asset consists of the following:

	<b>Estimated Useful Lives</b>	<b>Gross Carrying Amount</b>	<b>June 30, 2009 Accumulated Amortization</b>	<b>Net Carrying Amount</b>
Fanapt <sup>tm</sup>	8 years	\$ 12,000,000	\$ 229,352	\$ 11,770,648
		\$ 12,000,000	\$ 229,352	\$ 11,770,648

On May 6, 2009, the Company announced that the FDA had approved the NDA for Fanapt<sup>tm</sup>. As a result of the FDA's approval of the Company's NDA for Fanapt<sup>tm</sup>, it met a milestone under its license agreement with Novartis which required the Company to make a license payment of \$12 million to Novartis. The Company expects the patent for

Fanapt™ to last until May 15, 2017. This includes the Hatch-Waxman extension that provides patent protection for drug compounds for a period of up to five years to compensate for time spent in development and a six-month pediatric term extension. This term is our best estimate of the life of the patent, 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 \$229,352 for the six months ended June 30, 2009. The estimated annual amortization expense for intangible assets is approximately \$0.8 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™.

Of the \$12 million milestone payment, \$7 million was paid in May 2009 and the remaining \$5 million is due in November 2009; however, Novartis has the right to accelerate the due date in its sole discretion.

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

**9. Accrued Liabilities**

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

	<b>June 30, 2009</b>	<b>December 31, 2008</b>
Accrued research and development expenses	\$ 3,337,632	\$ 925,124
Accrued consulting and other professional fees	436,534	233,829
Employee benefits	170,169	126,816
Accrued severance	470,896	1,612,648
	<b>\$ 4,415,231</b>	<b>\$ 2,898,417</b>

**10. Commitments and Contingencies**

*Operating leases*

The Company has commitments totaling approximately \$5.3 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 six months ended June 30, 2009 for the liability for the cash portion of severance costs related to the reductions-in-force:

	<b>Six Months Ended June 30, 2009</b>			
	<b>Beginning Balance</b>	<b>Charge</b>	<b>Cash Paid</b>	<b>Ending Balance</b>
Workforce Reduction:				
Research Development	\$ 571,391	\$	\$ 402,828	\$ 168,563
General & Administrative	1,041,257		738,924	302,333
Total	<b>\$ 1,612,648</b>	<b>\$</b>	<b>\$ 1,141,752</b>	<b>\$ 470,896</b>

*Consulting fees*

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



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***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 June 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<sup>tm</sup>*. The Company acquired exclusive worldwide rights to patents for Fanapt<sup>tm</sup>, previously known as iloperidone, 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 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 is obligated to make future milestone payments to Novartis of less than \$100 million in the aggregate (the majority of which are tied to sales milestones), as well as royalty payments to Novartis at a rate which, as a percentage of net sales, is in the mid-twenties. In November 2007, the Company met a milestone under this license agreement relating to the acceptance of its filing of the NDA for Fanapt<sup>tm</sup> for the treatment of schizophrenia and made a license payment of \$5 million to Novartis. As a result of the FDA's approval of the Company's NDA for Fanapt<sup>tm</sup>, it met an additional milestone under this license agreement which requires the Company to make a license payment of \$12 million to Novartis. Of the \$12 million milestone payment, \$7 million was paid in May 2009 and the remaining \$5 million is due in November 2009; however, Novartis has the right to accelerate the due date in its sole discretion.

The rights with respect to the patents to develop and commercialize Fanapt<sup>tm</sup> may terminate, in whole or in part, if the Company fails to meet certain development or commercialization milestones relating to the time it takes for the Company to launch Fanapt<sup>tm</sup> commercially following regulatory approval, and the time it takes for the Company to receive regulatory approval following the submission of an NDA or equivalent foreign filing. Additionally, the Company's rights may terminate in whole or in part if the Company does not meet certain other obligations under the sublicense agreement to make royalty and milestone payments, if the Company fails to comply with requirements in the sublicense agreement regarding its financial condition, or if the Company does not abide by certain restrictions in

the sublicense agreement regarding other development activities.

*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

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future milestone payments to BMS of less than \$40 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 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.

*Future license payments.* No amounts were recorded as liabilities other than the \$5 million milestone payment due to Novartis with respect to the FDA approval of Fanapt<sup>tm</sup>, nor were any contractual obligations relating to the license agreements included in the condensed consolidated financial statements as of June 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 course of its business the Company regularly enters into agreements with clinical organizations to provide services relating to clinical development and clinical manufacturing activities under fee service arrangements. The Company's current agreements for clinical services may be terminated on no more than 60 days notice without incurring additional charges, other than charges for work completed but not paid for through the effective date of termination and other costs incurred by the Company's contractors in closing out work in progress as of the effective date of termination.

**11. Income Taxes**

On January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board Interpretation (FIN) No. 48, *Accounting for Uncertainty in Income Taxes*. The adoption of FIN No. 48 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.

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The Company has not recorded any tax provision or benefit for the six months ended June 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 June 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.

**12. Fair Value Measurements**

In September 2006, the FASB issued Statement No. 157, Fair Value Measurements (SFAS 157). SFAS 157 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 SFAS 157 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 SFAS 157 as of January 1, 2008, for financial instruments. Although the adoption of SFAS 157 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.

SFAS 157 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 June 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 2. 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 June 30, 2009:

**Fair Value Measurements at Reporting Date Using**

Description:	<b>June 30, 2009</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Available-for-sale securities	\$ 5,008,623	\$ 4,008,863	\$ 999,760	\$
Total	\$ 5,008,623	\$ 4,008,863	\$ 999,760	\$

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

Description :	<b>Fair Value Measurements at Reporting Date Using</b>			
	<b>December 31, 2008</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
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 August 10, 2009, which is the date the financial statements were issued.

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

Various statements in this report are forward-looking statements under the securities laws. Words such as, but not limited to, believe, expect, anticipate, estimate, intend, plan, targets, likely, will, would, and could, 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:

delays in the completion of our clinical trials;

a failure of our products to be demonstrably safe and effective;

our failure to obtain regulatory approval for our products or to comply with ongoing regulatory requirements for our products;

a lack of acceptance of our 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;

our failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage our growth;

a loss of any of our key scientists or management personnel;

losses incurred from product liability claims made against us; and

a loss of rights to develop and commercialize our products under our license and sublicense agreements.

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

We encourage you to read the discussion and analysis of our financial condition and our condensed consolidated financial statements contained in this quarterly report on Form 10-Q. We also encourage you to read Item 1A of Part II of this quarterly report on Form 10-Q, entitled "Risk Factors", which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of Part II of this report, other unknown or unpredictable factors also could affect our results. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.



## Overview

We are a biopharmaceutical company focused on the development and commercialization of clinical-stage products for central nervous system disorders, with exclusive worldwide commercial rights to two products. We believe that each of our products will address a large market with significant unmet medical needs by offering advantages over currently available therapies. Our product portfolio includes:

Fanapt<sup>™</sup> (iloperidone), a compound for the treatment of schizophrenia. On November 27, 2007, the FDA accepted a New Drug Application (NDA) for Fanapt<sup>™</sup> for the treatment of schizophrenia. On May 6, 2009, the FDA granted U.S. marketing approval of Fanapt<sup>™</sup> for the acute treatment of

schizophrenia in adults. We expect to commercialize Fanapt<sup>tm</sup> with our own sales force and/or commercial partners in the United States and to seek partners for commercialization of the compound outside of the United States. We plan to make Fanapt<sup>tm</sup> available in pharmacies in the United States prior to the end of 2009. Holders of an NDA have 60 days after approval to file for patent term restoration under the Hatch-Waxman Act. We submitted our application for patent term restoration with respect to Fanapt<sup>tm</sup> on June 9, 2009. On July 30, 2009, we signed a Medicaid Rebate Agreement with the Secretary of Health and Human Services relating to the sale of Fanapt<sup>tm</sup> to Medicaid patients.

Tasimelteon, a compound for the treatment of sleep and mood disorders, including Circadian Rhythm Sleep Disorders (CRSD). 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 \$243.9 million since the inception of our operations through June 30, 2009. We have no product revenues to date and, other than Fanapt<sup>tm</sup> in the United States, have no 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 future operating results will depend largely on our ability to successfully develop and commercialize our lead product, Fanapt<sup>tm</sup>, and on the progress of other products currently in our research and development pipeline. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks which are detailed in Item 1A of Part II of this quarterly report on Form 10-Q, entitled "Risk Factors".

Our activities will necessitate significant uses of working capital throughout 2009 and beyond. Based on our current operating plans, we believe that our existing cash, cash equivalents and marketable securities, will be sufficient to meet our anticipated operating needs through 2009. However, given the recent approval by the FDA of our NDA for Fanapt<sup>tm</sup>, we are currently evaluating alternative commercial strategies for the product. These strategies include, in addition to launching Fanapt<sup>tm</sup> on our own, entering into one or more partnerships, other collaboration agreements or strategic transactions that may provide capital to support our operations. If, however, we need to raise additional funds in order to execute on our operating plans, we may seek to sell debt securities or additional equity securities or obtain a bank credit facility. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. However, given the current global economic climate, we may have more difficulty raising funds than we would during a period of economic stability, and we may not be able to raise additional funds or enter into partnerships, other collaboration agreements or strategic transactions on acceptable terms, or at all. If we are unable to secure sufficient capital to fund our commercial and research and development activities, or attract a strategic partner, we may not be able to continue operations.

*Fanapt<sup>tm</sup>.* We have developed and will continue to develop Fanapt<sup>tm</sup> to treat schizophrenia. We submitted an NDA for Fanapt<sup>tm</sup> for the treatment of schizophrenia to the FDA on September 27, 2007 and on November 27, 2007, the FDA accepted our NDA. The application included data from 35 clinical trials and more than 3,000 patients treated with Fanapt<sup>tm</sup> and also contained pharmacogenetic data aimed to further improve the benefit/risk profile of Fanapt<sup>tm</sup> in the treatment of patients with schizophrenia. In July 2008, we announced that the FDA had initially determined that our NDA was not approvable and indicated, among other things, that we would have to conduct additional studies and

submit that data before the FDA would approve Fanapt<sup>™</sup> for commercial sale for the treatment of schizophrenia. In September 2008, we met with the FDA to discuss the FDA's determination. The FDA asked us to provide a complete response to the not approvable letter, which we submitted on November 6, 2008 and which was subsequently accepted by the FDA for review.

Pending the FDA's reply to our complete response, we suspended all non-essential Fanapt<sup>™</sup>-related activities. On May 6, 2009, we announced that the FDA had approved our NDA for Fanapt<sup>™</sup>. We plan to make Fanapt<sup>™</sup> available in pharmacies in the United States prior to the end of 2009. Holders of an NDA have 60 days after approval to file for patent term restoration under the Hatch-Waxman Act. We submitted our application for patent term restoration with respect to Fanapt<sup>™</sup> on June 9, 2009. On July 30, 2009, we signed a Medicaid Rebate Agreement with the Secretary of Health and Human Services relating to the sale of Fanapt<sup>™</sup> to Medicaid patients.

From inception to June 30, 2009 we incurred approximately \$82.0 million in research and development costs directly attributable to our development of Fanapt<sup>™</sup>, including a \$5.0 million milestone license fee paid to Novartis in 2007 upon the acceptance of our NDA. As a result of the FDA's approval of our NDA for Fanapt<sup>™</sup>, we met an additional milestone under this license agreement which requires us to make a license payment of \$12 million to Novartis. The \$12 million was capitalized and will be amortized over the remaining life of the patent. Of the \$12 million milestone payment, \$7 million was paid in May 2009 and the remaining \$5 million is due in November 2009; however, Novartis has the right to accelerate the due date in its sole discretion.

We are also developing a 4-week injectable formulation for Fanapt<sup>™</sup>, for which we already have early Phase II data from a study previously conducted by Novartis. We have completed essential manufacturing activities and intend to resume the development of the injectable formulation. We believe we will need to conduct additional trials with this formulation to be able to file for FDA approval.

*Tasimelteon.* Tasimelteon is our product under development to treat sleep and mood disorders. Tasimelteon is a melatonin receptor agonist that works by adjusting the human body clock of circadian rhythm. Tasimelteon has successfully completed a Phase III trial for the treatment of transient insomnia in November 2006. In June 2008, we announced positive top-line results from the Phase III trial of tasimelteon in chronic primary insomnia. The trial was a randomized, double-blind, and placebo-controlled study with 324 patients. The trial measured time to fall asleep and sleep maintenance, as well as next-day performance. In addition, we believe that tasimelteon may be effective in the treatment of insomnia caused by jet lag. We met with the FDA in June 2009 in an end of Phase II meeting to discuss this potential jet lag indication. We will continue to work with the FDA to characterize the path to an NDA for tasimelteon. Tasimelteon is also ready for Phase II trials for the treatment of depression.

From inception to June 30, 2009, we incurred approximately \$52.4 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 June 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 June 30, 2009 we incurred research and development expenses in the aggregate of approximately \$159.1 million, including stock-based compensation expenses of approximately \$8.3 million. We expect our research and development expenses to increase as we continue to develop our products. We also expect to incur licensing costs in the future that could be substantial, as we continue our efforts to develop our products and to evaluate potential in-license products or compounds.

The following table summarizes our product development initiatives for the three and six months ended June 30, 2009 and 2008 and for the period from March 13, 2003 (inception) to June 30, 2009. Included in this table are the research and development expenses recognized in connection with our products in clinical development. Included in Other product candidates are the costs directly related to research initiatives for all other product candidates.

	<b>Three Months Ended</b>		<b>Six Months Ended</b>		<b>Period from</b>
	<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>	<b>June 30,</b>	<b>March 13,</b>
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>	<b>2003</b>
					<b>(Inception) to</b>
					<b>June 30,</b>
					<b>2009</b>
Direct project costs(1)					
Fanapt™	\$ 6,031,000	\$ 2,090,000	\$ 7,467,000	\$ 4,417,000	\$ 81,996,000
Tasimelteon	662,000	2,179,000	1,112,000	9,764,000	52,422,000
VSF-173	1,000	281,000		558,000	6,711,000
Other product candidates	25,000	465,000	77,000	945,000	6,648,000
Total direct product costs	6,719,000	5,015,000	8,656,000	15,684,000	147,777,000
Indirect project costs(1)					
Facility	141,000	222,000	312,000	369,000	2,574,000
Depreciation	59,000	110,000	122,000	178,000	2,138,000
Other indirect overhead	277,000	134,000	439,000	353,000	6,625,000
Total indirect expenses	477,000	466,000	873,000	900,000	11,337,000
Total research and development expenses	\$ 7,196,000	\$ 5,481,000	\$ 9,529,000	\$ 16,584,000	\$ 159,114,000

(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. We expect our general and administrative expenses to increase in 2009 in connection with the commercial launch of Fanapt<sup>™</sup>. From inception through June 30, 2009, we incurred general and administrative expenses in the aggregate of approximately \$95.1 million, including stock-based compensation expenses of approximately \$40.9 million.

## **Critical Accounting Policies**

The preparation of our condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in the notes to our audited consolidated financial statements for the year ended December 31, 2008 included in our annual report on Form 10-K/A. However, we believe that the following critical accounting policies are important to understanding and evaluating our reported financial results, and we have accordingly included them in this quarterly report on Form 10-Q.

### ***Inventory***

We value our inventories at the lower of cost or net realizable value. We analyze our inventory levels quarterly and write down inventory that has become obsolete, or has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are written off to cost of sales. Prior to FDA approval, all Fanapt<sup>tm</sup> manufacturing-related costs were included in research and development expenses. Subsequent to FDA approval of Fanapt<sup>tm</sup>, 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 our collaborators are recognized when the underlying requirement is met.

As a result of the FDA's approval of our NDA for Fanapt<sup>tm</sup>, we met a milestone under our license agreement with Novartis which required us to make a license payment of \$12 million to Novartis. Of the \$12 million milestone payment, \$7 million was paid in May 2009 and the remaining \$5 million is due in November 2009; however, Novartis has the right to accelerate the due date in its sole discretion. The \$12 million is being amortized on a straight line basis over the remaining life of the patent for Fanapt<sup>tm</sup>, 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 six months ended June 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 Statement of Financial Accounting Standards No. 123(R), *Share Based Payment*, (SFAS 123(R)) on January 1, 2006 using the modified prospective transition method of implementation and adopted the accelerated attribution method. Prior to January 1, 2006 we followed APB Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation*.

We currently use the Black-Scholes-Merton option pricing model to determine the fair value of stock options. The determination of the fair value of stock options on the date of grant using an option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the expected stock price volatility over the expected term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatility rates are based on 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 Staff Accounting Bulletin (SAB) No. 107 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, recognized under SFAS 123(R) during the three and six months ended June 30, 2009 and 2008 was comprised of the following:

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30, 2009</b>	<b>June 30, 2008</b>	<b>June 30, 2009</b>	<b>June 30, 2008</b>
Research and development	\$ 582,000	\$ 697,000	\$ 810,000	\$ 1,852,000
General and administrative	2,172,000	3,270,000	4,247,000	7,234,000
Stock-based compensation expense	\$ 2,754,000	\$ 3,967,000	\$ 5,057,000	\$ 9,086,000

### ***Recent accounting pronouncements***

In May 2009, the FASB issued Statement No. 165, *Subsequent Events* (SFAS 165). SFAS 165 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. SFAS 165 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 Statement No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles (SFAS 168). SFAS 168 identifies the source of accounting principles and the framework for selecting the principles used in the preparation of financial statements. SFAS 168 is effective for interim and annual periods ending after September 15, 2009. We will update 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 ability to successfully commercialize our products. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses. As of June 30, 2009, we had a deficit accumulated during the development stage of approximately \$243.9 million. We anticipate incurring additional losses for the foreseeable future, and these losses may be incurred at increasing rates.

### *Three months ended June 30, 2009 compared to three months ended June 30, 2008*

*Research and development expenses.* Research and development expenses increased by approximately \$1.7 million, or 31.3%, to approximately \$7.2 million for the three months ended June 30, 2009 compared to approximately \$5.5 million for the three months ended June 30, 2008.

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

	<b>Three Months Ended</b>	
	<b>June 30, 2009</b>	<b>June 30, 2008</b>
Direct project costs:		
Clinical trials	\$ 14,000	\$ 1,034,000
Contract research and development, consulting, materials and other direct costs	5,594,000	2,181,000
Salaries, benefits and related costs	529,000	1,103,000
Stock-based compensation	582,000	697,000
Total direct costs	6,719,000	5,015,000
Indirect project costs	477,000	466,000
Total	\$ 7,196,000	\$ 5,481,000

Direct costs increased approximately \$1.7 million for the three months ended June 30, 2009 compared to the three months ended June 30, 2008 as a result of the \$5.2 million Success Fee due to our regulatory consultant upon the approval of Fanapt<sup>™</sup> by the FDA on May 6, 2009, combined with lower clinical trial and manufacturing expenses as well as lower salary and benefit expenses and stock based compensation expense due to our workforce reduction which occurred in the fourth quarter of 2008. Clinical trials expense decreased approximately \$1.0 million for the

three months ended June 30, 2009 compared to the three months ended June 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 the second quarter of 2008. Contract research and development, consulting, materials and other direct costs increased approximately \$3.4 million for the three months ended June 30, 2009 relative to the three months ended June 30, 2008, primarily as a result of the \$5.2 million Success Fee due to our regulatory consultant upon the approval of Fanapt™ by the FDA on May 6, 2009 and decreased manufacturing costs related to Fanapt™ and tasimelteon as manufacturing costs related to Fanapt™ are now capitalized. Salaries, benefits and related costs decreased approximately \$574,000 for the three months ended June 30, 2009 relative to the three months ended June 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 June 30, 2009 decreased by approximately \$115,000 compared to the three months ended June 30, 2008 as a result of the smaller expense generated by the reduced workforce.

*General and administrative expenses.* General and administrative expenses decreased by approximately \$3.5 million, or 41.0%, to approximately \$5.0 million for the three months ended June 30, 2009 from approximately \$8.5 million for the three months ended June 30, 2008.

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

	<b>Three Months Ended</b>	
	<b>June 30, 2009</b>	<b>June 30, 2008</b>
Salaries, benefits and related costs	\$ 501,000	\$ 1,099,000
Stock-based compensation	2,172,000	3,270,000
Marketing, legal, accounting and other professional expenses	1,688,000	3,300,000
Other expenses	627,000	786,000
Total	\$ 4,988,000	\$ 8,455,000

Salaries, benefits and related costs decreased by approximately \$598,000 for the three months ended June 30, 2009 compared to the three months ended June 30, 2008 primarily due to a reduction in marketing personnel as we reduced our staff after the receipt of the not approvable letter regarding Fanapt<sup>tm</sup> by the FDA in July 2008. Stock-based compensation expense decreased by approximately \$1.1 million for the three months ended June 30, 2009, compared to the three months ended June 30, 2008, as a result of the smaller expense generated by the reduced workforce. Marketing, legal, accounting and other professional costs decreased by approximately \$1.6 million for the three months ended June 30, 2009 compared to the three months ended June 30, 2008 due primarily to reduced commercial costs related to Fanapt<sup>tm</sup> after the receipt of the not approvable letter regarding Fanapt<sup>tm</sup> by the FDA in July 2008.

*Other income, net.* Interest and other income in the three months ended June 30, 2009 was approximately \$21,000 compared to approximately \$441,000 in the three months ended June 30, 2008. Interest income was lower for the three months ended June 30, 2009, compared to the three months ended June 30, 2008, due to lower average cash balances for the three months ended June 30, 2009.

***Six months ended June 30, 2009 compared to six months ended June 30, 2008***

*Research and development expenses.* Research and development expenses decreased by approximately \$7.1 million, or 42.5%, to approximately \$9.5 million for the six months ended June 30, 2009 compared to approximately \$16.6 million for the six months ended June 30, 2008.

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

	<b>Six Months Ended</b>	
	<b>June 30, 2009</b>	<b>June 30, 2008</b>

Direct project costs:

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Clinical trials	\$ 35,000	\$ 7,198,000
Contract research and development, consulting, materials and other direct costs	6,782,000	4,420,000
Salaries, benefits and related costs	1,029,000	2,214,000
Stock-based compensation	810,000	1,852,000
Total direct costs	8,656,000	15,684,000
Indirect project costs	873,000	900,000
Total	\$ 9,529,000	\$ 16,584,000

Direct costs decreased approximately \$7.0 million for the six months ended June 30, 2009 compared to the six months ended June 30, 2008 primarily as a result of lower clinical trial expenses relating to Fanapt™ and tasimelteon. Clinical trials expense decreased approximately \$7.2 million for the six months ended June 30, 2009 compared to the six months ended June 30, 2008 primarily due to our Phase III clinical trial of tasimelteon in primary insomnia being completed in June 2008. Contract research and development, consulting, materials and other direct costs increased approximately \$2.4 million for the six months ended June 30, 2009 relative to the six months ended June 30, 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™ by the FDA in conjunction with lower manufacturing costs related to Fanapt™ and tasimelteon. Salaries, benefits and related costs decreased approximately \$1.2 million for the six months ended June 30, 2009 relative to the six months ended June 30, 2008 primarily due to our workforce reduction which occurred in the fourth quarter of 2008. Stock-based compensation expense decreased by approximately \$1.0 million for the six months ended June 30, 2009 compared to the six months ended June 30, 2008 as a result of the smaller expense generated by the reduced workforce.

*General and administrative expenses.* General and administrative expenses decreased by approximately \$8.2 million, or 47.1% to approximately \$9.2 million for the six months ended June 30, 2009 from approximately \$17.4 million for the six months ended June 30, 2008.

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

	<b>Six Months Ended</b>	
	<b>June 30, 2009</b>	<b>June 30, 2008</b>
Salaries, benefits and related costs	\$ 967,000	\$ 2,089,000
Stock-based compensation	4,247,000	7,234,000
Marketing, legal, accounting and other professional services	2,831,000	6,518,000
Other expenses	1,167,000	1,573,000
<b>Total</b>	<b>\$ 9,212,000</b>	<b>\$ 17,414,000</b>

Salaries, benefits and related costs decreased by approximately \$1.1 million for the six months ended June 30, 2009 compared to the six months ended June 30, 2008 primarily due to our workforce reduction which occurred in the fourth quarter of 2008. Stock-based compensation expense decreased by approximately \$3.0 million for the six months ended June 30, 2009, compared to the six months ended June 30, 2008, as a result of the smaller expense generated by the reduced workforce. Marketing, legal, accounting and other professional services decreased by approximately \$3.7 million for the six months ended June 30, 2009, relative to the six months ended June 30, 2008, due primarily to reduced commercial costs related to Fanapt™ after the receipt of the not approvable letter regarding Fanapt™ by the FDA in July 2008.

*Other income, net.* Interest and other income in the six months ended June 30, 2009 was approximately \$75,000 compared to approximately \$1.3 million in the six months ended June 30, 2008. Interest income was lower for the six months ended June 30, 2009, compared to the six months ended June 30, 2008, due to lower average cash balances for the six months ended June 30, 2009.

***Intangible Asset, Net***



The intangible asset consisted of the following:

			<b>June 30, 2009</b>	
	<b>Estimated Useful Lives</b>	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
Fanapt™	8 years	\$ 12,000,000	\$ 229,000	\$ 11,771,000
		\$ 12,000,000	\$ 229,000	\$ 11,771,000

On May 6, 2009, we announced that the FDA had approved the NDA for Fanapt™. As a result of the FDA's approval of our NDA for Fanapt™, we met a milestone under the license agreement which required us to make a license payment of \$12 million to Novartis. We expect the patent for Fanapt™ 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 \$229,000 for the six months ended June 30, 2009. The estimated annual amortization expense for intangible assets is approximately \$0.8 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. We capitalized and began amortizing the asset immediately following the FDA approval of the NDA for Fanapt™.

### *Inventory*

Inventory consisted of the following:

	<b>June 30, 2009</b>
Raw materials	\$
Work-in-process	1,272,000
Finished goods	
Total inventory, net	\$ 1,272,000

### **Liquidity and Capital Resources**

We have funded our operations through June 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 June 30, 2009, our total cash and cash equivalents and marketable securities were approximately \$29.0 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 June 30, 2009, we also held a non-current deposit of \$430,000 that is used to collateralize a letter of credit issued for our current office lease expiring in 2016.

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

<b>June 30, 2009</b>	<b>December 31, 2008</b>
--------------------------	------------------------------

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Cash and cash equivalents	\$ 24,014,000	\$ 39,079,000
U.S. Treasury and government agencies	4,009,000	2,000,000
U.S. corporate debt	1,000,000	5,252,000
U.S. asset-backed securities		127,000
Marketable securities, short-term	5,009,000	7,379,000
Total	\$ 29,023,000	\$ 46,458,000
Restricted cash	\$ 430,000	\$ 430,000

As of June 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 statement No. 157, Fair Value Measurements (SFAS 157). SFAS 157 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 SFAS 157 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 SFAS 157 as of January 1, 2008, for financial instruments. Although the adoption of SFAS 157 did not materially impact its financial condition, results of operations, or cash flow, we are now required to provide additional disclosures as part of its financial statements.

SFAS 157 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 June 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 June 30, 2009:

Description :	<b>Fair Value Measurements at Reporting Date Using</b>			
	<b>Quoted Prices</b>			
	<b>in</b>			
	<b>June 30,</b>	<b>Active Markets</b>	<b>Significant</b>	<b>Significant</b>
	<b>2009</b>	<b>for Identical</b>	<b>Other</b>	<b>Unobservable</b>
		<b>Assets</b>	<b>Observable</b>	<b>Inputs</b>
		<b>(Level 1)</b>	<b>(Level 2)</b>	<b>(Level 3)</b>
Available-for-sale securities	\$ 5,009,000	\$ 4,009,000	\$ 1,000,000	\$
Total	\$ 5,009,000	\$ 4,009,000	\$ 1,000,000	\$

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

**Fair Value Measurements at Reporting Date Using  
Quoted Prices  
in**

		<b>Active Markets for Identical Assets  (Level 1)</b>	<b>Significant Other Observable Inputs  (Level 2)</b>	<b>Significant Unobservable Inputs  (Level 3)</b>
Description :	<b>December 31, 2008</b>			
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. Based on our current operating plans, we believe that our existing cash, cash equivalents and marketable securities, will

be sufficient to meet our anticipated operating needs through 2009. However, given the recent approval by the FDA of our NDA for Fanapt<sup>tm</sup>, we are currently evaluating alternative commercial strategies for the product. These strategies include, in addition to launching Fanapt<sup>tm</sup> on our own, entering into one or more partnerships, other collaboration agreements or strategic transactions that may provide capital to support our operations. If, however, we need to raise additional funds in order to execute on our operating plans, we may seek to sell debt securities or additional equity securities or obtain a bank credit facility. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. However, given the current global economic climate, we may have more difficulty raising funds than we would during a period of economic stability, and we may not be able to raise additional funds or enter into partnerships, other collaboration agreements or strategic transactions on acceptable terms, or at all. If we are unable to secure sufficient capital to fund our commercial and research and development activities, or attract a strategic partner, we may not be able to continue operations.

### Cash Flow

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

	<b>Six Months Ended</b>	
	<b>June 30, 2009</b>	<b>June 30, 2008</b>
Net cash provided by (used in)		
Operating activities	\$ (11,242,000)	\$ (27,217,000)
Investing activities	(4,706,000)	41,774,000
Financing activities	883,000	
Exchange rate effect on cash and equivalents		17,000
Net change in cash and cash equivalents	\$ (15,065,000)	\$ 14,574,000

Net cash used in operations was approximately \$11.2 million and approximately \$27.2 million for the six months ended June 30, 2009 and 2008, respectively. The net loss for the six months ended June 30, 2009 of approximately \$18.9 million was offset by increases in accrued expenses and accounts payable of \$2.9 million, decreases in prepaid expenses of \$0.2 million, increases in inventory of \$1.3 million, \$5.8 million in non-cash depreciation, amortization, and stock-based compensation expenses, and \$0.1 changes in net working capital outflows. Net cash used in investing activities for the six months ended June 30, 2009 was approximately \$4.7 million and consisted primarily of net maturities of marketable securities of \$2.3 million and a \$7.0 million milestone payment to Novartis. There was \$883,000 provided by financing activities for the six months ended June 30, 2009 from the exercise of employee stock options.

### Contractual Obligations and Commitments

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

#### Cash Payments Due by Period

July to

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	<b>Total</b>	<b>December 2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>After 2013</b>
Severance payments	\$ 471,000	\$ 458,000	\$ 13,000	\$	\$	\$	\$
Operating leases	5,330,000	343,000	706,000	727,000	749,000	771,000	2,034,000
<b>Total</b>	<b>\$ 5,801,000</b>	<b>\$ 801,000</b>	<b>\$ 719,000</b>	<b>\$ 727,000</b>	<b>\$ 749,000</b>	<b>\$ 771,000</b>	<b>\$ 2,034,000</b>

**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 six months ended June 30, 2009 for the liability for the cash portion of severance costs related to the reductions-in-force:

	<b>Six Months Ended June 30, 2009</b>			<b>Ending Balance</b>
	<b>Beginning Balance</b>	<b>Charge</b>	<b>Cash Paid</b>	
Workforce Reduction:				
Research Development	\$ 571,000	\$	\$ 402,000	\$ 169,000
General & Administrative	1,041,000		739,000	302,000
Total	\$ 1,612,000	\$	\$ 1,141,000	\$ 471,000

**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<sup>tm</sup> 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 our NDA for Fanapt<sup>tm</sup>, which amount was offset by the aggregate amount of all monthly retainer fees previously paid to the consultant (Success Fee). The Success Fee is to be paid in monthly \$1.0 million increments through October 1, 2009. In addition to these fees, we are obligated to reimburse the consultant for its ordinary and necessary business expenses incurred in connection with its engagement.

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

**License agreements**



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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 our two products in clinical development. We are obligated to make 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 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. During March 2007, we met our first milestone under the license agreement with Novartis for VSF-173 relating to the initiation of the Phase II clinical trial and subsequently paid a license fee of \$1.0 million. On November 3, 2008, we received written notice from Novartis that the license agreement related 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 hold any rights with respect to VSF-173 and Novartis has a non-exclusive worldwide license to all information and intellectual property generated by or on behalf of Vanda related to its development of VSF-173. As a result of the acceptance by FDA of our NDA for Fanapt<sup>™</sup> in October 2007, we met a milestone under our license agreement with Novartis and subsequently paid a \$5.0 million milestone license 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 our NDA for Fanapt<sup>™</sup>, we met an additional milestone under this license agreement which requires us 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 is due in November 2009; however, Novartis has the right to accelerate the due date in its sole discretion. For a more detailed description of the risks associated with the outcome of such clinical trials, regulatory filings, FDA approvals and product sales, please see the section Risk Factors, Item 1A of Part II of this quarterly report on Form 10-Q.

### **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 June 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 June 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 second 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 June 30, 2009.

## PART II OTHER INFORMATION

### Item 1. *Legal Proceedings.*

None.

### Item 1A. *Risk Factors*

*Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this report, including the consolidated financial statements and the related notes appearing in this quarterly report on Form 10-Q, 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 intend to begin selling, marketing and distributing our first approved product, Fanapt™, in 2009 and we will depend heavily on the success of this product in the marketplace.***

Prior to the anticipated commercial launch of Fanapt™, we have never sold or marketed our own products. Our ability to generate product revenue for the next few years will depend solely on the success of this product. The ability of Fanapt™ to generate revenue at the levels we expect will depend on many factors, including the following:

the ability of patients in the current uncertain economic climate to be able to afford Fanapt™ or obtain health care coverage that covers Fanapt™

acceptance of and ongoing satisfaction with Fanapt™ in the United States and foreign markets by the medical community, patients receiving therapy and third party payers

a satisfactory efficacy and safety profile as demonstrated in a broad patient population

successfully expanding and sustaining manufacturing capacity to meet demand

safety concerns in the marketplace for schizophrenia therapies

the competitive landscape for approved and developing therapies that will compete with Fanapt™

our ability to expand the indications for which we can market Fanapt™

***Our success is dependent on the success of our products. If our 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 our NDA for Fanapt™ and the positive results of our completed trials for Fanapt™ 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, whether in clinical

trials or commercially, may reveal that the product is ineffective, unacceptably toxic, has other undesirable side effects or is otherwise not fit for further use. If we are unable to discover and develop products that are safe and effective, our business will be materially harmed.

***Any failure or delay in completing clinical trials for our products could severely harm our business.***

Pre-clinical studies and clinical trials required to demonstrate the safety and efficacy of our products are time-consuming and expensive and together take several years to complete. The completion of clinical trials for our products may be delayed by many factors, including:

our inability to manufacture or obtain from third parties materials sufficient for use in pre-clinical studies and clinical trials

delays in patient enrollment and variability in the number and types of patients available for clinical trials

difficulty in maintaining contact with patients after treatment, resulting in incomplete data

poor effectiveness of products during clinical trials

unforeseen safety issues or side effects

governmental or regulatory delays and changes in regulatory requirements and guidelines

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

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

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

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

a drug candidate may not be shown to be safe or effective

the FDA may interpret data from pre-clinical and clinical trials in different ways than we do

the FDA may not approve our manufacturing process

the FDA may change their approval policies or adopt new regulations

the FDA may not meet, or may extend, the PDUFA date with respect to a particular NDA

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

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

warning letters

fines

civil penalties



injunctions

recall or seizure of products

total or partial suspension of production

refusal of the government to grant future approvals

withdrawal of approvals

criminal prosecution

Any delay or failure by us to obtain regulatory approvals for our products could diminish competitive advantages that we may attain and would adversely affect the marketing of our products. Other than Fanapt<sup>™</sup> in the United States, we have not received regulatory approval to market any product in any jurisdiction.

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

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

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

We intend to market our products outside the United States with one or more commercial partners. In order to market our products in foreign jurisdictions, we may be required to obtain separate regulatory approvals and to comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional trials, and the time required to obtain approval may differ from that required to obtain FDA approval. We have no experience with obtaining any such foreign approvals. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could harm our business materially.

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

Undesirable side effects caused by our products could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing or continued commercialization of our products and generating revenues from their sale. We will continue to assess the side effect profile of our products in our ongoing clinical development program.

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

regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication

regulatory authorities may withdraw their approval of the product

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product

our reputation may suffer

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

***Even after we obtain regulatory approvals, our products may never achieve market acceptance.***

Even after obtaining regulatory approvals for the sale of our products, the commercial success of these products will depend, among other things, on their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. The degree of market acceptance of any product will depend on a number of factors, including the demonstration of its safety and efficacy, its cost-effectiveness, its potential advantages over other therapies, the reimbursement policies of government and third-party payors with respect to such product, and the effectiveness of our marketing and distribution capabilities. If our products fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. If our products do not become widely accepted by physicians, patients, third-party payors and other members of the medical community, it is unlikely that we will ever become profitable.

***If we fail to obtain the capital necessary to fund our research and development activities and commercialization efforts, or enter into partnerships, other collaboration agreements or strategic transactions, we may be unable to continue operations.***

Our activities will necessitate significant uses of working capital throughout 2009 and beyond. Based on our current operating plans, we believe that our existing cash, cash equivalents and marketable securities, will be sufficient to meet our anticipated operating needs through 2009. However, given the recent approval by the FDA of our NDA for Fanapt<sup>™</sup>, we are currently evaluating alternative commercial strategies for the product. These strategies include, in addition to launching Fanapt<sup>™</sup> on our own, entering into one or more partnerships, other collaboration agreements or strategic transactions that may provide capital to support our operations. If, however, we need to raise additional funds in order to execute on our operating plans, we may seek to sell debt securities or additional equity securities or obtain a bank credit facility. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. However, given the current global economic climate, we may have more difficulty raising funds than we would during a period of economic stability, and we may not be able to raise additional funds or enter into partnerships, other collaboration agreements or strategic transactions on acceptable terms, or at all. If we are unable to secure sufficient capital to fund our commercial and research and development activities, or attract a strategic partner, we may not be able to continue operations.

***We have incurred operating losses in each year since our inception and expect to continue to incur substantial and increasing losses for the foreseeable future.***

We have a limited operating history. We have not generated any revenue from product sales to date and we cannot estimate with precision the extent of our future losses. Other than Fanapt<sup>™</sup> in the United States, we do not currently have any products that have been approved for commercial sale and we may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and

increasing losses for the foreseeable future, particularly in connection with the commercial launch of Fanapt<sup>™</sup> or if we otherwise increase our research, clinical development and administrative activities. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. We have been engaged in identifying and developing compounds since March 2003. As of June 30, 2009, we have accumulated net losses of approximately \$243.9 million. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our products, obtain necessary regulatory approvals, and have our products manufactured and marketed. We cannot assure you that we will be profitable even if we successfully commercialize our products. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

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

We are dependent on contract research organizations, third-party vendors and investigators for pre-clinical testing and clinical trials related to our drug discovery and development efforts and we will likely continue to depend on them to assist in our future discovery and development efforts. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. If they fail to devote sufficient time and resources to our drug development programs or if their performance is substandard, it will delay the development and commercialization of our products. The parties with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our products. Moreover, these parties may also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors, it could harm our competitive position.

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

***We rely on a limited number of manufacturers for our products and our business will be seriously harmed if these manufacturers are not able to satisfy our demand and alternative sources are not available.***

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

Our manufacturing strategy presents the following additional risks:

because most of our third-party manufacturers and formulators are located outside of the United States, there may be difficulties in importing our compounds or their components into the United States as a

result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging

because of the complex nature of our products, our manufacturers may not be able to successfully manufacture our products in a cost-effective and/or timely manner

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

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

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

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

developing products

undertaking pre-clinical testing and clinical trials

obtaining FDA and other regulatory approvals of products

manufacturing and marketing products

These companies may invest heavily and quickly to discover and develop novel products that could make our products obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing superior products or other competing products before we do.

We believe the primary competitors for each of our products are as follows:

For Fanapt<sup>™</sup> in the treatment of schizophrenia, the atypical antipsychotics risperidone, including the depot formulation Risperdal<sup>®</sup> Consta<sup>®</sup>, and Invega<sup>®</sup> (paliperidone), each by Ortho-McNeil-Janssen Pharmaceuticals, Inc., Zyprexa<sup>®</sup> (olanzapine) by Eli Lilly and Company, Seroquel<sup>®</sup> (quetiapine) by AstraZeneca PLC, Abilify<sup>®</sup> (aripiprazole) by Bristol-Myers Squibb Company/Otsuka Pharmaceutical Co., Ltd., Geodon<sup>®</sup> (ziprasidone) by Pfizer Inc., and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are generic). In addition to the approved products, compounds in

Phase III trials (or for which an NDA has been recently filed) for the treatment of schizophrenia include bifeprunox (Solvay S.A./Lundbeck A/S), and asenapine (Schering-Plough Corporation) and pimavanserin (Acadia Pharmaceuticals).

For tasimelteon in the treatment of insomnia, Rozerem<sup>tm</sup> (ramelteon) by Takeda Pharmaceuticals Company Limited, hypnotics such as Ambien<sup>®</sup> CR (zolpidem) by sanofi-aventis, Lunesta<sup>®</sup> (eszopiclone) by Sepracor Inc. and Sonata<sup>®</sup> (zaleplon) by King Pharmaceuticals, Inc., generic compounds such as zolpidem, trazodone and doxepin, and over-the-counter remedies such as Benadryl<sup>®</sup> and Tylenol PM<sup>®</sup>. In addition to the approved products, compounds in Phase III trials for insomnia (or for which an



NDA has been recently filed) include indiplon (Neurocrine Biosciences, Inc.) low-dose doxepin (Silenor<sup>tm</sup>) by Somaxon Pharmaceuticals, Inc. and Intermezza<sup>®</sup> (zolpidem tartarate sublingual lozenge) by Transcept Pharmaceuticals, Inc.

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

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

***We have no experience selling, marketing or distributing products and no internal capability to do so.***

At present, we have limited marketing and sales personnel. In order for us to commercialize Fanapt<sup>tm</sup> or any other product, we must either acquire or internally develop sales, marketing and distribution capabilities, or enter into collaborations with partners to perform these services for us. We may not be able to establish sales and distribution partnerships on acceptable terms or at all, and if we do enter into a distribution arrangement, our success will be dependent upon the performance of our partner. In the event that we attempt to acquire or develop our own in-house sales, marketing and distribution capabilities, factors that may inhibit our efforts to commercialize our products without partners or licensees include:

our inability to recruit and retain adequate numbers of effective sales and marketing personnel

the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products

the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage against companies with broader product lines

unforeseen costs associated with creating our own sales and marketing team or with entering into a partnering agreement with an independent sales and marketing organization

***We will need to increase the size of our organization and we may experience difficulties in managing this growth.***

As of June 30, 2009, we had 21 full-time employees. In connection with the commercial launch of Fanapt<sup>tm</sup> and the potential resumption of our developmental activities, we will need to expand our managerial, operational, financial and other resources in order for us to manage and fund our operations, continue our development activities and commercialize our products. Our current personnel, systems and facilities are not adequate to support this future growth. To manage our growth, we must:

manage our clinical trials effectively

manage our internal development efforts effectively

improve our operational, financial, accounting and management controls, reporting systems and procedures

build marketing and sales organizations in order to commercialize Fanapt<sup>tm</sup>

attract and retain sufficient numbers of talented employees

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

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

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

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

We are highly dependent on principal members of our management team and scientific staff, including our Chief Executive Officer, Mihael H. Polymeropoulos, M.D. These executives each have significant pharmaceutical industry experience. The loss of any such executives, including Dr. Polymeropoulos, or any other principal member of our management team or scientific staff, would impair our ability to identify, develop and market new products.

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

The risk that we may be sued on product liability claims is inherent in the development of pharmaceutical products. For example, we face a risk of product liability exposure related to the testing of our products in clinical trials and will face even greater risks upon commercialization by us of our products. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because our products are intended to treat behavioral disorders, and it is possible that we may be held liable for the behavior and actions of patients who use our products. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products. Although we maintain product liability insurance, our aggregate coverage limit under this insurance is \$5.0 million, and while we believe this amount of insurance is sufficient to cover our product liability exposure, these limits may not be high enough to fully cover potential liabilities. In addition, product liability insurance is becoming increasingly expensive, and we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims, which could prevent or inhibit the commercial production and sale of our products.

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

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

Specifically, in both the United States and some foreign jurisdictions there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. In the United States, the Medicare Prescription Drug Improvement and Modernization Act of 2003 reforms the way Medicare will cover and reimburse for pharmaceutical products. This legislation could decrease the coverage and price that we may receive for our products. Other third-party payors are increasingly challenging the prices

charged for medical products and services. It will be time-consuming and expensive for us to go through the process of seeking reimbursement from Medicare and

private payors. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. Further federal and state proposals and healthcare reforms are likely which could limit the prices that can be charged for the drugs we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the Medicare prescription drug coverage legislation, by the possible effect of this legislation on amounts that private insurers will pay and by other healthcare reforms that may be enacted or adopted in the future.

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

***Recently enacted legislation may make it more difficult and costly for us to obtain regulatory approval of, and to produce, market and distribute our products.***

On September 27, 2007, then-President Bush signed into law the Food and Drug Administration Amendments Act of 2007 or the FDAAA. The FDAAA grants a variety of new powers to the FDA, many of which are aimed at assuring drug safety and monitoring the safety of drug products after approval. The recently enacted amendments will among other things, require some new drug applicants to submit risk evaluation and minimization strategies to monitor and address potential safety issues for products upon approval, grant the FDA the authority to impose risk management measures for marketed products and to mandate labeling changes in certain circumstances, and establish new requirements for disclosing the results of clinical trials. Companies that violate the new law are subject to substantial civil monetary penalties. Additional measures have also been enacted to address the perceived shortcomings in the FDA's handling of drug safety issues, and to limit pharmaceutical company sales and promotional practices. While we expect the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry as well as our business will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute existing products. Our ability to commercialize approved products successfully may be hindered, and our business may be harmed as a result.

***Our quarterly operating results may fluctuate significantly.***

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

our addition or termination of development programs

variations in the level of expenses related to our products or future development programs

our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements

any intellectual property infringement lawsuit in which we may become involved

regulatory developments affecting our products or those of our competitors

product sales

cost of product sales

marketing and other expenses

manufacturing or supply issues

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

### **Risks related to intellectual property and other legal matters**

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

Fanapt<sup>™</sup> (iloperidone) is based in part on patents and other intellectual property owned by sanofi-aventis and Novartis. Titan Pharmaceuticals, Inc. (Titan) holds an exclusive license from sanofi-aventis to the intellectual property owned by sanofi-aventis, and Titan has sublicensed its rights under such license on an exclusive basis to Novartis. We have acquired exclusive rights to this and other intellectual property through a further sublicense from Novartis. Our rights with respect to the intellectual property to develop and commercialize Fanapt<sup>™</sup> may terminate, in whole or in part, if we fail to meet certain milestones contained in our sublicense agreement with Novartis relating to the time it takes for us to launch Fanapt<sup>™</sup> commercially following regulatory approval, and the time it takes for us to receive regulatory approval following our submission of the requisite foreign filings. We may also lose our rights to develop and commercialize Fanapt<sup>™</sup> if we fail to pay royalties to Novartis, if we fail to comply with certain requirements in the sublicense agreement regarding our financial condition, or if we fail to comply with certain restrictions regarding our other development activities. Finally, our rights to develop and commercialize Fanapt<sup>™</sup> may be impaired if we do not cure breaches by Novartis and Titan of similar obligations contained in these sublicense and license agreements, although we are not aware of any such breach by Titan or Novartis. In the event of an early termination of our sublicense agreement, all rights licensed and developed by us under this agreement may be extinguished, which would have a material adverse effect on our business.

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

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

In addition to the rights we have licensed from Novartis and BMS relating to our products, we rely upon intellectual property we own relating to these products, including patents, patent applications and trade secrets. As of June 30, 2009 we had two issued patents, protecting the composition of matter for iloperidone and tasimelteon in the U.S. and other major markets. In addition, we had eight U.S. national stage applications under U.S.C. 371, ten pending Patent Cooperation Treaty applications and eight pending provisional patent applications in the United States, and, which

permit the pursuit of patents outside of the U.S., relating to our products. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around these patents. In addition, we rely on trade secret protection and confidentiality agreements to protect



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

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

The United States Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, provides for an extension of patent protection for drug compounds for a period of up to five years to compensate for time spent in development. Assuming we gain a five-year extension for each of Fanapt™ and tasimelteon, and that we continue to have rights under our sublicense and license agreements with respect to these products, we would have exclusive rights to Fanapt™'s United States new chemical entity patent (the primary patent covering the compound as a new composition of matter) until 2016 and to tasimelteon's United States new chemical entity patent until 2022. In Europe, similar legislative enactments allow patent protection in the European Union to be extended for up to five years through the grant of a Supplementary Protection Certificate. Assuming we gain such a five-year extension for each of Fanapt™ and tasimelteon, and that we continue to have rights under our sublicense and license agreements with respect to these products, we would have exclusive rights to Fanapt™'s European new chemical entity patents until 2015 and to tasimelteon's European new chemical entity patents until 2022. Additionally, a directive in the European Union provides that companies who receive regulatory approval for a new compound will have a 10-year period of market exclusivity for that compound (with the possibility of a further one-year extension) in most countries in Europe, beginning on the date of such European regulatory approval, regardless of when the European new chemical entity patent covering such compound expires. A generic version of the approved drug may not be marketed or sold in Europe during such market exclusivity period. This directive may be of particular importance with respect to Fanapt™, since the European new chemical entity patent for Fanapt™ will likely expire prior to the end of this 10-year period of market exclusivity. However, there is no assurance that we will receive the extensions of our patents or other exclusive rights available under the Hatch-Waxman Act or similar foreign legislation. Holders of an NDA have 60 days after approval to file for patent term restoration under the Hatch-Waxman Act. We submitted our application for patent term restoration with respect to Fanapt™ on June 9, 2009. If we fail to receive such extensions and exclusive rights, our ability to prevent competitors from manufacturing, marketing and selling generic versions of our products will be materially impaired.

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

Our commercial success depends in part on our not infringing the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to develop and commercialize one or more of our products. Defense of these claims, regardless of their merit, would divert substantial financial and employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or

pay royalties. In addition, even in the absence of litigation, we may need to obtain additional licenses from third parties to advance our research or allow commercialization of our products. We may fail to obtain any of these licenses at a reasonable cost or on

reasonable terms, if at all. In that event, we would be unable to develop and commercialize further one or more of our products.

In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties. Prosecution of these claims to enforce our rights against others could divert substantial financial and employee resources from our business. If we fail to enforce our proprietary rights against others, our business will be harmed.

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

Our research, development and commercialization activities involve the controlled use of potentially hazardous substances, including toxic chemical and biological materials. We could be held liable for any contamination, injury or other damages resulting from these hazardous substances. In addition, our operations produce hazardous waste products. While third parties are responsible for disposal of our hazardous waste, we could be liable under environmental laws for any required cleanup of sites at which our waste is disposed. Federal, state, foreign and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials. If we fail to comply with these laws and regulations at any time, or if they change, we may be subject to criminal sanctions and substantial civil liabilities, which may adversely affect our business.

Even if we continue to comply with all applicable laws and regulations regarding hazardous materials, we cannot eliminate the risk of accidental contamination or discharge and our resultant liability for any injuries or other damages caused by these accidents. Although we maintain pollution liability insurance, our coverage limit under this insurance is \$2,000,000, and while we believe this amount and type of insurance is sufficient to cover risks typically associated with our handling of materials, the insurance may not cover all environmental liabilities, and these limits may not be high enough to cover potential liabilities for these damages fully. The amount of uninsured liabilities may exceed our financial resources and materially harm our business.

### **Risks related to our common stock**

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

The stock market has from time to time experienced significant price and volume fluctuations, and the market prices of the securities of life sciences companies without product revenues, such as ours, have historically been highly volatile. Between June 30, 2008 and June 30, 2009, the high and low sale prices of our common stock as reported on the NASDAQ Global Market varied between \$14.79 and \$0.45. The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our common stock:

publicity regarding actual or potential testing or trial results relating to products under development by us or our competitors

the outcome of regulatory review relating to products under development by us or our competitors

regulatory developments in the United States and foreign countries

developments concerning any collaboration or other strategic transaction we may undertake

announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors

safety issues with our products

our ability to successfully execute our commercialization strategies

actual or anticipated variations in our quarterly operating results

changes in estimates of our financial results or recommendations by securities analysts

additions or departures of key personnel or members of our board of directors

publicity regarding actual or potential transactions involving the Company

economic and other external factors beyond our control

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

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

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

In addition to our outstanding common stock, as of June 30, 2009, there were a total of 4,379,520 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options and restricted stock units granted under our Second Amended and Restated Management Equity Plan and 2006 Equity Incentive Plan. Upon the exercise of these options in accordance with their respective terms, these shares may be resold freely, subject to restrictions imposed on our affiliates under Rule 144. If significant sales of these shares occur in short periods of time, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms.

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

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

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

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

authorize the issuance of blank check preferred stock that could be issued by our board of directors to thwart a takeover attempt

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do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of the stock to elect some directors

establish a classified board of directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting following their election

require that directors only be removed from office for cause

provide that vacancies on the board of directors, including newly-created directorships, may be filled only by a majority vote of directors then in office

limit who may call special meetings of stockholders

prohibit stockholder action by written consent, requiring all actions to be taken at a meeting of the stockholders

establish advance notice requirements for nominating candidates for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings

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

***We may lose some or all of the value of some of our marketable securities.***

We engage one or more third parties to manage some of our cash consistent with an investment policy that allows a range of investments and maturities. The investments are intended to preserve principal while providing liquidity adequate to meet projected cash requirements. Risks of principal loss are intended to be minimized through diversified short and medium term investments of high quality, but the investments are not, in every case, guaranteed or fully insured. In light of recent changes in the credit market, some high quality short-term investment securities, similar to the types of securities that we invest in, have suffered illiquidity or events of default. From time to time, we may suffer losses on our marketable securities, which could have a material adverse impact on our operations.

***Unstable market conditions may have serious adverse consequences on our business.***

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

There is a risk that one or more of our current service providers, manufacturers and other partners may encounter difficulties during challenging economic times, which would directly affect our ability to attain our operating goals on schedule and on budget.

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

None.

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

None.

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

None.

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

None.



**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
10.33	Amended and Restated Employment Agreement for William D. Clark.
10.34	Amended and Restated Employment Agreement for Mihael H. Polymeropoulos.
10.35	Employment Agreement for Stephanie Irish.
10.36	Employment Agreement for John Feeney.
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and Acting Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002.

The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Vanda Pharmaceuticals Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Vanda Pharmaceuticals Inc.

August 10, 2009

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

August 10, 2009

*/s/ Stephanie R. Irish*

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

**VANDA PHARMACEUTICALS INC.**

**EXHIBIT INDEX**

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