

Vanda Pharmaceuticals Inc.
Form 10-Q
May 09, 2008

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

Form 10-Q

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2008**
- 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)*

**9605 Medical Center Drive, Suite 300
Rockville, Maryland**

(Address of Principal Executive Offices)

03-0491827

*(I.R.S. Employer
Identification No.)*

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 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

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(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 May 9, 2008, there were 26,652,728 shares of the registrant's Common Stock issued and outstanding.

Vanda Pharmaceuticals Inc.
(A Development Stage Enterprise)

Form 10-Q Index

For the Three Months Ended March 31, 2008

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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)**

	March 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 56,015,493	\$ 41,929,533
Marketable securities	15,028,210	43,243,960
Prepaid expenses, deposits and other current assets	1,176,179	1,781,881
Total current assets	72,219,882	86,955,374
Marketable securities, long-term	5,994,202	7,979,331
Property and equipment, net	1,602,025	1,345,845
Deposits	150,000	150,000
Restricted cash	430,230	430,230
Total assets	\$ 80,396,339	\$ 96,860,780
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 1,825,933	\$ 2,988,069
Accrued liabilities	8,491,785	9,789,738
Total current liabilities	10,317,718	12,777,807
Deferred rent	422,407	354,042
Total liabilities	10,740,125	13,131,849
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.001 par value; 20,000,000 shares authorized and none issued and outstanding at March 31, 2008 and December 31, 2007		
Common stock, \$0.001 par value, 150,000,000 shares authorized as of March 31, 2008 and December 31, 2007; and 26,652,728 shares issued and outstanding as of March 31, 2008 and December 31, 2007	26,653	26,653
Additional paid-in capital	262,706,082	257,600,368
Accumulated other comprehensive income	29,874	12,176

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Deficit accumulated during the development stage	(193,106,395)	(173,910,266)
Total stockholders' equity	69,656,214	83,728,931
Total liabilities and stockholders' equity	\$ 80,396,339	\$ 96,860,780

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

VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended		Period from
	March 31,	March 31,	March 13,
	2008	2007	2003
			(Inception) to
			March 31,
			2008
Revenues from services	\$	\$	\$ 81,545
Operating expenses:			
Research and development	11,102,665	10,592,059	136,752,438
General and administrative	8,959,214	6,233,549	65,968,477
Total operating expenses	20,061,879	16,825,608	202,720,915
Loss from operations	(20,061,879)	(16,825,608)	(202,639,370)
Other income (expense):			
Interest income	865,750	1,433,654	9,564,539
Interest expense			(80,485)
Other income, net			71,947
Total other income, net	865,750	1,433,654	9,556,001
Loss before tax provision	(19,196,129)	(15,391,954)	(193,083,369)
Tax provision		806	23,026
Net loss	(19,196,129)	(15,392,760)	(193,106,395)
Beneficial conversion feature deemed dividend to preferred stockholders			(33,486,623)
Net loss attributable to common stockholders	\$ (19,196,129)	\$ (15,392,760)	\$ (226,593,018)
Basic and diluted net loss per share attributable to common stockholders	\$ (0.72)	\$ (0.61)	
Shares used in calculation of basic and diluted net loss per share attributable to common stockholders	26,648,344	25,340,455	

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	Additional	Accumulated	Deficit	Accumulated	Comprehensive	Total
	Shares	Paid-In	Other	During the	Comprehensive	Loss	
	Par	Capital	Income	Stage	Development	Stage	Loss
	Value	Capital	Income	Stage	Development	Loss	Total
Balances at							
December 31, 2007	26,652,728	\$ 26,653	\$ 257,600,368	\$ 12,176	\$ (173,910,266)		\$ 83,728,931
Employee stock-based compensation		5,118,537					5,118,537
Non-employee stock-based compensation		(12,823)					(12,823)
Comprehensive loss:							
Net loss					(19,196,129)	\$ (19,196,129)	
Translation adjustment			16,220				16,220
Net unrealized gains on marketable securities			1,478				1,478
Comprehensive loss						\$ (19,178,431)	(19,178,431)
Balances at							
March 31, 2008	26,652,728	\$ 26,653	\$ 262,706,082	\$ 29,874	\$ (193,106,395)		\$ 69,656,214

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)

	Three Months Ended		Period from
	March 31,	March 31,	March 13,
	2008	2007	2003
			(Inception) to
			March 31,
			2008
Cash flows from operating activities			
Net loss	\$ (19,196,129)	\$ (15,392,760)	\$ (193,106,395)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	122,629	148,671	2,091,484
Employee and non-employee stock-based compensation	5,105,714	4,107,972	36,041,237
Loss on disposal of assets	610		58,241
Accretion of discount on investments	(162,519)	(230,268)	(2,154,674)
Changes in assets and liabilities:			
Prepaid expenses, deposits and other current assets	606,421	109,921	(1,176,179)
Deposits			(150,000)
Accounts payable	(1,355,101)	(767,846)	1,632,978
Accrued expenses	(1,299,209)	(1,419,185)	8,491,785
Other liabilities	68,365	38,361	422,407
Net cash used in operating activities	(16,109,219)	(13,405,134)	(147,849,116)
Cash flows from investing activities			
Purchases of property and equipment	(186,442)	(118,678)	(3,624,175)
Proceeds from sale of property and equipment			200,179
Purchases of marketable securities	(1,485,150)	(65,477,330)	(254,517,812)
Proceeds from sales of marketable securities	2,790,026		88,505,774
Maturities of marketable securities	29,060,000	950,000	147,175,000
Investment in restricted cash			(430,230)
Net cash provided by (used in) investing activities	30,178,434	(64,646,008)	(22,691,264)
Cash flows from financing activities			
Proceeds from borrowings on note payable			515,147
Principal payments on obligations under capital lease			(91,797)
Principal payments on note payable			(515,147)
Proceeds from issuance of preferred stock, net of issuance costs			61,795,187
Proceeds from exercise of stock options and warrants		56,516	307,510
Proceeds from issuance of common stock, net of issuance costs		111,291,219	164,588,801

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Net cash provided by financing activities		111,347,735	226,599,701
Effect of foreign currency translation	16,745	(4,150)	(43,828)
Net increase in cash and cash equivalents	14,085,960	33,292,443	56,015,493
Cash and cash equivalents			
Beginning of period	41,929,533	30,928,895	
End of period	\$ 56,015,493	\$ 64,221,338	\$ 56,015,493

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

VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. Business Organization and Presentation

Business organization

Vanda Pharmaceuticals Inc. (Vanda or the Company) is a biopharmaceutical company focused on the development and commercialization of small molecule therapeutics, with exclusive worldwide commercial rights to three product candidates in clinical development for various central nervous system disorders. Vanda commenced its operations in 2003. The Company's lead product candidate, Fanapta[®] (iloperidone, also previously referred to by the Company as Fiapta), is a compound for the treatment of schizophrenia and bipolar disorder. The Company submitted a New Drug Application (NDA) for Fanapta[™] in schizophrenia to the United States Food and Drug Administration (FDA) on September 27, 2007. On November 27, 2007, the FDA accepted the NDA for Fanapta[™] in schizophrenia. Under the Prescription Drug User Fee Act (PDUFA) of 1992, Vanda expects a PDUFA action on or about July 27, 2008. The Company's second product candidate, tasimelteon (VEC-162), 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 November 2007 the Company initiated and in February 2008 completed an enrollment in a Phase III trial of tasimelteon in chronic primary insomnia. Vanda expects to report top-line results in June 2008. Tasimelteon is also ready for Phase II trials for the treatment of depression. The third product candidate, VSF-173, is a compound for the treatment of excessive sleepiness in the Phase II program.

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 2008 and beyond. Additionally, the Company's capital requirements will depend on many factors, including the success of the Company's research and development efforts, payments received under contractual agreements with other parties, if any, and the status of competitive products. The Company plans to continue financing its operations with cash received from financing activities. 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 into the fourth quarter of 2008. If Fanapta[™] is approved by the FDA on the expected Prescription Drug User Fee Act (PDUFA) action date of or about July 27, 2008, the Company intends to pursue additional financing, in part to fund additional marketing and product launch costs. The Company believes that it would be able to raise sufficient capital to fund the product launch and operations into 2009. However, if the Company cannot obtain additional financing, management has the ability and intent to implement a reduced spending plan to fund operations at least through the first quarter of 2009. In budgeting for its activities, the Company has relied on a number of assumptions, including assumptions that the Company will continue to expend funds in preparation of a commercial launch of Fanapta[™], that it will complete its Phase III clinical trial of tasimelteon in chronic primary insomnia in accordance with the Company's expectations, that it will not engage in further in-licensing activities, that it will not receive any proceeds from potential partnerships, that it will not expend funds on the bipolar indication for Fanapta[™], that it will not conduct additional trials for the

injectable formulation for Fanapta™, that it will not conduct additional trials for VSF-173, that it will continue to evaluate clinical and pre-clinical compounds for potential development, that it will be able to continue the manufacturing of its product candidates at commercially reasonable prices, that it will be able to retain its key personnel, and that it will not incur any significant contingent liabilities.

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

The Company may need to raise additional funds more quickly if one or more of its assumptions proves to be incorrect or if it chooses to expand its product development efforts more rapidly than presently anticipated or seek to acquire additional product candidates, and the Company may decide to raise additional funds even before they are needed if the conditions for raising capital are favorable. However, the Company may not be able to raise additional funds on acceptable terms, or at all. If the Company is unable to secure sufficient capital to fund its research and development activities, the Company may not be able to continue operations, or the Company may have to enter into collaboration agreements that could require the Company to share commercial rights to its products to a greater extent or at earlier stages in the drug development process than is currently intended. These collaborations, if consummated prior to proof-of-efficacy or safety of a given product candidate, could impair the Company's ability to realize value from that product candidate.

Basis of presentation

The accompanying unaudited condensed consolidated financial statements of Vanda Pharmaceuticals Inc. 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, 2007 included in the Company's annual report on the Form 10-K. The financial information as of March 31, 2008 and for the three months ended March 31, 2008 and 2007 and for the period from March 13, 2003 (inception) to March 31, 2008, 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, 2007 was derived from audited financial statements but does not include all disclosures required by GAAP.

The results of the Company's operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year. The financial information included herein should be read in conjunction with the consolidated financial statements and notes in the Company's annual report incorporated by reference in the Form 10-K for the year ended December 31, 2007. The condensed consolidated financial statements include the accounts of the Company and its wholly-owned Singapore subsidiary that ceased operations during 2007. All inter-company balances and transactions have been eliminated.

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 of three months or less at the date of purchase.

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

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 value, with the 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 or accreted, respectively, to maturity and included in interest income. The Company uses the specific identification method in computing realized gains and losses on the sale of investments, which would be included in the condensed consolidated statements of operations when generated. Marketable securities with a maturity of more than one year as of the balance sheet date are classified as long-term securities.

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 highly-rated financial institutions and does not hold any investment securities as of March 31, 2008 that have been affected by the recent credit crisis. At March 31, 2008, 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 granted subsequent to January 1, 2006, expenses are amortized under 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 condensed consolidated statements of operations for the three months ended March 31, 2008 and 2007 is based on awards ultimately expected to vest, it has been reduced for 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 subsequent to 2006 were estimated to be approximately 2% based on the Company's historical experience.

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

Total stock-based compensation expense recognized during the three months ended March 31, 2008 and 2007 and the period from March 13, 2003 (inception) to March 31, 2008 was comprised of the following:

	Three Months Ended March 31, 2008	Three Months Ended March 31, 2007	Period from March 13, 2003 (Inception) to March 31, 2008
Research and development	\$ 1,155,393	\$ 1,003,370	\$ 6,947,718
General and administrative	3,963,144	2,995,676	28,930,886
Stock-based compensation expense	\$ 5,118,537	\$ 3,999,046	\$ 35,878,604
Stock-based compensation expense per basic and diluted share of common stock	\$ 0.19	\$ 0.16	
Shares used in calculation of stock-based compensation expense per share	26,648,344	25,340,455	

As of March 31, 2008, approximately \$23.3 million of total unrecognized compensation costs related to non-vested awards are expected to be recognized over a weighted average period of 1.5 years.

As of March 31, 2008, 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 1,164,351 shares were subject to outstanding options granted under the 2004 Plan as of March 31, 2008, and no additional options will be granted under this plan. As of March 31, 2008 there are 3,451,250 shares of the Company's common stock reserved under the 2006 Plan of which 2,694,979 shares were subject to outstanding options to employees and non-employees.

Options are subject to terms and conditions established by the compensation committee of the board of directors. None of the stock-based awards are classified as a liability as of March 31, 2008. Option awards have 10-year contractual terms and all options granted prior to December 31, 2006 and options granted to new employees vest and become exercisable on the first anniversary of the grant date with respect to 25% of the option awards. The remaining 75% of the option awards vest and become exercisable monthly in equal installments thereafter over three years. 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.

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. 110 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

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

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 three months ended March 31, 2008 and 2007 were as follows:

	Three Months Ended March 31, 2008	March 31, 2007
Expected dividend yield	0%	0%
Weighted average expected volatility	68%	73%
Weighted average expected term (years)	6.25	6.25
Weighted average risk-free rate	3.14%	4.86%

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

	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2007	1,169,975	\$ 1.77		
Forfeited	(336)	2.51		
Cancelled	(5,288)	4.73		
Outstanding at March 31, 2008	1,164,351	1.76	7.48	\$ 2,820,204
Exercisable at March 31, 2008	676,373	1.68	7.43	\$ 1,686,868

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Term (Years)	Aggregate
--	-----------------------------	--	--	------------------

		at Grant Date		Intrinsic Value
Outstanding at December 31, 2007	1,768,635	\$ 26.08		
Granted	966,000	5.76		
Forfeited	(1,507)	30.65		
Cancelled	(38,149)	17.98		
Outstanding at March 31, 2008	2,694,979	18.90	9.20	\$
Exercisable at March 31, 2008	550,559	24.91	8.89	\$

The weighted average grant-date fair value of options granted during the three months ended March 31, 2008 was \$3.70 per share. For the three months ended March 31, 2008 and 2007 the Company received a total of \$0 and \$56,516, respectively, in cash from options exercised under the stock-based arrangements.

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

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

monitors, data management organizations and investigators in conjunction with clinical trials, fees to contract manufacturers in conjunction with the production of clinical materials, and fees for marketing and other commercialization activities. Pursuant to management's assessment of the services that have been performed on clinical trials and other contracts, the Company recognizes these expenses as the services are provided. Such management assessments include, but are not limited to: (1) an evaluation by the project manager of the work that has been completed during the period, (2) measurement of progress prepared internally and/or provided by the third-party service provider, (3) analyses of data that justify the progress, and (4) management's judgment.

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, depreciation of capital resources used to develop products, all 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, including payments made to date under the license agreements. Manufacturing-related costs are also included in research and development expenses as the Company does not yet have FDA approval for any of its product candidates. 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 costs also include third party expenses incurred to support business development, marketing and other business activities related to our product candidate Fanapta™, in anticipation of its commercial launch.

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 may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

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

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 June 2007, the Emerging Issues Task Force issued EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3), which provides guidance to research and development companies on how to account for the nonrefundable portion of an advance payment made for research and development activities. The Company adopted EITF 07-3 on January 1, 2008 and this pronouncement has not had an impact on our results of operations and financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007) (SFAS 141R), *Business Combinations* and SFAS No. 160 (SFAS 160), *Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No. 51*. SFAS 141R will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS 141R and SFAS 160 will be applied to acquisitions that close in years beginning after December 15, 2008. Early adoption is not permitted. These pronouncements are not expected to have significant impact on the Company's results of operations and financial condition.

In December 2007, the FASB ratified EITF Issue 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). The consensus prohibits the equity method of accounting for collaborative arrangements under APB 18, *The Equity Method of Accounting for Investments in Common Stock*, unless a legal entity exists. Payments between the collaborative partners will be evaluated and reported in the income statement based on applicable GAAP. Absent specific GAAP, the participants to the arrangement will apply other existing GAAP by analogy or apply a reasonable and rational accounting policy consistently. The guidance in EITF 07-1 is effective for periods that begin after December 15, 2008 and will apply to arrangements in existence as of the effective date. The effect of the new consensus will be accounted for as a change in accounting principle through retrospective application. The Company is currently evaluating the impact of EITF 07-1 on its results of operations and financial condition.

In December 2007, the SEC issued SAB No. 110, *Share-Based Payment*, or SAB 110, which expresses the views of the SEC regarding the use of a simplified method, as discussed in SAB 107, in developing an estimate of the expected term of plain vanilla share options in accordance with SFAS 123R. In SAB 110, the SEC stated that it understood that the detailed information necessary to calculate an expected term for plain vanilla options may not be widely available by December 31, 2007, as previously discussed within SAB 107. Accordingly, the SEC will continue to accept, under certain circumstances, the use of the simplified method beyond December 31, 2007. As allowed under SAB 110, the Company has continued to use the simplified method in estimating the expected term of its stock options until such time as more relevant detailed information becomes available.

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.

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

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 and warrants to purchase common stock, 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 effect, 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.

	Three Months Ended	
	March 31, 2008	March 31, 2007
Numerator:		
Net loss	\$ (19,196,129)	\$ (15,392,760)
Denominator:		
Weighted average shares of common stock outstanding	26,652,728	25,365,415
Weighted average unvested shares of common stock subject to repurchase	(4,384)	(24,960)
Denominator for basic and diluted net loss per share	26,648,344	25,340,455
Basic and diluted net loss per share applicable to common stockholders	\$ (0.72)	\$ (0.61)
Anti-dilutive securities not included in diluted net loss per share calculation:		
Options to purchase common stock	3,859,330	2,769,711

4. Marketable Securities

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Short-term :				
U.S. Treasury and government agencies	\$ 2,000,344	\$	\$ (346)	\$ 1,999,998
U.S. corporate debt	9,367,503	23,970		9,391,473
U.S. asset-based securities	3,632,633	4,106		3,636,739
	\$ 15,000,480	\$ 28,076	\$ (346)	\$ 15,028,210

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Long-term:

U.S. corporate debt	\$ 1,990,739	\$	\$ (24,179)	\$ 1,966,560
U.S. asset-based securities	4,001,319	26,323		4,027,642
	\$ 5,992,058	\$ 26,323	\$ (24,179)	\$ 5,994,202

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

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2007:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Short-term :				
U.S. Treasury and government agencies	\$ 3,980,732	\$	\$ (897)	\$ 3,979,835
U.S. corporate debt	33,301,950	48,247	(11,417)	33,338,780
U.S. asset-based securities	5,920,992	4,353		5,925,345
	\$ 43,203,674	\$ 52,600	\$ (12,314)	\$ 43,243,960
Long-term:				
U.S. Treasury and government agencies	\$ 1,999,104	\$ 2,844	\$	\$ 2,001,948
U.S. corporate debt	1,988,637		(18,597)	1,970,040
U.S. asset-based securities	4,003,480	3,863		4,007,343
	\$ 7,991,221	\$ 6,707	\$ (18,597)	\$ 7,979,331

5. Prepaid Expenses, Deposits and Other Current Assets

The following is a summary of the Company's prepaid expenses, deposits and other current assets, as of March 31, 2008, and December 31, 2007:

	March 31, 2008	December 31, 2007
Current deposits with vendors	\$ 455,000	\$ 455,000
Prepaid insurance	125,893	395,203
Prepaid research and development expenses	138,733	175,955
Accrued interest income	126,087	603,556
Other prepaid expenses	250,070	146,771
Other receivables	80,396	5,396
	\$ 1,176,179	\$ 1,781,881

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6. Property and Equipment

The following is a summary of the Company's property and equipment at cost, as of March 31, 2008, and December 31, 2007:

	Estimated Useful Life (Years)	March 31, 2008	December 31, 2007
Laboratory equipment	5	\$ 1,281,877	\$ 1,281,877
Computer equipment	3	756,424	758,776
Furniture and fixtures	7	283,231	187,317
Leasehold improvements	10	468,923	505,684
Construction in Progress		320,244	
		3,110,699	2,733,654
Less accumulated depreciation and amortization		(1,508,674)	(1,387,809)
		\$ 1,602,025	\$ 1,345,845

Depreciation and amortization expense for the three months ended March 31, 2008 and 2007 were \$122,629 and \$148,671, respectively, and for the period from March 13, 2003 (inception) to March 31, 2008 was \$2,091,484.

7. Accrued Liabilities

The following is a summary of accrued liabilities, as of March 31, 2008, and December 31, 2007:

	March 31, 2008	December 31, 2007
Accrued research and development expenses	\$ 6,835,482	\$ 7,151,360
Bonus accrual	272,211	957,035
Accrued consulting and other professional fees	1,121,321	1,307,650
Employee benefits	171,540	168,275
Lease abandonment	43,247	84,617
Other accrued expenses	47,984	120,801
	\$ 8,491,785	\$ 9,789,738

8. Commitments and Contingencies

Operating leases

The Company has commitments totaling approximately \$6.2 million under operating real estate leases for its current and former headquarters located in Rockville, Maryland, expiring in 2016 and 2008. In September 2007, the Company entered into an agreement to sublease its former headquarters for the remainder of the lease for approximately \$52,000, of which \$36,000 has been received as of March 31, 2008.

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 has agreed to indemnify, hold harmless, and to reimburse the indemnified party for losses suffered or incurred by the indemnified party,

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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 agreed to indemnify its officers and directors for certain events or occurrences, subject to certain limits. The Company believes that the fair value of the indemnification agreements is minimal, and accordingly the Company has not recognized any liabilities relating to these agreements as of March 31, 2008.

License agreements

The Company's rights to develop and commercialize the clinical-stage product candidates are subject to the terms and conditions of licenses granted to the Company by other pharmaceutical companies.

Fanaptatm. The Company acquired exclusive worldwide rights to patents for *Fanaptatm* 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. 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 *Fanaptatm* for the treatment of schizophrenia and made a license payment of \$5 million to Novartis.

The rights with respect to the patents to develop and commercialize *Fanaptatm* 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 *Fanaptatm* 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 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 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

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milestones in initiating and completing certain clinical work. During March 2006, the Company met its first milestone relating to the initiation of the Phase III clinical trial for tasimelteon and recorded a license fee expense of \$1,000,000.

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. If the Company seeks a co-promotion agreement for tasimelteon, BMS has a right of first negotiation to enter into such an agreement with the Company.

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.

VSF-173. In June 2004, the Company entered into a license agreement with Novartis under which the Company received an exclusive worldwide license to develop and commercialize VSF-173. In consideration for the license, the Company paid Novartis an initial license fee of \$500,000. The Company is also obligated to make future milestone payments to Novartis of less than \$50 million in the aggregate (the majority of which are tied to sales milestones) and royalty payments at rates which, as a percentage of net sales, range from the low-to-mid teens. In March 2007, the Company met its first milestone under this license agreement relating to the initiation of the Phase II clinical trial for VSF-173, and recorded a license fee expense of \$1,000,000.

Novartis has the right to co-develop and exclusively commercialize VSF-173 on its own after the completion of Phase II and Phase III programs in exchange for certain milestones and royalty payments. In the event that Novartis chooses not to exercise either of these options and the Company decides to enter into a partnering arrangement to commercialize VSF-173, Novartis has a right of first refusal to negotiate such an agreement with the Company, as well as a right to submit a last matching counteroffer regarding such an agreement. In addition, the rights with respect to VSF-173 may terminate, in whole or in part, if the Company fails to meet certain development and commercialization milestones described in the license agreement relating to the time it takes the Company to complete the development work on VSF-173. These rights may also terminate in whole or in part if the Company fails to make royalty or milestone payments or if the Company does not comply with requirements in the license agreement regarding its financial condition. In the event of an early termination of the license agreement, all rights licensed and developed by the Company under this agreement may revert back to Novartis.

Future license payments. No amounts were recorded as liabilities nor were any contractual obligations relating to the license agreements included in the condensed consolidated financial statements as of March 31, 2008, 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

The Company entered into agreements with several organizations to provide services relating to clinical development, clinical manufacturing activities and marketing services under fee service arrangements. The Company's current agreements for these 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

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of termination and other costs incurred by the Company's contractors in closing out work in progress as of the effective date of termination.

9. 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.

The Company has not recorded any tax provision or benefit for the three months ended March 31, 2008 or 2007, except for an estimated tax expense resulting from the research and development agreement with the Company's subsidiary in Singapore for the three month period ended March 31, 2007. 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 March 31, 2008 and December 31, 2007. 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.

10. 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. Under FAS No. 159, entities are permitted to choose to measure many financial instruments and certain other items at fair value. The Company did not elect the fair value measurement option under FAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* including an amendment to FAS 115 (SFAS 159), for any of its financial assets or liabilities.

SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

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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

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As of March 31, 2008, 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.

	Fair Value Measurements at Reporting Date Using			
	Quoted Prices			
	in			
	Active Markets			
	for			
	Identical Assets	Significant Other	Significant	
		Observable	Unobservable	
March 31,	(Level 1)	Inputs	Inputs	
2008	(Level 2)	(Level 3)		
Description :				
Available-for-sale securities	\$ 21,022,412	\$	\$ 21,022,412	\$
Total	\$ 21,022,412	\$	\$ 21,022,412	\$

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. (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 product candidates to be demonstrably safe and effective;

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

a lack of acceptance of our product candidates in the marketplace, or a failure to become or remain profitable;

our inability to obtain the capital necessary to fund our research and development activities;

our failure to identify or obtain rights to new product candidates;

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

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

losses incurred from product liability claims made against us; and

a loss of rights to develop and commercialize our products 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 "Risk Factors" of Part II of this quarterly report on Form 10-Q, 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 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 product candidates for central nervous system disorders, with exclusive worldwide commercial rights to three product candidates in clinical development. Our lead product candidate, Fanapta[™] (iloperidone, also previously referred to as Fiapta), is a compound for the treatment of schizophrenia and bipolar disorder. On November 27, 2007 the United States Food and Drug Administration (FDA) accepted our New Drug Application (NDA) for Fanapta[™] in schizophrenia. Our second product candidate, tasimelteon (VEC-162) is a compound for the treatment of sleep and mood disorders. In November 2006 we announced positive top-line results from our Phase III trial of tasimelteon in transient insomnia. In November 2007 we initiated, and in February 2008 we

completed, an enrollment in a Phase III trial of tasimelteon in chronic primary insomnia. Vanda expects to report top-line results in June 2008. Tasimelteon is also ready for Phase II trials for the treatment of depression. Our third product candidate, VSF-173, is a compound for the treatment of excessive sleepiness and is currently in a Phase II program.

We expect a decision from the FDA on the NDA for Fanapta™ in schizophrenia on or about July 27, 2008, its PDUFA action date, although the FDA may not meet, or may extend, the PDUFA action date. We will have to conduct additional Phase III trials for tasimelteon in chronic sleep disorders prior to our filing of an NDA for tasimelteon. We will have to conduct additional Phase II trials for VSF-173 in order to further its development. Assuming successful outcomes of our clinical trials and approval by the FDA, we expect to commercialize Fanapta™ and VSF-173 with our own sales force in the U.S. and through a partnership in non-U.S. markets, and expect to commercialize tasimelteon through a partnership with a global pharmaceutical company, although we have not yet identified such a global partner.

We are a development stage enterprise and have accumulated net losses of approximately \$193.1 million since the inception of our operations through March 31, 2008. We have no product revenues to date and have no approved products 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 product candidates. Our future operating results will depend largely on our ability to successfully develop and commercialize our lead product candidate, Fanapta™, and on the progress of other product candidates 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 Risk Factors of Part II of this quarterly report on Form 10-Q.

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 into the fourth quarter of 2008. If Fanapta™ is approved by the FDA on the expected PDUFA action date of or about July 27, 2008, the Company intends to pursue additional financing, in part to fund additional marketing and product launch costs. The Company believes that it would be able to raise sufficient capital to fund the product launch and operations into 2009. However, if the Company cannot obtain additional financing, management has the ability and intent to implement a reduced spending plan to fund operations at least through the first quarter of 2009. In budgeting for our activities, we have relied on a number of assumptions, including assumptions that we will continue to expend funds in preparation of a commercial launch of Fanapta™, that we will complete our Phase III clinical trial of tasimelteon for the treatment of chronic primary insomnia in accordance with our expectations, that we will not engage in further in-licensing activities, that we will not receive any proceeds from potential partnerships, that we will not expend funds on the bipolar indication for Fanapta™, that we will not conduct additional trials for the injectable formulation for Fanapta™, that we will not conduct additional trials for VSF-173, that we will continue to evaluate clinical and pre-clinical compounds for potential development, that we will be able to continue the manufacturing of our product candidates at commercially reasonable prices, that we will be able to retain our key personnel, and that we will not incur any significant contingent liabilities. We may need to raise additional funds more quickly if one or more of our assumptions proves to be incorrect, if we choose to expand our product development efforts more rapidly than presently anticipated, or if we seek to acquire additional product candidates. We may also decide to raise additional funds even before they are needed if the conditions for raising capital are favorable.

In our capital-raising efforts, we may seek to sell additional equity or debt 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.

We cannot assure you that additional capital will be available when we need it on terms that are acceptable to us, or at all. The unavailability of financing may require us to delay, scale back or eliminate expenditures for our research, development and marketing activities necessary to commercialize our potential biopharmaceutical products. If we are unable to secure sufficient capital to fund our research and development activities, we may not be able to continue operations or we may have to enter into collaboration agreements

that could require us to share commercial rights to our products to a greater extent or at earlier stages in the drug development process than we currently intend. Collaborations that are consummated by us prior to proof-of-efficacy and safety of a product candidate could impair our ability to realize value from that product candidate. In the absence of our ability to raise additional capital resources, we are prepared and have the ability to curtail the existing operating needs and commitments to have the operating funds through the first quarter of 2009.

Fanaptatm. Fanaptatm is our product candidate under development to treat schizophrenia and bipolar disorder. We submitted an NDA for Fanaptatm for the treatment of schizophrenia to the FDA on September 27, 2007 and on November 27, 2007 the FDA accepted our NDA. We continue to work closely with the FDA throughout their review process and anticipate a decision on our NDA on its PDUFA action date of or about July 27, 2008, although the FDA may not meet, or may extend, the PDUFA action date. The application includes data from 35 clinical trials and more than 3,000 patients treated with Fanaptatm and also contains pharmacogenetic data aimed to further improve the benefit/risk profile of Fanaptatm in the treatment of patients with schizophrenia.

From inception to March 31, 2008 we incurred approximately \$68.4 million in research and development costs directly attributable to our development of Fanaptatm, including a \$5.0 million milestone license fee paid to Novartis in 2007 upon the acceptance of our NDA.

We expect to increase our pre-launch commercial activities relating to Fanaptatm, and we expect to start marketing Fanaptatm commercially in early 2009. However, the time it takes to receive cash inflows from the sale of Fanaptatm is highly dependent on facts and circumstances that we may not be able to control and are subject to a number of risks. For example, delays in the approval process and subsequent commercial launch of Fanaptatm following our filing may occur if the FDA fails to attend to our filing in a timely manner or requires further data to approve Fanaptatm. Please see Item 1A Risk Factors of Part II of this quarterly report on Form 10-Q for a more detailed discussion of these and other risks.

We are also developing a 4-week injectable formulation for Fanaptatm, 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 conduct additional clinical trials following FDA approval of the oral dose formulation for Fanaptatm.

Tasimelteon. Tasimelteon is our product candidate 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 November 2007 we initiated and in February 2008 completed an enrollment in a Phase III trial of tasimelteon to evaluate the safety and efficacy of tasimelteon in chronic primary insomnia. The trial is a randomized, double-blind, and placebo-controlled study with 324 patients. The trial measures time to fall asleep and sleep maintenance, as well as next-day performance. We expect to complete the study and to report its top-line results in June 2008. We will have to conduct additional trials prior to our filing of an NDA for tasimelteon to treat sleep disorders. Tasimelteon is also ready for Phase II trials for the treatment of depression.

From inception to March 31, 2008, we incurred approximately \$47.6 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. VSF-173 is an oral compound that has demonstrated effects on animal sleep/wake patterns and gene expression suggestive of a stimulant effect. In a recently completed Phase II trial of VSF-173 in excessive sleepiness, the compound demonstrated improvement compared to placebo on the Maintenance of Wakefulness Test (MWT), though not statistically significant, and dose-dependent, statistically significant improvements versus placebo on a number of secondary endpoints taken in the recovery sleep period after dosing, including number of awakenings, and

sleep efficiency and wake after sleep onset in the first third of the recovery sleep period. VSF-173 was also demonstrated to be safe and well-tolerated. We will have to conduct additional Phase II trials of VSF-173 in order to further its development.

Excessive sleepiness is a common symptom that can significantly impair a person's ability to function. The effects of excessive sleepiness range from mild sleepiness to unrecognized episodes of microsleeps and uncontrollable sleep attacks. Excessive sleepiness is a symptom of many disorders, including obstructive sleep apnea, narcolepsy, shift worker sleep disorder, Parkinson's disease and Alzheimer's disease.

From inception to March 31, 2008, we incurred approximately \$6.3 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, 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, including payments made to date under our license agreements. 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 product candidates and pharmacogenetics and pharmacogenomics expertise. From inception through March, 31, 2008 we incurred research and development expenses in the aggregate of approximately \$136.8 million, including stock-based compensation expenses of approximately \$6.9 million. We expect our research and development expenses to increase as we continue to develop our product candidates. We also expect to incur licensing costs in the future that could be substantial, as we continue our efforts to develop our product candidates and to evaluate potential in-license product candidates.

The following table summarizes our product development initiatives for the three months ended March 31, 2008 and 2007 and for the period from March 13, 2003 (inception) to March 31, 2008. Included in this table are the research and development expenses recognized in connection with our product candidates in clinical development. Included in Other product candidates are the costs directly related to research initiatives for all other product candidates.

	Three Months Ended		Period from
	March 31,	March 31,	March 13,
	2008	2007	2003
			(Inception) to
			March 31,
			2008
Direct project costs(1)			
Fanapta™ (iloperidone)	\$ 2,326,000	\$ 5,322,000	\$ 68,370,000
Tasimelteon (VEC-162)	7,586,000	2,796,000	47,552,000
VSF-173	277,000	1,484,000	6,250,000
Other product candidates	459,000	459,000	5,588,000
Total direct product costs	10,648,000	10,061,000	127,760,000
Indirect project costs(1)			
Facility	148,000	131,000	1,727,000
Depreciation	89,000	110,000	1,775,000
Other indirect overhead	218,000	290,000	5,490,000

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Total indirect expenses	455,000	531,000	8,992,000
Total research and development expenses	\$ 11,103,000	\$ 10,592,000	\$ 136,752,000

- (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 that our general and administrative expenses will continue to increase as we support our discovery and research development efforts, for our commercial development activities and fulfill our reporting and other regulatory obligations applicable to public companies. From inception through March 31, 2008, we incurred general and administrative expenses in the aggregate of approximately \$66.0 million, including stock-based compensation expenses of approximately \$28.9 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, 2007 included in our annual report on Form 10-K. However, we believe that the following critical accounting policies relating to accrued expenses and stock-based compensation expense are important to understanding and evaluating our reported financial results, and we have accordingly included them in this quarterly report on Form 10-Q.

Accrued expenses

As part of the process of preparing financial statements we are required to estimate accrued expenses. The estimation of accrued expenses involves identifying services that have been performed on our behalf, and then estimating the level of service performed and the associated cost incurred for such services as of each balance sheet date in the financial statements. Accrued expenses include professional service fees, such as those for 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 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. 110 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 the inception and do not plan to pay dividends in the foreseeable future. The stock-based compensation expense for a period is also affected by expected forfeiture rate for the respective option grants. If our estimates of the fair value of these equity instruments or expected forfeitures are too high or too low, it would have the effect of overstating or understating expenses.

Total employee stock-based compensation expense recognized during the three months ending March 31, 2008 and 2007 was comprised of the following:

	Three Months Ended	
	March 31, 2008	March 31, 2007
Research and development	\$ 1,156,000	\$ 1,003,000
General and administrative	3,963,000	2,996,000
Stock-based compensation	\$ 5,119,000	\$ 3,999,000

Recent accounting pronouncements

In June 2007, the Emerging Issues Task Force issued EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3), which provides guidance to research and development companies on how to account for the nonrefundable portion of an advance payment made for research and development activities. We adopted EITF 07-3 on January 1, 2008 and this pronouncement has not had an impact on our results of operations and financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007) (SFAS 141R), *Business Combinations* and SFAS No. 160 (SFAS 160), *Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No. 51*. SFAS 141R will change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods. SFAS 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS 141R and SFAS 160 will be applied to acquisitions that close in years beginning after December 15, 2008. Early adoption is not permitted. These pronouncements are not expected to have significant impact on our results of operations and financial condition.

In December 2007, the FASB ratified EITF Issue 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). The consensus prohibits the equity method of accounting for collaborative arrangements under APB 18, *The Equity Method of Accounting for Investments in Common Stock*, unless a legal entity exists. Payments between the collaborative partners will be evaluated and reported in the income statement based on applicable GAAP. Absent specific GAAP, the participants to the arrangement will apply other existing GAAP by analogy or apply a reasonable

and rational accounting policy consistently. The guidance in Issue EITF 07-1 is effective for periods that begin after December 15, 2008 and will apply to arrangements in existence as of the effective date. The effect of the new consensus will be accounted for as a change in accounting principle through retrospective application. We are currently evaluating the impact of EITF 07-1 on our results of operations and financial condition.

In December 2007, the SEC issued SAB No. 110, *Share-Based Payment*, or SAB 110, which expresses the views of the SEC regarding the use of a simplified method, as discussed in SAB 107, in developing an