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, 2008

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File Number: 000-51863

VANDA PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	**03-0491827**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer) Identification No.*
9605 Medical Center Drive, Suite 300 Rockville, Maryland	**20850**
(Address of principal executive offices)	*(Zip Code*

(240) 599-4500

(Registrant's telephone number, including area code)

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

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

Large accelerated filer o	Accelerated filer ☑	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of August 8, 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 and Six Months Ended June 30, 2008

Part I — FINANCIAL INFORMATION

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

VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	June 30, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 56,503,815	$ 41,929,533
Marketable securities	6,564,684	43,243,960
Prepaid expenses, deposits and other current assets	2,030,329	1,781,881
Total current assets	65,098,828	86,955,374
Marketable securities, long-term	2,557,411	7,979,331
Property and equipment, net	2,021,374	1,345,845
Deposits	150,000	150,000
Restricted cash	430,230	430,230
Total assets	$ 70,257,843	$ 96,860,780
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,825,757	$ 2,988,069
Accrued liabilities	3,856,127	9,789,738
Total current liabilities	9,681,884	12,777,807
Deferred rent	490,776	354,042
Total liabilities	10,172,660	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 June 30, 2008 and December 31, 2007	—	—
Common stock, $0.001 par value; 150,000,000 shares authorized as of June 30, 2008 and December 31, 2007; and 26,652,728 shares issued and outstanding as of June 30, 2008 and December 31, 2007	26,653	26,653
Additional paid-in capital	266,674,962	257,600,368
Accumulated other comprehensive income (loss)	(15,155)	12,176
Deficit accumulated during the development stage	(206,601,277)	(173,910,266)
Total stockholders' equity	60,085,183	83,728,931
Total liabilities and stockholders' equity	$ 70,257,843	$ 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		Six Months Ended		Period from March 13, 2003 (Inception) to June 30, 2008
	June 30, 2008	June 30, 2007	June 30, 2008	June 30, 2007	
Revenues from services	$ —	$ —	$ —	$ —	$ 81,545
Operating expenses:					
Research and development	5,480,909	10,193,825	16,583,574	20,785,884	142,233,347
General and administrative	8,454,985	7,449,375	17,414,199	13,682,924	74,423,462
Total operating expenses	13,935,894	17,643,200	33,997,773	34,468,808	216,656,809
Loss from operations	(13,935,894)	(17,643,200)	(33,997,773)	(34,468,808)	(216,575,264)
Other income (expense):					
Interest income	441,012	1,659,781	1,306,762	3,093,435	10,005,551
Interest expense	—	—	—	—	(80,485)
Other income	—	—	—	—	71,947
Total other income	441,012	1,659,781	1,306,762	3,093,435	9,997,013
Loss before tax provision	(13,494,882)	(15,983,419)	(32,691,011)	(31,375,373)	(206,578,251)
Tax provision	—	1,604	—	2,410	23,026
Net loss	(13,494,882)	(15,985,023)	(32,691,011)	(31,377,783)	(206,601,277)
Beneficial conversion feature — deemed dividend to preferred stockholders	—	—	—	—	(33,486,623)
Net loss attributable to common stockholders	$ (13,494,882)	$ (15,985,023)	$ (32,691,011)	$ (31,377,783)	$ (240,087,900)
Basic and diluted net loss per share applicable to common stockholders	$ (0.51)	$ (0.60)	$ (1.23)	$ (1.21)	
Shares used in calculation of basic and diluted net loss per share applicable to common stockholders	26,649,439	26,567,160	26,648,892	25,978,437	

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

VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Comprehensive Loss	Total
	Shares	Par Value					
Balances at December 31, 2007	26,652,728	$ 26,653	$ 257,600,368	$ 12,176	$ (173,910,266)		$ 83,728,931
Employee stock-based compensation	—	—	9,085,978	—	—		9,085,978
Non-employee stock-based compensation	—	—	(11,384)	—	—		(11,384)
Comprehensive loss:							
Net loss	—	—	—	—	(32,691,011)	$ (32,691,011)	
Cumulative translation adjustment	—	—	—	16,220	—	16,220	
Net unrealized loss on marketable securities	—	—	—	(43,551)	—	(43,551)	
Comprehensive loss						$ (32,718,342)	(32,718,342)
Balances at June 30, 2008	26,652,728	$ 26,653	$ 266,674,962	$ (15,155)	$ (206,601,277)		$ 60,085,183

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

VANDA PHARMACEUTICALS INC.
(A Development Stage Enterprise)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Six Months Ended		Period from March 13, 2003 (Inception) to June 30, 2008
	June 30, 2008	June 30, 2007	
Cash flows from operating activities			
Net loss	$ (32,691,011)	$ (31,377,783)	$ (206,601,277)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	259,707	293,660	2,228,563
Employee and non-employee stock-based compensation	9,074,594	9,323,664	40,010,117
Loss on disposal of assets	211	—	57,842
Accretion of discount on investments	(195,911)	(859,296)	(2,188,068)
Changes in assets and liabilities:			
Prepaid expenses, deposits and other current assets	(247,729)	(1,354,085)	(2,030,329)
Deposits	—	—	(150,000)
Accounts payable	2,425,921	(183,682)	5,414,000
Accrued expenses	(5,979,353)	(33,290)	3,811,641
Other liabilities	136,734	(13,661)	490,776
Net cash used in operating activities	(27,216,837)	(24,204,473)	(158,956,735)
Cash flows from investing activities			
Purchases of property and equipment	(479,581)	(202,683)	(3,917,313)
Proceeds from sale of property and equipment	—	—	200,179
Purchases of marketable securities	(2,081,121)	(93,239,541)	(255,113,783)
Proceeds from sales of marketable securities	4,875,076	—	90,590,824
Maturities of marketable securities	39,460,000	23,025,000	157,575,000
Investment in restricted cash	—	—	(430,230)
Net cash provided by (used in) investing activities	41,774,374	(70,417,224)	(11,095,323)
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	—	79,587	307,510
Proceeds from issuance of common stock, net of issuance costs	—	111,254,850	164,588,801
Net cash provided by financing activities	—	111,334,437	226,599,701
Effect of foreign currency translation	16,745	(10,678)	(43,828)
Net increase in cash and cash equivalents	14,574,282	16,702,062	56,503,815
Cash and cash equivalents			
Beginning of period	41,929,533	30,928,895	—
End of period	$ 56,503,815	$ 47,630,957	$ 56,503,815

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

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, iloperidone, is a compound for the treatment of schizophrenia and bipolar disorder. The Company submitted a New Drug Application (NDA) for iloperidone 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 iloperidone in schizophrenia. In July 2008, the Company announced that the FDA had determined that Vanda's NDA was not approvable, which will require the Company, among other things, to conduct additional studies and submit that data before the FDA will approve iloperidone for commercial sale for the treatment of schizophrenia. The Company has suspended all iloperidone-related activities pending further review by management and discussion with the FDA. 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 June 2008 the Company announced positive top-line results from the Phase III trial of tasimelteon in chronic primary insomnia. 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, the satisfaction of certain regulatory requirements, payments received under contractual agreements with other parties, if any, and the status of competitive products. However, given the recent decision by the FDA with respect to the NDA for iloperidone, and that the additional studies required by the FDA prior to its approval of iloperidone would require significant capital in excess of the Company's currently available resources, the Company's management intends to operate under a reduced spending plan, and believes that the Company's existing cash, cash equivalents and marketable securities will be sufficient to fund operations at least through the fourth quarter of 2009 if such reduced spending plan is implemented. In budgeting for its activities, the Company has relied on a number of assumptions, including assumptions that the Company will not conduct any additional clinical trials for either of the oral or injectable formulations of iloperidone, that it will not expend funds on the bipolar indication for iloperidone, that it will not engage in any further commercial activities related to iloperidone, that it will not engage in further in-licensing activities, that it will not receive any proceeds from potential partnerships, that it will not conduct additional trials for tasimelteon or VSF-173, that it will be able to retain its key personnel, that it will amend the NDA for iloperidone and continue to seek FDA approval, that it will continue to evaluate clinical and pre-clinical compounds for potential development, and that it will not incur any significant contingent liabilities.

The Company may need to raise additional funds if one or more of its assumptions proves to be incorrect or if it chooses to resume its commercialization efforts with respect to iloperidone, expand its product

development efforts, conduct additional clinical trials for one or more of its product candidates 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 June 30, 2008 and for the periods of the three and six months ended June 30, 2008 and 2007 and for the period from March 13, 2003 (inception) to June 30, 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.

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.

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 June 30, 2008 that have been affected by the recent credit crisis. At June 30, 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 and six months ended June 30, 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.

Total stock-based compensation expense recognized during the three and six months ended June 30, 2008 and 2007 and the period from March 13, 2003 (inception) to June 30, 2008 was comprised of the following:

	Three Months Ended		Six Months Ended		Period from March 13, 2003 (Inception) to June 30, 2008
	June 30, 2008	June 30, 2007	June 30, 2008	June 30, 2007	
Research and development	$ 696,937	$ 1,191,998	$ 1,852,330	$ 2,195,367	$ 7,644,655
General and administrative	3,270,503	3,953,536	7,233,648	6,949,212	32,201,389
Stock-based compensation expense	$ 3,967,440	$ 5,145,534	$ 9,085,978	$ 9,144,579	$ 39,846,044
Stock-based compensation expense per basic and diluted share of common stock	$ 0.15	$ 0.19	$ 0.34	$ 0.35	
Shares used in calculation of stock-based compensation expense per share	26,649,439	26,567,160	26,648,892	25,978,437	

As of June 30, 2008, approximately $19.8 million of total unrecognized compensation costs related to non-vested awards are expected to be recognized over a weighted average period of 1.37 years.

As of June 30, 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 1,160,026 shares were subject to outstanding options granted under the 2004 Plan as of June 30, 2008, and no additional options will be granted under this plan. As of June 30, 2008 there are 3,451,250 shares of the Company's common stock reserved under the 2006 Plan of which 2,838,473 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 June 30, 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

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, 2008 and 2007 were as follows:

	Six Months Ended	
	June 30, 2008	June 30, 2007
Expected dividend yield	0%	0%
Weighted average expected volatility	68%	71% - 73%
Weighted average expected term (years)	6.05	6.25
Weighted average risk-free rate	3.28%	4.84%

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	(3,622)	4.53		
Cancelled	(6,327)	5.18		
Outstanding at June 30, 2008	1,160,026	1.74	7.23	$ 2,354,626
Exercisable at June 30, 2008	758,343	1.65	7.15	$ 1,600,107

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

	Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2007	1,768,635	$ 26.08		
Granted	1,122,000	5.63		
Forfeited	(10,316)	25.39		
Cancelled	(41,846)	17.76		
Outstanding at June 30, 2008	2,838,473	18.11	9.00	$ —
Exercisable at June 30, 2008	716,386	23.38	8.72	$ —

The weighted average grant-date fair value of options granted during the six months ended June 30, 2008 was $3.07 per share. For the six months ended June 30, 2008 and 2007 the Company received a total of $0 and $79,587, 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

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 the Company's product candidate iloperidone, in anticipation of its potential 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.

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 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.

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 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		Six Months Ended	
	June 30, 2008	June 30, 2007	June 30, 2008	June 30, 2007
Numerator:				
Net loss	$ (13,494,882)	$ (15,985,023)	$ (32,691,011)	$ (31,377,783)
Denominator:				
Weighted average shares of common stock outstanding	26,652,728	26,587,482	26,652,728	26,001,078
Weighted average unvested shares of common stock subject to repurchase	(3,289)	(20,322)	(3,836)	(22,641)
Denominator for basic and diluted net loss per share	26,649,439	26,567,160	26,648,892	25,978,437
Basic and diluted net loss per share applicable to common stockholders	$ (0.51)	$ (0.60)	$ (1.23)	$ (1.21)
Anti-dilutive securities not included in diluted net loss per share calculation:				
Options to purchase common stock	3,998,499	2,840,684	3,998,499	2,840,684

4. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of June 30, 2008:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Short-term :				
U.S. Treasury and government agencies	$ 2,000,174	$ —	$ (470)	$ 1,999,704
U.S. corporate debt	4,589,638	428	(25,086)	4,564,980
	$ 6,589,812	$ 428	$ (25,556)	$ 6,564,684
Long-term:				
U.S. asset-based securities	$ 2,547,438	$ 9,973	$ —	$ 2,557,411

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 June 30, 2008, and December 31, 2007:

	June 30, 2008	December 31, 2007
Current deposits with vendors	$ 455,000	$ 455,000
Prepaid insurance	806,171	395,203
Prepaid research and development expenses	390,195	175,955
Accrued interest income	129,328	603,556
Other prepaid expenses	249,635	146,771
Other receivables	—	5,396
	$ 2,030,329	$ 1,781,881

6. Property and Equipment

The following is a summary of the Company's property and equipment — at cost, as of June 30, 2008, and December 31, 2007:

	Estimated Useful Life (Years)	June 30, 2008	December 31, 2007
Laboratory equipment	5	$ 1,356,133	$ 1,281,877
Computer equipment	3	776,921	758,776
Furniture and fixtures	7	705,784	187,317
Leasehold improvements	10	828,287	505,684
		3,667,125	2,733,654
Less — accumulated depreciation and amortization		(1,645,751)	(1,387,809)
		$ 2,021,374	$ 1,345,845

Depreciation and amortization expense for the six months ended June 30, 2008 and 2007 were $259,707 and $293,660, respectively, and for the period from March 13, 2003 (inception) to June 30, 2008 was $2,228,563.

7. Accrued Liabilities

The following is a summary of accrued liabilities, as of June 30, 2008, and December 31, 2007:

	June 30, 2008	December 31, 2007
Accrued research and development expenses	$ 1,938,161	$ 7,151,360
Bonus accrual	562,918	957,035
Accrued consulting and other professional fees	1,077,623	1,307,650
Employee benefits	252,816	168,275
Lease abandonment	—	84,617
Other accrued expenses	24,609	120,801
	$ 3,856,127	$ 9,789,738

8. Commitments and Contingencies

Operating leases

The Company has commitments totaling approximately $6.0 million under operating real estate leases for its headquarters located in Rockville, Maryland, expiring in 2016.

Guarantees and indemnifications

The Company has entered into a number of standard intellectual property indemnification agreements in the ordinary course of its business. Pursuant to these agreements, the Company has agreed to indemnify, hold harmless, and 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 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 June 30, 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.

Iloperidone. The Company acquired exclusive worldwide rights to patents for 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. 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 iloperidone 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 iloperidone 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 iloperidone 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 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 June 30, 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 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 six months ended June 30, 2008 or 2007, except for an estimated tax expense resulting from the research and development agreement with the Company's former subsidiary in Singapore for the six months ended June 30, 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 June 30, 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. Trading in shares of the company's stock has resulted "ownership changes" as defined in Section 382 of the Internal Revenue Code of 1986, as amended. As a result, the Company's net operating loss carry forwards totaling $104 million at December 31, 2007 are subject to an annual limitation pursuant to the provisions of Section 382, which the company estimates to be significant.

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:

- 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, 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		
	June 30, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Description :				
Available-for-sale securities	$ 9,122,095	$ —	$ 9,122,095	$ —
Total	$ 9,122,095	$ —	$ 9,122,095	$ —

11. Subsequent Event.

On July 25, 2008, the Company received a letter from the FDA stating that the Company's NDA for iloperidone in schizophrenia was not approvable. The FDA indicated that it would require an additional clinical trial comparing iloperidone to placebo and including an active comparator such as olanzapine (Zyprexa®, Eli Lilly and Company) or risperidone (Risperdal®, Ortho-McNeil-Janssen Pharmaceuticals, Inc.) in patients with schizophrenia to further demonstrate the compound's efficacy. The FDA also stated that it would require the Company to obtain additional safety data for patients at a dose range of 20 to 24 mg/day of iloperidone.

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

Various statements in this report are "forward-looking statements" under the securities laws. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," and "could," and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Vanda Pharmaceuticals Inc. (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, iloperidone 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 iloperidone in schizophrenia. In July 2008, we announced that the FDA had determined that our NDA was not approvable, which will require us, among other things, to conduct additional studies and submit that data before the FDA will approve iloperidone for commercial sale for the treatment of schizophrenia. We have suspended all iloperidone-related activities

pending further review by management and discussion with the FDA. 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 June 2008 the Company announced positive top-line results from the Phase III trial of tasimelteon in chronic primary insomnia. 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 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 iloperidone 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 $206.6 million since the inception of our operations through June 30, 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, iloperidone, 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.

Our activities will necessitate significant uses of working capital throughout 2008 and beyond. Additionally, our capital requirements will depend on many factors, including the success of our research and development efforts, the satisfaction of certain regulatory requirements, payments received under contractual agreements with other parties, if any, and the status of competitive products. However, given the recent decision by the FDA with respect to the NDA for iloperidone, and that the additional studies required by the FDA prior to its approval of iloperidone would require significant capital in excess of our currently available resources, our management intends to operate under a reduced spending plan, and believes that our existing cash, cash equivalents and marketable securities will be sufficient to fund operations at least through the fourth quarter of 2009 if such reduced spending plan is implemented. In budgeting for our activities, we have relied on a number of assumptions, including assumptions that we will not conduct any additional clinical trials for either of the oral or injectable formulations of iloperidone, that we will not expend funds on the bipolar indication for iloperidone, that we will not engage in any further commercial activities related to iloperidone, that we will not engage in further in-licensing activities, that we will not receive any proceeds from potential partnerships, that we will not conduct additional trials for tasimelteon or VSF-173, that we will be able to retain our key personnel, that we will amend the NDA for iloperidone and continue to seek FDA approval, that we will continue to evaluate clinical and pre-clinical compounds for potential development, and that we will not incur any significant contingent liabilities.

We may need to raise additional funds if one or more of our assumptions proves to be incorrect or if we choose to resume our commercialization efforts with respect to iloperidone, expand our product development efforts, conduct additional clinical trials for one or more of our product candidates or seek to acquire additional product candidates, and we may 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. However, we may not be able to raise additional funds on acceptable terms, or at all. If we are unable to secure sufficient capital to fund our 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 is currently intended. These collaborations, if

consummated prior to proof-of-efficacy or safety of a given product candidate, could impair our ability to realize value from that product candidate.

Iloperidone. Iloperidone is our product candidate under development to treat schizophrenia and bipolar disorder. We submitted an NDA for iloperidone 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 iloperidone and also contained pharmacogenetic data aimed to further improve the benefit/risk profile of iloperidone in the treatment of patients with schizophrenia. In July 2008, we announced that the FDA had determined that our NDA was not approvable, which will require us, among other things, to conduct additional studies and submit that data before the FDA will approve iloperidone for commercial sale for the treatment of schizophrenia. Performance and completion of these additional studies will require years of testing and, even if positive results are achieved, may not result in the FDA's approval of iloperidone. We have suspended all iloperidone-related activities pending further review by management and discussion with the FDA.

From inception to June 30, 2008 we incurred approximately $70.5 million in research and development costs directly attributable to our development of iloperidone, including a $5.0 million milestone license fee paid to Novartis in 2007 upon the acceptance of our NDA.

We are also developing a 4-week injectable formulation for iloperidone, 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 iloperidone.

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 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. 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 June 30, 2008, we incurred approximately $49.7 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 June 30, 2008, we incurred approximately $6.5 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 June 30, 2008 we incurred research and development expenses in the aggregate of approximately $142.2 million, including stock-based compensation expenses of approximately $7.6 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 and six months ended June 30, 2008 and 2007 and for the period from March 13, 2003 (inception) to June 30, 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		Six Months Ended		Period from March 13, 2003 (Inception) to June 30, 2008
	June 30, 2008	June 30, 2007	June 30, 2008	June 30, 2007	
Direct project costs(1)					
iloperidone	$ 2,090,000	$ 5,072,000	$ 4,417,000	$ 10,394,000	$ 70,460,000
Tasimelteon (VEC-162)	2,179,000	3,233,000	9,764,000	6,028,000	49,731,000
VSF-173	281,000	811,000	558,000	2,295,000	6,531,000
Other product candidates	465,000	446,000	945,000	906,000	6,053,000
Total direct product costs	5,015,000	9,562,000	15,684,000	19,623,000	132,775,000
Indirect project costs(1)					
Facility	222,000	151,000	369,000	282,000	1,949,000
Depreciation	110,000	115,000	178,000	225,000	1,885,000
Other indirect overhead	134,000	366,000	353,000	656,000	5,624,000
Total indirect expenses	466,000	632,000	900,000	1,163,000	9,458,000
Total research and development expenses	$ 5,481,000	$ 10,194,000	$ 16,584,000	$ 20,786,000	$ 142,233,000

(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 June 30, 2008, we incurred general and administrative expenses in the aggregate of approximately $74.4 million, including stock-based compensation expenses of approximately $32.2 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 stock-based compensation expense recognized during the three and six months ending June 30, 2008 and 2007 was comprised of the following:

	Three Months Ended		Six Months Ended	
	June 30, 2008	June 30, 2007	June 30, 2008	June 30, 2007
Research and development	$ 697,000	$ 1,192,000	$ 1,852,000	$ 2,195,000
General and administrative	3,270,000	3,954,000	7,234,000	6,949,000
Stock-based compensation expense	$ 3,967,000	$ 5,146,000	$ 9,086,000	$ 9,144,000

Recent accounting pronouncements

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.

Results of Operations

We have a limited history of operations. We anticipate that our quarterly 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, and the timing and outcome of clinical trials and related possible regulatory approvals. Our limited operating history makes predictions of future operations difficult or impossible. Since our inception, we have incurred significant losses. As of June 30, 2008, we had a deficit accumulated during the development stage of approximately $206.6 million. We anticipate incurring additional losses for the foreseeable future and these losses may be incurred at increasing rates.

Three months ended June 30, 2008 compared to three months ended June 30, 2007

Research and development expenses. Research and development expenses decreased by approximately $4.7 million, or 46.2%, to approximately $5.5 million for the three months ended June 30, 2008 compared to approximately $10.2 million for the three months ended June 30, 2007.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the three months ended June 30, 2008 and 2007:

	Three Months Ended	
	June 30, 2008	June 30, 2007
Direct project costs:		
Clinical trials	$ 1,034,000	$ 2,117,000
Contract research and development, consulting, materials and other direct costs	2,181,000	5,288,000
Salaries, benefits and related costs	1,103,000	965,000
Stock-based compensation	697,000	1,192,000
Total direct costs	5,015,000	9,562,000
Indirect project costs	466,000	632,000
Total	$ 5,481,000	$ 10,194,000

Direct costs decreased approximately $4.5 million for the three months ended June 30, 2008 compared to the three months ended June 30, 2007 as a result of lower expenses relating to our NDA for iloperidone and lower clinical trial expenses. Clinical trials expense decreased approximately $1.1 million for the three months ended June 30, 2008 compared to the three months ended June 30, 2007 primarily due to lower clinical trial costs relating to tasimelteon and iloperidone. Contract research and development, consulting, materials and other direct costs decreased approximately $3.1 million for the three months ended June 30, 2008 relative to the three months ended June 30, 2007, primarily as a result of decreased iloperidone NDA related expenses and manufacturing costs related to tasimelteon. Salaries, benefits and related costs increased approximately $139,000 for the three months ended June 30, 2008 relative to the three months ended June 30, 2007 primarily due to cost of living adjustments. Stock-based compensation expense decreased by approximately $495,000 compared to the three months ended June 30, 2007 as a result of the lower fair market value of options granted during the 2008.

General and administrative expenses. General and administrative expenses increased by approximately $1.0 million, or 13.5%, to approximately $8.5 million for the three months ended June 30, 2008 from approximately $7.4 million for the three months ended June 30, 2007.

The following table discloses the components of our general and administrative expenses for the three months ended June 30, 2008 and 2007:

	Three Months Ended	
	June 30, 2008	June 30, 2007
Salaries, benefits and related costs	$ 1,099,000	$ 786,000
Stock-based compensation	3,271,000	3,954,000
Marketing and related consulting services	2,487,000	976,000
Legal, accounting and other professional expenses	812,000	935,000
Other expenses	786,000	798,000
Total	$ 8,455,000	$ 7,449,000

Salaries, benefits and related costs increased by approximately $313,000 for the three months ended June 30, 2008 compared to the three months ended June 30, 2007 primarily due to an increase in marketing

personnel as we continued to build our marketing capabilities in anticipation of the commercial launch of iloperidone and cost of living adjustments. Stock-based compensation expense decreased by approximately $683,000 for the three months ended June 30, 2008, compared to the three months ended June 30, 2007, as a result of the lower fair market value of options granted during 2008. Marketing and related consulting services expenses increased by approximately $1.5 million for the three months ended June 30, 2008, relative to the three months ended June 30, 2007, due to the increase in marketing activity related to our anticipated commercial launch of iloperidone. These increased expenses include market research, branding, medical community cultivation and publication planning costs. The Company has suspended all iloperidone-related activities pending further review by management and discussion with the FDA. Legal, accounting and other professional costs decreased by approximately $123,000 for the three months ended June 30, 2008 compared to the three months ended June 30, 2007 due primarily to lower professional fees related to compliance with the Sarbanes-Oxley Act of 2002.

Other income, net. Interest and other income in the three months ended June 30, 2008 was approximately $441,000 compared to approximately $1.7 million in the three months ended June 30, 2007. Interest income was lower for the three months ended June 30, 2008, compared to the three months ended June 30, 2007, due to lower average cash balances and lower short-term interest rates for the three months ended June 30, 2008.

Our interest income for the three months ended June 30, 2008 and 2007 are disclosed on the following table:

	Three Months Ended	
	June 30, 2008	June 30, 2007
Interest income	$441,000	$1,660,000

Six months ended June 30, 2008 compared to six months ended June 30, 2007

Research and development expenses. Research and development expenses decreased by approximately $4.2 million, or 20.2%, to approximately $16.6 million for the six months ended June 30, 2008 compared to approximately $20.8 million for the six months ended June 30, 2007.

The following table discloses the components of research and development expenses reflecting all of our project expenses for the six months ended June 30, 2008 and 2007:

	Six Months Ended	
	June 30, 2008	June 30, 2007
Direct project costs:		
Clinical trials	$ 7,198,000	$ 4,879,000
Contract research and development, consulting, materials and other direct costs	4,420,000	9,530,000
Milestone license fees	—	1,000,000
Salaries, benefits and related costs	2,214,000	2,019,000
Stock-based compensation	1,852,000	2,195,000
Total direct costs	15,684,000	19,623,000
Indirect project costs	900,000	1,163,000
Total	$ 16,584,000	$ 20,786,000

Direct costs decreased approximately $3.9 million for the six months ended June 30, 2008 compared to the six months ended June 30, 2007 as a result of lower expenses relating to our NDA for iloperidone and the absence of any milestone license fee payments in 2008. Clinical trials expense increased approximately $2.3 million for the six months ended June 30, 2008 compared to the six months ended June 30, 2007 primarily due to the cost incurred during the six months ended June 30, 2008 in our Phase III clinical

trial of tasimelteon that we initiated during the fourth quarter of 2007. Contract research and development, consulting, materials and other direct costs decreased approximately $5.1 million for the six months ended June 30, 2008 relative to the six months ended June 30, 2007, primarily as a result of decreased iloperidone NDA related expenses and lower tasimelteon manufacturing costs. Salaries, benefits and related costs increased approximately $195,000 for the six months ended June 30, 2008 relative to the six months ended June 30, 2007 primarily due to cost of living adjustments. Stock-based compensation expense decreased by approximately $343,000 compared to the six months ended June 30, 2007 as a result of the lower fair market value of options granted during the six months ended June 30, 2008.

General and administrative expenses. General and administrative expenses increased by approximately $3.7 million, or 27.3% to approximately $17.4 million for the six months ended June 30, 2008 from approximately $13.7 million for the six months ended June 30, 2007.

The following table discloses the components of our general and administrative expenses for the six months ended June 30, 2008 and 2007:

	Six Months Ended	
	June 30, 2008	June 30, 2007
Salaries, benefits and related costs	$ 2,089,000	$ 1,571,000
Stock-based compensation	7,234,000	6,949,000
Marketing and related consulting services	4,818,000	1,969,000
Legal, accounting and other professional expenses	1,700,000	1,661,000
Other expenses	1,573,000	1,533,000
Total	$ 17,414,000	$ 13,683,000

Salaries, benefits and related costs increased by approximately $518,000 for the six months ended June 30, 2008 compared to the six months ended June 30, 2007 due to an increase in marketing personnel as we continued to build our marketing capabilities in anticipation of the potential commercial launch of iloperidone and cost of living adjustments. Stock-based compensation expense increased by approximately $285,000 for the six months ended June 30, 2008, compared to the six months ended June 30, 2007, as a result of additional options granted during the six months ended June 30, 2008. Marketing and related consulting services expenses increased by approximately $2.8 million for the six months ended June 30, 2008, relative to the six months ended June 30, 2007, due to the increase in marketing activity related to our anticipated commercial launch of iloperidone. These increased expenses include market research, branding, medical community cultivation, and publication planning costs.

Other income, net. Interest and other income in the six months ended June 30, 2008 was approximately $1.3 million compared to approximately $3.1 million in the six months ended June 30, 2007. Interest income was lower for the six months ended June 30, 2008, compared to the six months ended June 30, 2007, due to lower average cash balances and lower short-term interest rates for the six months ended June 30, 2008.

Our interest income for the six months ended June 30, 2008 and 2007 are disclosed on the following table:

	Six Months Ended	
	June 30, 2008	June 30, 2007
Interest income	$1,307,000	$3,093,000

Liquidity and Capital Resources

We have funded our operations through June 30, 2008 principally with the net proceeds from private preferred stock offerings of 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, 2008, our total cash and cash equivalents and marketable securities were approximately $65.6 million compared to approximately $93.2 million at December 31, 2007. 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, 2008 the Company also held a non-current deposit of $430,000 that is used to collateralize a letter of credit issued for its current office lease expiring in 2016.

As of June 30, 2008 and December 31, 2007, our liquidity resources are summarized as follows:

	June 30, 2008	December 31, 2007
Cash and cash equivalents	$ 56,504,000	$ 41,930,000
U.S. Treasury and government agencies	2,000,000	3,980,000
U.S. corporate debt	4,565,000	33,339,000
U.S. asset-backed securities	—	5,925,000
Marketable securities, short-term	6,565,000	43,244,000
U.S. Treasury and government agencies	—	2,002,000
U.S. corporate debt	—	1,970,000
U.S. asset-backed securities	2,557,000	4,007,000
Marketable securities, long-term	2,557,000	7,979,000
Total	$ 65,626,000	$ 93,153,000
Restricted cash	$ 430,000	$ 430,000

As of June 30, 2008, 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.

Our activities will necessitate significant uses of working capital throughout 2008 and beyond. Additionally, our capital requirements will depend on many factors, including the success of our research and development efforts, the satisfaction of certain regulatory requirements, payments received under contractual agreements with other parties, if any, and the status of competitive products. However, given the recent decision by the FDA with respect to the NDA for iloperidone, and that the additional studies required by the FDA prior to its approval of iloperidone would require significant capital in excess of our currently available resources, our management intends to operate under a reduced spending plan, and believes that our existing cash, cash equivalents and marketable securities will be sufficient to fund operations at least through the fourth quarter of 2009 if such reduced spending plan is implemented. In budgeting for our activities, we have relied on a number of assumptions, including assumptions that we will not conduct any additional clinical trials for either of the oral or injectable formulations of iloperidone, that we will not expend funds on the bipolar indication for iloperidone, that we will not engage in any further commercial activities related to iloperidone, that we will not engage in further in-licensing activities, that we will not receive any proceeds from potential partnerships, that we will not conduct additional trials for tasimelteon or VSF-173, that we will be able to retain our key personnel, that we will amend the NDA for iloperidone and continue to seek FDA approval, that we will continue to evaluate clinical and pre-clinical compounds for potential development, and that we will not incur any significant contingent liabilities.

We may need to raise additional funds if one or more of our assumptions proves to be incorrect or if we choose to resume our commercialization efforts with respect to iloperidone, expand our product development efforts, conduct additional clinical trials for one or more of our product candidates or seek to acquire additional product candidates, and we may 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. However, we may not be able to raise additional funds on acceptable terms, or at all. If we are unable to secure sufficient capital to fund our 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 is currently intended. These collaborations, if consummated prior to proof-of-efficacy or safety of a given product candidate, could impair our ability to realize value from that product candidate.

Cash Flow

The following table summarizes our cash flows for the six months ended June 30, 2008, and June 30, 2007:

	Six Months Ended	
	June 30, 2008	June 30, 2007
Net cash provided by (used in)		
Operating activities	$ (27,217,000)	$ (24,204,000)
Investing activities	41,774,000	(70,417,000)
Financing activities	—	111,334,000
Exchange rate effect on cash and equivalents	17,000	(11,000)
Net increase in cash and cash equivalents	$ 14,574,000	$ 16,702,000

Net cash used in operations was approximately $27.2 million and approximately $24.2 million for the six months ended June 30, 2008 and 2007, respectively. The net loss for the six months ended June 30, 2008 of approximately $32.7 million was offset primarily by non-cash charges for stock-based compensation of approximately $9.1 million, by depreciation and amortization of approximately $260,000, by an increase in prepaid expenses of approximately $248,000, by a decrease in accrued expenses and accounts payable of approximately $3.6 million, and other net changes in working capital. Net cash provided by investing activities for the six months ended June 30, 2008 was approximately $41.8 million and consisted primarily of net proceeds of marketable securities of approximately $42.3 million offset by $480,000 of capital expenditures. There was no cash provided by financing activities for the six months ended June 30, 2008.

Contractual Obligations and Commitments

The following table summarizes our long-term contractual cash obligations as of June 30, 2008:

	Cash Payments Due by Period						
	Total	July to December 2008	2009	2010	2011	2012	After 2012
Operating leases	$6,006,000	$333,000	$685,000	$706,000	$727,000	$749,000	$2,806,000

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.

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 iloperidone 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 commercial activities and our ongoing clinical development processes. These contractual obligations are not reflected in the table above because we may terminate them on no more than 60 days notice without incurring additional charges (other than charges for work completed but not paid

for through the effective date of termination and other costs incurred by our contractors in closing out work in progress as of the effective date of termination).

License agreements

In February 2004 and June 2004, we entered into separate licensing agreements with Bristol-Myers Squibb and Novartis, respectively, for the exclusive rights to develop and commercialize our three compounds 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 Bristol-Myers Squibb and made an associated milestone payment 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 made an associated milestone payment of $1.0 million. In November 2007, the Company met a milestone under this license agreement with Novartis relating to the acceptance of the NDA for iloperidone in schizophrenia and made a license payment of $5.0 million to Novartis. No other amounts were recorded as liabilities nor were any other contractual obligations relating to the license agreements included in the condensed consolidated financial statements as of June 30, 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 FDA regulatory approvals, growth in product sales and other factors. 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” of this quarterly report on Form 10-Q.

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. 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 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:

- 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, 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		
	June 30, 2008	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Description :				
Available-for-sale securities	$ 9,122,000	$ —	$ 9,122,000	$ —
Total	$ 9,122,000	$ —	$ 9,122,000	$ —

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

Foreign Exchange

We currently incur a portion of our operating expenses in currencies other than U.S. dollars, the reporting currency for our consolidated financial statements, and we have determined that such operating expenses have not been significant to date. As a result, we have not been impacted materially by changes in exchange rates and do not expect to be impacted materially for the foreseeable future. However, if our operating expenses incurred outside of the United States increase, our results of operations could be adversely impacted by changes in exchange rates. We do not currently hedge foreign currency exposure and do not intend to do so in the foreseeable future.

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 a change 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 Company's management, including the Chief Executive Officer and Chief Financial Officer, the Company evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2008. Based upon that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective as of June 30, 2008, the end of the period covered by this quarterly report, to ensure that the information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the second quarter of 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

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

None.

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

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 condensed consolidated financial statements and the related notes contained 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

If we fail to obtain approval for and commercialize our most advanced product candidate, iloperidone, we may have to curtail our product development programs and our business would be materially harmed.

We have invested a significant portion of our time, financial resources and collaboration efforts in the development of our most advanced product candidate, iloperidone, a compound for the treatment of schizophrenia and bipolar disorder. Our near-term ability to generate revenues and our future success, in large part, depends on the development and commercialization of iloperidone.

In November 2007, we announced that the FDA had accepted our New Drug Application (NDA) for iloperidone in schizophrenia. On July 25, 2008, the Company received a letter from the FDA stating that our NDA for iloperidone in schizophrenia was not approvable. The FDA indicated that it would require an additional clinical trial comparing iloperidone to placebo and including an active comparator such as olanzapine (Zyprexa®, Eli Lilly and Company) or risperidone (Risperdal®, Ortho-McNeil-Janssen Pharmaceuticals, Inc.) in patients with schizophrenia to further demonstrate the compound's efficacy. The FDA also stated that it would require the Company to obtain additional safety data for patients at a dose range of 20 to 24 mg/day of iloperidone. If we are unable to satisfactorily demonstrate efficacy compared to placebo as well as an active comparator, if the FDA disagrees with our characterization approach or does not agree that we have demonstrated adequate efficacy for iloperidone, if we fail to resolve questions raised in the FDA's correspondence regarding the iloperidone NDA or if we otherwise fail to meet FDA requirements for the NDA or obtain FDA approval for, and successfully commercialize, iloperidone, we may never realize revenue from this product and we may have to curtail our other product development programs. As a result, our business would be materially harmed.

Our success is dependent on the success of our three product candidates in clinical development: iloperidone, tasimelteon and VSF-173. If any of these product candidates are determined to be unsafe or ineffective in humans, whether in clinical trials or commercially, our business will be materially harmed.

Despite the positive results of our completed trials, we are uncertain whether any of our current product candidates in clinical development will ultimately prove to be effective and safe in humans. Frequently, product candidates 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 any of our product candidates, whether in clinical trials or commercially, may reveal that the product candidate 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 product candidates could severely harm our business.

Pre-clinical studies and clinical trials required to demonstrate the safety and efficacy of our product candidates are time-consuming and expensive and together take several years to complete. The completion of clinical trials for our product candidates 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 product candidates 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 any of our product candidates, we may not receive the regulatory approvals needed to market that product candidate. Therefore, any failure or delay in commencing or completing these clinical trials would harm our business materially.

We face heavy government regulation, and FDA regulatory approval of our products is uncertain.

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 product candidates.

Moreover, if and when our products do obtain marketing approval, the marketing, distribution and manufacture of such products would 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 product candidates could diminish competitive advantages that we may attain and would adversely affect the marketing of our products. We have not received regulatory approval to market any of our product candidates in any jurisdiction.

In November 2007, we announced that the FDA had accepted the NDA for iloperidone in schizophrenia. In July 2008, we announced that the FDA had determined that our NDA was not approvable, which will require us, among other things, to conduct additional studies and submit that data before the FDA will approve iloperidone for commercial sale for the treatment of schizophrenia. Performance and completion of additional clinical studies will require years of testing and, even if positive results are achieved, may not result in the FDA's approval of iloperidone.

Even if we do receive regulatory approval for our drug candidates, 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 product candidates 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 product candidates 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 our product candidates and generating revenues from their sale. For example, like many other drugs in its class, iloperidone is associated with a prolongation of the heart's QTc interval, which is a measurement of specific electrical activity in the heart as captured on an electrocardiogram, corrected for heart rate. A QTc interval that is significantly prolonged may result in an abnormal heart rhythm with adverse consequences including fainting, dizziness, loss of consciousness and death. No patient in the controlled portion of any of iloperidone's clinical trials was observed to have an interval that exceeded a 500-millisecond threshold of particular concern to the FDA. Two patients experienced a prolongation of 500 milliseconds or more during the open-label extension of one trial. We will continue to assess the side effect profile of iloperidone and our other product candidates in our ongoing clinical development program.

In addition, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the 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 candidate, which in turn could delay or prevent us from generating significant revenues from its sale.

Our product candidates may never achieve market acceptance even if we obtain regulatory approvals.

Even if we receive regulatory approvals for the sale of our product candidates, 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 of our product candidates 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 the product candidate, and the effectiveness of our marketing and distribution capabilities. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. If our product candidates 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, we may be unable to continue operations or we may be forced to share our rights to commercialize our product candidates with third parties on terms that may not be attractive to us.

Our activities will necessitate significant uses of working capital throughout 2008 and beyond. Additionally, our capital requirements will depend on many factors, including the success of our research and development efforts, the satisfaction of certain regulatory requirements, payments received under contractual agreements with other parties, if any, and the status of competitive products. However, given the recent decision by the FDA with respect to the NDA for iloperidone, and that the additional study or studies required by the FDA in order to obtain approval of iloperidone would require significant capital in excess of our currently available resources, our management intends to operate under a reduced spending plan, and believes that our existing cash, cash equivalents and marketable securities will be sufficient to fund operations at least through the fourth quarter of 2009 if such reduced spending plan is implemented. In budgeting for our activities, we have relied on a number of assumptions, including assumptions that we will not conduct any additional clinical trials for either of the oral or injectable formulations of iloperidone, that we will not expend funds on the bipolar indication for iloperidone, that we will not engage in any further commercial activities

related to iloperidone, that we will not engage in further in-licensing activities, that we will not receive any proceeds from potential partnerships, that we will not conduct additional trials for tasimelteon or VSF-173, that we will be able to retain our key personnel, that we will amend the NDA for iloperidone and continue to seek FDA approval, that we will continue to evaluate clinical and pre-clinical compounds for potential development, and that we will not incur any significant contingent liabilities.

We may need to raise additional funds if one or more of our assumptions proves to be incorrect or if we choose to resume our commercialization efforts with respect to iloperidone, expand our product development efforts, conduct additional clinical trials for one or more of our product candidates or seek to acquire additional product candidates, and we may 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. However, we may not be able to raise additional funds on acceptable terms, or at all. If we are unable to secure sufficient capital to fund our 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 is currently intended. These collaborations, if consummated prior to proof-of-efficacy or safety of a given product candidate, could impair our ability to realize value from that product candidate.

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. 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 as we 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 and product candidates since March 2003. As of June 30, 2008, we have accumulated net losses of approximately $206.6 million. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, 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 product candidates. 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 product candidates. Moreover, these parties may also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors, it could harm our competitive position.

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 product candidates could be delayed.

We rely on a limited number of manufacturers for our product candidates 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 product candidates. 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 product candidates in a timely manner from these third parties could delay clinical trials and prevent us from developing our product candidates in a cost-effective manner or on a timely basis. In addition, manufacturers of our product candidates 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 product candidates could be interrupted, resulting in delays and additional costs. In addition, if the facilities of such manufacturers do not pass a pre-approval plant inspection, the FDA will not grant approval of our products.

Our manufacturing strategy presents the following additional risks:

- the manufacturing process for VSF-173 has not been tested in quantities needed for continued clinical trials or commercial sales, and delays in scale-up to commercial quantities of tasimelteon and VSF-173 could delay clinical trials, regulatory submissions and commercialization of these product candidates
- 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 compounds, our manufacturers may not be able to successfully manufacture our compounds in a cost-effective and/or timely manner

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

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. 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 and potential regulatory approval of our product candidates could be delayed, significantly affecting our ability to develop our product candidates. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would materially affect our ability to generate revenues from the sale of our product candidates.

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 product candidates and our ability to identify and develop additional product candidates through the application of our pharmacogenetics and pharmacogenomics expertise. Large, fully integrated pharmaceutical companies, either alone or together with collaborative partners, have substantially greater financial resources and have significantly greater experience than we do in:

- developing products
- 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 product candidates obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing superior products or other competing products before we do.

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

- For iloperidone in the treatment of schizophrenia, the atypical antipsychotics Risperdal® (risperidone), including the depot formulation Risperdal® Consta®, and Invega® (paliperidone), each by Ortho-McNeil-Janssen Pharmaceuticals, Inc., Zyprexa® (olanzapine) by Eli Lilly and Company, Seroquel® (quetiapine) by AstraZeneca PLC, Abilify® (aripiprazole) by Bristol-Myers Squibb Company/Otsuka Pharmaceutical Co., Ltd., Geodon® (ziprasidone) by Pfizer Inc., 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™ (ramelteon) by Takeda Pharmaceuticals Company Limited, hypnotics such as Ambien® (zolpidem) by sanofi-aventis (including Ambien CR®), Lunesta® (eszopiclone) by Sepracor Inc. and Sonata® (zaleplon) by King Pharmaceuticals, Inc., generic compounds such as trazodone and doxepin, and over-the-counter remedies such as Benadryl® and Tylenol PM®. In addition to the approved products, compounds in Phase III trials for insomnia (or for which an NDA has been recently filed) include indiplon (Neurocrine Biosciences, Inc.) and low-dose doxepin (Silenor™) by Somaxon Pharmaceuticals, Inc.
- For tasimelteon in the treatment of depression, antidepressants such as Paxil® (paroxetine) by GlaxoSmithKline (GSK), Zoloft® (sertraline) by Pfizer, Prozac® (fluoxetine) by Eli Lilly, Lexapro (escitalopram) by Lundbeck A/S /Forest Pharmaceuticals Inc., and Effexor® (venlafaxine) by Wyeth as well as other compounds such as Wellbutrin® (buproprion) by GSK and Cymbalta® (duloxetine) by Eli Lilly. In addition to the approved products, compounds in Phase III trials for depression include agomelatine (Novartis and Les Laboratories Servier).
- For VSF-173 in the treatment of excessive sleepiness, Provigil® (modafinil) and Nuvigil® (armodafinil) by Cephalon Inc., and Xyrem® (sodium oxybate) by Jazz Pharmaceuticals, Inc.

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 any of our product candidates following regulatory approval, 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 product
- 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 our growth.

As of June 30, 2008, we had 52 full-time employees. 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 product candidates. 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 iloperidone
- 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 product candidates, our ability to develop a diverse product portfolio may be limited.

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

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 product candidates.

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 product candidates in clinical trials and will face even greater risks upon any commercialization by us of our product candidates. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because our compounds 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 compounds. 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 general liability and product liability insurance, our aggregate coverage limit under this insurance is $10,000,000, 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 candidate 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 our product candidates and to produce, to market and to distribute our existing products.

On September 27, 2007, 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 would 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 existing three product candidates or future development programs
- our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements
- any intellectual property infringement lawsuit in which we may become involved
- regulatory developments affecting our product candidates or those of our competitors

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 product candidates are subject in part to the terms and conditions of licenses or sublicenses granted to us by other pharmaceutical companies. With respect to tasimelteon and VSF-173, these terms and conditions include options in favor of these pharmaceutical companies to reacquire rights to commercialize and develop these product candidates in certain circumstances.

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 iloperidone 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 iloperidone commercially following regulatory approval, and the time it takes for us to receive regulatory approval following our

submission of an NDA or equivalent foreign filing. We may also lose our rights to develop and commercialize iloperidone 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 iloperidone 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 (VEC-162) 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. If we seek a co-promotion agreement for tasimelteon, BMS has a right of first negotiation to enter into such an agreement with us. 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.

VSF-173 is based in part on patents and other intellectual property that we have licensed on an exclusive basis from Novartis. Novartis has the option to reacquire rights to co-develop and exclusively commercialize VSF-173 following the completion of the Phase II trials, and an additional option to reacquire co-development rights and exclusive commercialization rights following the completion of the Phase III clinical trials, subject in each case to Novartis' payment of pre-determined royalties and other payments to us. In the event that Novartis chooses not to exercise either of these options and we decide to enter into a partnering arrangement to help us commercialize VSF-173, Novartis has a right of first refusal to negotiate such an agreement with us, as well as a right to submit a last matching counteroffer regarding such an agreement. In addition, our rights with respect to VSF-173 may terminate, in whole or in part, if we fail to meet certain development and commercialization milestones described in our license agreement relating to the time it takes us to complete our development work on VSF-173. These rights may also terminate in whole or in part if we fail to make royalty or milestone payments or if we do not comply with requirements in our license agreement regarding our financial condition. In the event of an early termination of our license agreement, all rights licensed and developed by us under this agreement may revert back to Novartis. Any termination or reversion of our rights to develop or commercialize VSF-173, including any reacquisition by Novartis 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 product candidates, we rely upon intellectual property we own relating to our products, including patents, patent applications and trade secrets. As of June 30, 2008 we had thirteen pending provisional patent applications in the United States, three U.S. national stage applications under U.S.C. 371 and six pending Patent Cooperation Treaty applications, which permit the pursuit of patents outside of the U.S., relating to our product candidates in clinical development. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around these patents. In addition, we rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug development processes that involve proprietary know-how, information and technology that is not covered by patent applications. While we require all of our employees, consultants, advisors and

any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the 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 product candidates, 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 our current product candidates in clinical development, and that we continue to have rights under our sublicense and license agreements with respect to these product candidates, we would have exclusive rights to iloperidone's United States "new chemical entity" patent (the primary patent covering the compound as a new composition of matter) until 2016, to tasimelteon's United States new chemical entity patent until 2022 and to VSF-173's United States new chemical entity patent until 2019. 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 our current product candidates in clinical development, and that we continue to have rights under our sublicense and license agreements with respect to these product candidates, we would have exclusive rights to iloperidone's European new chemical entity patents until 2015, to tasimelteon's European new chemical entity patents until 2022 and to VSF-173's European new chemical entity patents until 2017. 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 iloperidone, since the European new chemical entity patent for iloperidone 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. 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 harmed.

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 product candidates. 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 product candidates. 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 product candidates.

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 and development 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, 2007 and June 30, 2008, the high and low sale prices of our common stock as reported on the NASDAQ Global Market varied between $21.50 and $2.70. 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
- 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 early investors in our company who held our stock prior to the sale of shares in our initial public offering continue to hold a substantial number of shares of our common stock. Additionally, a small number of institutional investors and private equity funds continue to 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, the holders of a substantial number of shares of our common stock have rights, subject to certain conditions, to require us to file registration statements to permit the resale of these 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, 2008 there were a total of 3,998,499 shares of common stock that we have registered and that we are obligated to issue upon the exercise of currently outstanding options 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 we fail to maintain the requirements for continued listing on the NASDAQ Global Market, our common stock could be delisted from trading, which would adversely affect the liquidity of our common stock and our ability to raise additional capital.

Our common stock is currently listed for quotation on the NASDAQ Global Market. We are required to meet specified financial requirements in order to maintain our listing on the NASDAQ Global Market. One such requirement is that we maintain a minimum closing bid price of at least $1.00 per share for our common stock. Our common stock has recently closed at prices below the minimum bid requirement. If the closing bid price of a share of the Company's common stock were to fall below $1.00 for a period of thirty (30) consecutive business days, the Company would receive a deficiency notice from NASDAQ advising us that we have 180 calendar days to regain compliance by maintaining a minimum closing bid price of at least $1.00 for a minimum of ten consecutive business days. Under certain circumstances, NASDAQ could require that the minimum closing bid price exceed $1.00 for more than ten consecutive days before determining that a company complies with its continued listing standards. If in the future, we fail to satisfy the NASDAQ Global Market's continued listing requirements, our common stock could be delisted from the NASDAQ Global Market, in which case we may transfer to the NASDAQ Capital Market, which generally has lower financial requirements for initial listing or, if we fail to meet its listing requirements, the over-the-counter bulletin board. There are many factors that may adversely affect our minimum bid price, including those described in Item 1A "Risk Factors" of Part II of this quarterly report on Form 10-Q, which contains a more complete discussion of those factors and other risks. Many of these factors are outside of our control. As a result, we may not be able to sustain compliance with the minimum bid price rule in the long term. Any potential delisting of our common stock from the NASDAQ Global Market would make it more difficult for our stockholders to sell our stock in the public market and would likely result in decreased liquidity and increased volatility for our common stock.

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, could prevent or delay a change in control of our company.

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

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

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

We registered shares of our common stock in connection with our follow-on offering under the Securities Act. Our Registration Statement on Form S-1 (Reg. No. 333-139485 and No. 333-140081) in connection with our follow-on offering was declared effective by the SEC on January 18, 2007. The offering was consummated on January 24, 2007 with respect to all 4,370,000 shares of our common stock that were offered, including 570,000 of such shares that were offered pursuant to the exercise by the underwriters of their over-allotment option. The managing underwriters of the offering were J.P. Morgan Securities Inc., Morgan Stanley & Co., Incorporated, Banc of America Securities LLC and Natexis Bleichroeder Inc.

All 4,370,000 shares of our common stock sold in the follow-on offering were sold to the public at the offering price of $27.29 per share. The aggregate price of the offering was approximately $119.3 million. The net offering proceeds to us after deducting underwriting discounts and commissions, as well as estimated offering expenses, were approximately $111.3 million. We incurred total expenses in connection with the offering of approximately $8.0 million which consisted of approximate direct payments of:

(i) $772,000 in legal, accounting and printing fees

(ii) $7,155,000 in underwriters' discounts, fees and commissions and

(iii) $75,000 in miscellaneous expenses

We have used a portion of, and intend to continue to use, the proceeds of our follow-on offering for general corporate and research and development expenses, including for our clinical trials for iloperidone, tasimelteon and VSF-173, the generation and submission of an NDA for iloperidone, the initiation and implementation of our commercialization strategy of iloperidone, and clinical manufacturing and other expenses relating to the development of our lead product candidates, however, given the recent decent by the FDA with respect to our NDA for iloperidone, we have suspended all iloperidone-related activities pending further review by management and discussion with the FDA. The unused net proceeds from the follow-on offering are invested in investment grade securities. This use of proceeds is not materially different from the use of proceeds described in the final prospectuses for our follow-on offering.

The amount and timing of our actual expenditures may vary significantly depending on numerous factors, such as the progress of our product development and commercialization efforts and the amount of cash used by our operations.

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

None.

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

On May 8, 2008, we held our 2008 Annual Meeting of Stockholders. At the meeting, the following matters were approved by the votes specified below:

1. Richard W. Dugan and Brian K. Halak, Ph.D were elected to serve as directors of Vanda until the 2011 annual meeting or until their successors are duly elected and qualified. With respect to Mr. Dugan 19,682,202 shares of common stock were voted in favor of his election and 2,589,778 shares of common stock were withheld. With respect to Dr. Halak 19,683,102 shares of common stock were voted in favor of his election and 2,588,878 shares were withheld. There were no abstentions or broker non-votes. The terms of Drs. Karabelas and Polymeropoulos and Messrs. Pien, Ramsay and Watkins continued after the meeting.

2. The ratification of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the year ending December 31, 2008 was approved. The votes were cast as follows: 21,948,015 shares of common stock were voted for the ratification, 321,964 shares of common stock were voted against the ratification and 2,001 shares of common stock abstained from the vote. There were no broker non-votes.

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

None.

Item 6. ***Exhibits***

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

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

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

August 8, 2008

/s/ Steven A. Shallcross

Steven A. Shallcross
Senior Vice President,
Chief Financial Officer and Treasurer
(Principal financial and accounting officer)

August 8, 2008

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

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EXHIBIT 31.1

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

I, Mihael H. Polymeropoulos, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2008

/s/ Mihael H. Polymeropoulos

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

EXHIBIT 31.2

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

I, Steven A. Shallcross, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2008

/s/ Steven A. Shallcross
Steven A. Shallcross
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

Certification

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

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

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

The Quarterly Report on Form 10-Q for the quarter ended June 30, 2008 (the Form 10-Q) of the Company fully complies with the requirements of Section 13(a) and 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the consolidated financial condition and results of operations of the Company.

Date: August 8, 2008

/S/ Mihael H. Polymeropoulos

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

Date: August 8, 2008

/S/ Steven A. Shallcross

Steven A. Shallcross
Chief Financial Officer
(Principal Financial and Accounting Officer)

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

End of Filing