

Vanda Pharmaceuticals Inc.

Form 10-Q

May 08, 2007

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

**Form 10-Q**

(Mark One)

- þ** **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)**  
**OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the quarterly period ended March 31, 2007**
- 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**  
*(State or Other Jurisdiction of  
Incorporation or Organization)*

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

**9605 Medical Center Drive, Suite 300**  
**Rockville, Maryland**  
*(Address of Principal Executive Offices)*

**20850**  
*(Zip Code)*

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

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

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. Please see definition of "accelerated and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☐ Accelerated Filer ☐ Non-Accelerated Filer ☒

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

As of May 2, 2007, there were 26,579,237 shares of the Registrant's Common Stock issued and outstanding.

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

**Form 10-Q Index**

**For the Three Months Ended March 31, 2007**

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**PART I FINANCIAL INFORMATION****Item 1. Financial Statements (Unaudited)****VANDA PHARMACEUTICALS INC.  
(A Development Stage Enterprise)****CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)**

	<b>March 31, 2007</b>	<b>December 31, 2006</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 64,221,338	\$ 30,928,895
Marketable securities	62,698,169	941,981
Prepaid expenses, deposits and other current assets	1,838,638	1,949,466
Total current assets	128,758,145	33,820,342
Marketable securities, long-term	3,000,181	
Property and equipment, net	1,829,893	1,859,704
Deposits	150,000	150,000
Restricted cash	430,230	430,230
Total assets	\$ 134,168,449	\$ 36,260,276
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities		
Accounts payable	\$ 2,010,347	\$ 2,783,249
Accrued expenses	4,904,128	6,322,808
Total current liabilities	6,914,475	9,106,057
Deferred rent	246,075	238,413
Deferred grant revenue	142,411	129,950
Other long-term liabilities	59,683	28,984
Total liabilities	7,362,644	9,503,404
Commitments and contingencies		
Stockholders' equity		
Common stock, \$0.001 par value, 150,000,000 and 150,000,000 shares authorized as of March 31, 2007 and December 31, 2006, respectively; 26,561,779 and 22,128,534 shares issued and outstanding as of March 31, 2007 and December 31, 2006, respectively	26,562	22,129

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Additional paid-in capital	242,029,862	126,578,588
Accumulated other comprehensive loss	(17,283)	(3,269)
Deficit accumulated during the development stage	(115,233,336)	(99,840,576)
Total stockholders' equity	126,805,805	26,756,872
Total liabilities and stockholders' equity	\$ 134,168,449	\$ 36,260,276

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

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

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

	<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>	<b>Period from March 13, 2003 (Inception) to March 31, 2007</b>
Revenues from services	\$	\$	\$ 81,545
Operating expenses:			
Research and development	10,592,059	15,488,554	89,006,965
General and administrative	6,233,549	2,924,948	30,439,304
Total operating expenses	16,825,608	18,413,502	119,446,269
Loss from operations	(16,825,608)	(18,413,502)	(119,364,724)
Other income (expense):			
Interest income	1,433,654	293,861	4,225,224
Interest expense		(2,809)	(80,485)
Other income			602
Total other income, net	1,433,654	291,052	4,145,341
Loss before tax provision	(15,391,954)	(18,122,450)	(115,219,383)
Tax provision	806		13,953
Net loss	(15,392,760)	(18,122,450)	(115,233,336)
Beneficial conversion feature deemed dividend to preferred stockholders			(33,486,623)
Net loss attributable to common stockholders	\$ (15,392,760)	\$ (18,122,450)	\$ (148,719,959)
Basic and diluted net loss per share applicable to common stockholders	\$ (0.61)	\$ (385.61)	
Shares used in calculation of basic and diluted net loss per share applicable to common stockholders	25,340,455	46,997	

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

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

	Common Stock Shares	Stock Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Comprehensive Loss	Total
<b>Balances at December 31, 2006</b>	22,128,534	\$ 22,129	\$ 126,578,588	\$ (3,269)	\$ (99,840,576)		\$ 26,756,872
Follow-on offering of common stock, net of issuance costs	4,370,000	4,370	111,286,849				111,291,219
Employee stock-based compensation			3,999,046				3,999,046
Exercise of stock options	63,245	63	56,453				56,516
Non-employee stock-based compensation			108,926				108,926
Comprehensive loss:							
Net loss					(15,392,760)	\$ (15,392,760)	
Accumulative translation adjustment				(12,785)		(12,785)	
Net unrealized losses on marketable securities				(1,229)		(1,229)	
Comprehensive loss						\$ (15,406,774)	(15,406,774)
<b>Balances at March 31, 2007</b>	26,561,779	\$ 26,562	\$ 242,029,862	\$ (17,283)	\$ (115,233,336)		\$ 126,805,805

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



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

	<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>	<b>Period from March 13, 2003  (Inception) to March 31, 2007</b>
<b>Cash flows from operating activities</b>			
Net loss	\$ (15,392,760)	\$ (18,122,450)	\$ (115,233,336)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	148,671	120,235	1,575,431
Employee and non-employee stock-based compensation	4,107,972	1,520,317	15,420,682
Loss on disposal of assets		29,528	29,528
Accretion of discount on investments	(230,268)	(92,261)	(651,342)
Changes in assets and liabilities:			
Prepaid expenses, deposits and other current assets	109,921	(252,666)	(1,834,523)
Long-term deposits			(150,000)
Accounts payable	(767,846)	1,122,758	2,001,454
Accrued expenses	(1,419,185)	4,627,273	4,901,261
Deferred grant revenue			129,950
Other liabilities	38,361	328,546	305,758
Net cash used in operating activities	(13,405,134)	(10,718,720)	(93,505,137)
<b>Cash flows from investing activities</b>			
Purchases of property and equipment	(118,678)	(358,048)	(3,310,291)
Purchases of marketable securities	(65,477,330)	(1,639,702)	(179,556,114)
Proceeds from sales of marketable securities			82,137,888
Maturities of marketable securities	950,000	4,270,000	32,370,000
Investments in restricted cash			(430,230)
Net cash (used in) provided by investing activities	(64,646,008)	2,272,250	(68,788,747)
<b>Cash flows from financing activities</b>			
Proceeds from borrowings on note payable			515,147
Principal payments on obligations under capital lease		(344)	(94,456)
Principal payments on note payable		(45,873)	(515,147)
Proceeds from the issuance of preferred stock, net of issuance costs			61,795,187
Proceeds from exercise of stock options and warrants	56,516	294	215,386

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Proceeds from issuance of common stock, net of issuance costs	111,291,219			164,625,169
Net cash provided by (used in) financing activities	111,347,735	(45,923)		226,541,286
Effect of foreign currency translation	(4,150)	(458)		(26,064)
Net increase (decrease) in cash and cash equivalents	\$ 33,292,443	\$ (8,492,851)	\$	64,221,338
<b>Cash and cash equivalents</b>				
Beginning of period	\$ 30,928,895	\$ 21,012,815	\$	
End of period	\$ 64,221,338	\$ 12,519,964	\$	64,221,338
<b>Supplemental disclosure</b>				
Cash payments for interest	\$	\$ 3,186	\$	73,804
<b>Supplemental disclosure of non-cash financing activities</b>				
Equipment acquired through obligation under capital lease	\$	\$	\$	95,305

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

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

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

**1. Business organization and presentation**

**Business organization**

Vanda Pharmaceuticals Inc. (Vanda or the Company) is a biopharmaceutical company focused on the development and commercialization of small molecule therapeutics, with exclusive worldwide commercial rights to three product candidates in clinical development for various central nervous system disorders. Vanda commenced its operations on March 13, 2003. The Company's lead product candidate, iloperidone, is a compound for the treatment of schizophrenia and bipolar disorder, which has demonstrated positive top-line results from a Phase III clinical trial in schizophrenia completed in December 2006. The Company expects to file a New Drug Application (NDA) for iloperidone in schizophrenia with the United States Food and Drug Administration (FDA) by the end of 2007. The Company's second product candidate, VEC-162, is a compound for the treatment of sleep and mood disorders, which demonstrated positive top-line results from a Phase III clinical trial in transient insomnia completed in November 2006. VEC-162 is also ready for Phase II trials for the treatment of depression. The Company expects to conduct another trial of VEC-162 in the third quarter of 2007. The Company's third product candidate, VSF-173, is a compound for the treatment of excessive sleepiness and the Company recently initiated its first VSF-173 Phase II clinical trial.

**Initial public and follow-on offerings**

The Company completed its initial public offering in April 2006. The offering totaled 5,964,188 shares of common stock at a public offering price of \$10.00 per share, resulting in net proceeds to the Company of approximately \$53.3 million after deducting payments of underwriters' discounts and commissions and offering expenses.

In January 2007 the Company completed its follow-on offering. The offering totaled 4,370,000 shares of common stock at a public offering price of \$27.29 per share, resulting in net proceeds to the Company of approximately \$111.3 million after deducting underwriting discounts and commissions and offering expenses.

**Capital resources**

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, raising capital and market research. 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 2007 and beyond. Additionally, the Company's capital requirements will depend on many factors, including the success of the Company's research and development efforts, payments received under contractual agreements with other parties, if any, and the status of competitive products. The Company plans to continue financing its operations with cash received from financing activities and believes that its current capital resources will be sufficient to meet its current operating needs into early 2008, and after that time, the Company will require additional capital. In budgeting for our activities, we have relied on a number of assumptions, including assumptions that we will file an NDA for iloperidone in schizophrenia with the FDA by the end of 2007, that we will continue to expend funds in preparation of a commercial launch of iloperidone, that we will expend funds on the extended-release injectable formulation of iloperidone, that we

will initiate another VEC-162 trial in the third quarter of 2007 and that this trial will be conducted in accordance with our expectations, that we will conduct our VSF-173 Phase II trial for excessive sleepiness in accordance with our expectations, that we will not engage in further in-licensing activities, that we will not receive any proceeds from potential partnerships, that we will not expend funds on the bipolar indication for iloperidone, that we will continue to evaluate pre-

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

clinical compounds for potential development, that we will be able to continue the manufacturing of our product candidates at commercially reasonable prices, that we will be able to retain our key personnel, and that we will not incur any significant contingent liabilities.

The Company may need to raise additional funds more quickly if one or more of the above assumptions proves to be incorrect, if the Company chooses to expand its product development efforts more rapidly than presently anticipated or if the Company seeks to acquire additional product candidates. 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.

**Basis of presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States 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 generally accepted accounting principles for complete financial statements and should be read in conjunction with the Company's consolidated financial statements for the year ended December 31, 2006 included in the Company's annual report on the Form 10-K. The financial information as of March 31, 2007 and for the periods of the three months ended March 31, 2007 and March 31, 2006 and for the period from March 13, 2003 (inception) to March 31, 2007, 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 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 Form 10-K for calendar year 2006.

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned Singapore subsidiary. All inter-company balances and transactions have been eliminated.

**2. Summary of Significant Accounting Policies**

***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. 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 loss. Interest income, amortization of premium and accretion of discount on marketable securities, and realized gains and losses on securities are included in interest income in the statements of operations. Marketable securities with a maturity of more than one year at the end of the period are classified as long-term securities.

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

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

***Restricted cash***

During 2005, in conjunction with the lease of the new office and laboratory space in Rockville, MD, the Company provided the landlord with a letter of credit, which was collateralized with a deposit in the amount of \$430,230. The deposit is recorded as non-current restricted cash at March 31, 2007 since the letter of credit is required until the lease expires in 2016.

***Concentrations of credit risk***

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. The Company places its cash and cash equivalents and marketable securities with highly-rated financial institutions. At March 31, 2007, the Company maintained all of its cash and cash equivalents in four 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 employee stock-based compensation expenses in accordance with the Financial Accounting Standards Board (FASB) revised SFAS No. 123, *Share-Based Payment* (SFAS 123(R)). Accordingly, compensation costs for all stock-based awards to employees are measured based on the grant date fair value of those awards and recognized over the period during which the employee 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 in 2006 and 2007, 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 first three months of 2006 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 during 2006 and 2007 were estimated to be approximately 2% based on the Company's historical experience.

Total employee stock-based compensation expense recognized during the three months ended March 31, 2007 and 2006 comprised of the following:

<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>	<b>Period from March 13, 2003 (Inception) to March 31, 2007</b>
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Research and development	\$	1,003,370	\$	142,629	\$	2,536,380
General and administrative		2,995,676		1,344,582		12,695,314
Stock-based compensation expense	\$	3,999,046	\$	1,487,211	\$	15,231,694
Stock-based compensation expense per basic and diluted share of common stock	\$	0.16	\$	31.64		

As of March 31, 2007, \$38.3 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of 3.2 years.



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

As of March 31, 2007, 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 1,282,211 shares were subject to outstanding options granted under the 2004 Plan as of March 31, 2007, and no additional options will be granted under this plan. Reserved under the 2006 Plan as of March 31, 2007 are 2,385,141 shares of the Company's common stock of which 1,487,500 shares were subject to outstanding options to employees and non-employees as of March 31, 2007.

Options are subject to terms and conditions established by the compensation committee of the board of directors. None of the stock-based awards are classified as a liability as of March 31, 2007. 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 the 25% of the option awards and the remaining 75% of the option award 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. Certain option awards provide for accelerated vesting if there is a change in control.

The fair value of each option award is estimated on the date of grant using a Black-Scholes option pricing model (Black-Scholes 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 SAB 107 as the options meet the plain vanilla criteria required by this method. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has not paid dividends to its stockholders since its inception and does not plan to pay cash dividends in the foreseeable future.

Assumptions used in the Black-Scholes model for employee stock options granted during the three months ended March 31, 2007 were as follows:

Expected dividend yield	0.00%
Expected volatility	73.00%
Expected term (years)	6.25
Weighted average risk-free interest rate	4.86%

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

Number of Shares	Weighted Average Exercise Price at Grant Date	Weighted Average Remaining Term (Years)	Aggregate Intrinsic Value
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Outstanding at December 31, 2006	1,347,205	\$	1.69		
Forfeited	(1,749)		1.51		
Exercised	(63,245)		0.89	\$	1,606,852
Outstanding at March 31, 2007	1,282,211	\$	1.73	8.47	\$ 28,976,600
Exercisable at March 31, 2007	420,156	\$	1.60	8.46	\$ 9,551,952

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

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, 2006	359,527	\$ 20.21		
Granted	1,137,301	30.60		
Forfeited	(9,328)	27.39		
Outstanding at March 31, 2007	1,487,500	\$ 28.10	9.77	\$ (5,570,345)
Exercisable at March 31, 2007	51,324	\$ 28.82	9.79	\$ (228,655)

The weighted average grant-date fair value of options granted during the three months ended March 31, 2007 was \$21.19 per share. For the three months ended March 31, 2007 and 2006 the Company received a total of \$56,516 and \$294, respectively, in cash from options exercised under the stock-based arrangements.

***Equity instruments issued to non-employees***

The equity instruments issued to non-employees in exchange for services are recorded at the fair value of the equity instruments on the measurement date. The measurement of expense is subject to periodic adjustment as the underlying equity instruments vest and the performance by the third party is complete. The Company recognizes the fair value of non-employee equity instruments in the same periods and in the same manner as if the Company had paid cash for the services.

As of March 31, 2007 an aggregate of 38,125 shares were subject to outstanding options granted to non-employees under the 2004 Plan and 2006 Plan of which 34,074 options are subject to vesting. Total non-employee equity-based compensation expense, recognized during the first three months of 2007 and 2006 was comprised of the following:

	Three Months Ended March 31, 2007	Three Months Ended March 31, 2006
Research and development	\$ 51,606	\$ 33,105
General and administrative	57,320	

\$ 108,926 \$ 33,105

During 2006 the Company entered into two additional consulting agreements that may require the Company to grant options to purchase up to 20,000 shares of common stock to consultants subject to certain performance criteria. As of March 31, 2007 the options have not been issued as the performance criteria have not been satisfied and the terms of the stock option grants have not been finalized.

***Recognition of expenses from outsourced contracts***

Pursuant to management's assessment of the services that have been performed on clinical trials and other contracts, the Company recognizes operating 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.

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

***Research and development expenses***

The Company's research and development expenses consist primarily of fees paid to third parties in connection with the services they provide for our clinical trials, costs of contract manufacturing services, license fees, 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, other related costs and stock-based compensation related to our research and development personnel. We expense research and development costs as they are incurred, including payments made to date under our license agreements. Manufacturing-related costs are also included in research and development expenses as we do not yet have FDA approval for any of our product candidates. Costs related to our 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.

***General and administrative expenses***

General and administrative costs consist primarily of salaries, other related costs and stock-based compensation for personnel serving executive, finance, accounting, information technology and human resource functions, facility costs not otherwise included in research and development expenses, insurance costs and professional fees for legal, accounting and other professional services. General and administrative costs also include third party expenses incurred to support business development, marketing and other business activities related to our product candidate iloperidone, in anticipation of its commercial launch.

***Income taxes***

The Company accounts for income taxes under the liability method in accordance with 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.

***Use of estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates that affect the reported amounts of assets and liabilities at the date of the financial statements, disclosure of contingent assets and liabilities, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

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

***Deferred grant revenue***

Vanda Singapore entered into an agreement with the Economic Development Board of Singapore (EDB) to provide a grant for a development project. During 2005, the Company received its first reimbursement under the agreement. Given that the Company has not met all of the conditions attached to the grant expected to be met to date and under certain conditions EDB may reclaim funds paid to date, the payment has been recorded as deferred grant revenue at March 31, 2007.

***Recent accounting pronouncements***

In September 2006, the FASB issued FASB Statement No. 157, *Fair Value Measurements* (SFAS 157), which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under generally accepted accounting principles. SFAS 157 outlines a common definition of fair value and the new standard intends to make the measurement of fair value more consistent and comparable and improve disclosures about those measures. The Company will need to adopt SFAS 157 for financial statements issued for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of SFAS 157 on its results of operations and financial condition.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115* (SFAS 159). According to this standard the entities will now be permitted to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis (the fair value option). SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of SFAS 159 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 Staff Accounting Bulletin (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 the Company's Series A Preferred Stock and Series B Preferred Stock outstanding prior to the consummation of the Company's initial public offering, 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 affect, resulting in dilutive loss per share attributable to common stockholders and basic loss per share attributable to common stockholders being equivalent. The Company did not have any shares of common stock issued for nominal consideration as defined under the terms of SAB No. 98, which would be included in EPS calculations.





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

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

	<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>
Numerator:		
Net loss attributable to common stockholders	\$ (15,392,760)	\$ (18,122,450)
Denominator:		
Weighted average shares of common stock outstanding	25,365,415	99,526
Weighted average unvested shares of common stock subject to repurchase	(24,960)	(52,529)
Denominator for basic and diluted net loss per share	25,340,455	46,997
Basic and diluted net loss per share applicable to common stockholders	\$ (0.61)	\$ (385.61)
Anti-dilutive securities not included in diluted net loss per share calculation:		
Series A and B Preferred Stock		15,794,632
Options to purchase common stock	2,769,711	1,569,667
Warrants to purchase common stock		50,335
	2,769,711	17,414,634

Upon consummation of the initial public offering on April 12, 2006, all shares of the Company's Series A Preferred Stock and Series B Preferred Stock were converted into an aggregate of 15,794,632 shares of common stock. Additionally, the holders of the warrants to purchase common stock exercised their warrants upon the Company's initial public offering.

#### **4. Marketable Securities**

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

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Market Value</b>
<b>Short-term</b>				
U.S. Treasury and government agencies	\$ 16,788,621	\$ 2,979	\$	\$ 16,791,600
U.S. corporate debt	45,454,749	4,150	(8,535)	45,450,364
U.S. asset-based securities	456,199	6		456,205

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\$ 62,699,569	\$ 7,135	\$ (8,535)	\$ 62,698,169
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**Long-term**

U.S. Treasury and government agencies	\$ 3,000,000	\$ 181	\$	\$ 3,000,181
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\$ 3,000,000	\$ 181	\$	\$ 3,000,181
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**VANDA PHARMACEUTICALS INC.**  
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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2006:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
U.S. corporate debt	\$ 941,970	\$ 36	\$ (25)	\$ 941,981
	\$ 941,970	\$ 36	\$ (25)	\$ 941,981

**5. Prepaid expenses, deposits and other current assets**

The following is a summary of the Company's prepaid expenses, deposits and other current assets:

	March 31, 2007	December 31, 2006
Deposits with vendors	\$ 820,000	\$ 820,000
Prepaid insurance	106,626	337,332
Accrued interest income	425,387	97,575
Other prepaid expenses	468,281	517,629
Prepaid follow-on offering costs		69,064
Other receivables	18,344	107,866
	\$ 1,838,638	\$ 1,949,466

**6. Property and Equipment**

Property and equipment at cost:

	Estimated Useful Life (Years)	March 31, 2007	December 31, 2006
Laboratory equipment	5	\$ 1,679,760	\$ 1,675,375
Computer equipment	3	856,354	741,404
Furniture and fixtures	7	169,568	169,549
Leasehold improvements	10	739,428	736,518

	3,445,110	3,322,846
Less accumulated depreciation and amortization	(1,615,217)	(1,463,142)
	\$ 1,829,893	\$ 1,859,704

Depreciation and amortization expense for the three months ended March 31, 2007 was \$148,671, for the three months ended March 31, 2006 was \$120,235 and for the period from March 13, 2003 (inception) to March 31, 2007 was \$1,575,431.

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

**7. Accrued Expenses**

Accrued expenses consist of the following:

	<b>March 31, 2007</b>	<b>December 31, 2006</b>
Accrued research and development expenses	\$ 3,788,910	\$ 3,552,050
License fees		1,000,000
Bonus accrual	231,425	1,084,512
Accrued professional fees	408,331	329,177
Employee benefits	185,182	78,656
Lease abandonment , current portion	250,529	232,388
Other accrued expenses	39,751	46,025
	<b>\$ 4,904,128</b>	<b>\$ 6,322,808</b>

**8. Commitments and Contingencies**

*Operating leases*

The Company has commitments totaling approximately \$4.8 million under operating real estate leases for its current and former headquarters located in Rockville, Maryland, expiring in 2016 and 2008, respectively, and for its research facility in Singapore expiring in 2009.

*Guarantees and indemnifications*

The Company has entered into a number of standard intellectual property indemnification agreements in the ordinary course of its business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company's products. The term of these indemnification agreements is generally perpetual from the date of execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes that the fair value of the indemnification agreements is minimal, and accordingly the Company has not recognized any liabilities relating to these agreements as of March 31, 2007.

**Licensing 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

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

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. The Company may meet a milestone in 2007 under this license agreement, for which the Company would be obligated to make a license payment of \$5 million.

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.

*VEC-162.* 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 VEC-162. 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 VEC-162 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 VEC-162 to use commercially reasonable efforts to develop and commercialize VEC-162 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 VEC-162 and recorded a license fee expense of \$1,000,000.

BMS holds certain rights with respect to VEC-162 in the license agreement. If the Company has not agreed to one or more partnering arrangements to develop and commercialize VEC-162 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 VEC-162 on its own on pre-determined financial terms, including milestone and royalty payments. If the Company seeks a co-promotion agreement for VEC-162, BMS has a right of first negotiation to enter into such an agreement with the Company.

Either party may terminate the VEC-162 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 VEC-162 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. During the three months ended March 31, 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.



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

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 other contractual obligations relating to the license agreements included in the condensed consolidated financial statements as of March 31, 2007, 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 agreements***

The Company entered into agreements with several organizations to provide services relating to clinical development and clinical manufacturing activities 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.

**11. Income Taxes**

On January 1, 2007, the Company adopted the provisions of Financial Standards Accounting Board Interpretation (FIN) No. 48, *Accounting for Uncertainty in Income Taxes*. The adoption of FIN No. 48 did not have a material effect on our financial position or results of operations. In addition, there are no uncertain tax positions whose resolution in the next 12 months is expected to materially affect operating results. The Company accounts for income taxes using the asset and liability method. Deferred income taxes are recognized by applying enacted statutory tax rates applicable to future years to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The measurement of deferred tax assets is reduced, if necessary, by a valuation allowance for any tax benefits for which future realization is uncertain.

The Company has not recorded any tax provision or benefit for the three months ended March 31, 2007 or December 31, 2006, except for an estimated tax expense resulting from the research and development agreement with the Company's subsidiary in Singapore. The Company has provided a valuation allowance for the full amount of its net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss

cannot be sufficiently assured at March 31, 2007 and December 31, 2006. 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.

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

### **Forward Looking Statements**

*Various statements in this report are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. 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. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Vanda 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 Vanda's 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;*

*a 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;*

*a 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;*

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

*the increased expenses and administrative workload associated with being a public company.*

*The information in this report is provided only as of the date of this report, and Vanda undertakes no obligation to update any forward-looking statements contained in this report on account of new information, future events, or otherwise, except as required by law.*

*Forward-looking statements, therefore, should be considered in light of all of the information included or referred to in this report, including the Risk Factors section set forth as Item 1A of Part II of this report. You should also read the following discussion and analysis of financial condition and results of operations together with our condensed consolidated financial statements and related notes included elsewhere in this report.*

### **Our Business**

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 for various central nervous system disorders. Our lead product candidate, iloperidone, is a compound for the treatment of schizophrenia and bipolar disorder. In December 2006 we announced positive top-line results from our Phase III trial of iloperidone for schizophrenia. Our second product candidate, 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 VEC-162 in transient insomnia. VEC-162 is also ready for Phase II trials for the treatment of depression. We expect to conduct another trial of VEC-162 in the third quarter of 2007. Our third product candidate, VSF-173, is a compound for the treatment of excessive sleepiness and we recently initiated our first VSF-173 Phase II clinical trial.

We expect to file a New Drug Application (NDA) for iloperidone in schizophrenia with the United States Food and Drug Administration (FDA) by the end of 2007. We will have to conduct additional trials for VEC-162 prior to our filing of an NDA for VEC-162, and we expect to begin our next trial in the third quarter of 2007. Assuming successful outcomes of our clinical trials and approval by the FDA, we may commercialize iloperidone and VSF-173 with our own sales force in the U.S., and expect to commercialize VEC-162 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 \$115.2 million since the inception of our operations through March 31, 2007. We have no product revenues to date and have no approved products for sale. Since inception we have devoted substantially all of our efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, raising capital and market research. Our future operating results will depend largely on our ability to successfully develop and commercialize our lead product candidates, iloperidone and VEC-162, 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 the Risk factors section of this quarterly report on Form 10-Q.

We completed our initial public offering in April 2006. The offering totaled 5,964,188 shares of common stock at a public offering price of \$10.00 per share, resulting in net proceeds to the Company of approximately \$53.3 million, after deducting underwriters' discounts and commissions as well as offering expenses.

In January 2007 we completed our follow-on offering. The offering totaled 4,370,000 shares of common stock at the public offering price of \$27.29 per share, resulting in net proceeds to the Company of approximately \$111.3 million after deducting underwriting discounts and commissions and offering expenses.

Based on our current operating plans, we believe that our existing cash, cash equivalents and marketable securities, including the proceeds from the follow-on offering we completed in January 2007, will be sufficient to meet our anticipated operating needs through early 2008, and after that time we will require additional capital. In budgeting for our activities, we have relied on a number of assumptions, including assumptions that we will file an NDA for iloperidone in schizophrenia with the FDA by the end of 2007, that we will continue to expend funds in preparation of a commercial launch of iloperidone, that we will expend funds on the extended-release injectable formulation of iloperidone, that we will initiate another VEC-162 trial in the third quarter of 2007 and that this trial will be conducted in accordance with our expectations, that we will conduct our VSF-173 Phase II trial for excessive sleepiness in accordance with our expectations, that we will not engage in further in-licensing activities, that we will not receive any proceeds from potential partnerships, that we will not expend funds on the bipolar indication for iloperidone, that we will continue to evaluate pre-clinical compounds for potential development, that we will be able to continue the manufacturing of our product candidates at commercially reasonable prices, that we will be able to retain our key personnel, and that we will not incur any significant contingent liabilities.

We may need to raise additional funds more quickly if one of the above assumptions proves to be incorrect, if we choose to expand our product development efforts more rapidly than presently anticipated or seek to acquire additional product candidates, and we may also decide to raise additional funds even before they are needed if the conditions for raising capital are favorable. 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.

### *Iloperidone*

We reported positive top-line results from our Phase III trial of iloperidone in schizophrenia in December 2006. The primary endpoint of the trial was efficacy versus placebo on the Positive and Negative Symptoms Scale (PANSS), for which iloperidone demonstrated statistically significant improvement. Iloperidone also demonstrated statistically significant improvement versus placebo in several other measures of efficacy. Iloperidone also appeared to be safe and well-tolerated in the trial, which reinforced the results of

three short-term and three long-term clinical trials of iloperidone conducted by Novartis or by Vanda and comprising a total of over 3,000 patients, in which iloperidone differentiated itself from currently available atypical antipsychotics by offering a number of reduced side effects.

From inception to March 31, 2007 we incurred approximately \$50.7 million in research and development costs directly attributable to our development of iloperidone. During the first quarter of 2007, we held our Pre-NDA meeting with the FDA. This meeting was largely procedural, and focused on the structure and content of our NDA submission. Based on this meeting, we remain confident that we will be able to file our NDA for iloperidone in schizophrenia in the fourth quarter of 2007. We would then expect to launch iloperidone commercially in early 2009. However, the time it takes to receive cash inflows from the sale of iloperidone are highly dependent on facts and circumstances that we may not be able to control and are subject to a number of risks. For example, delays in the approval process and subsequent commercial launch of iloperidone following our filing may occur if the FDA fails to attend to our filing in a timely manner or requires further data to approve iloperidone. Please see the Risk factors section of this quarterly report on Form 10-Q for a more detailed discussion of these and other risks.

### ***VEC-162***

In November 2006 we announced positive top-line results from our Phase III trial of VEC-162 in the treatment of transient insomnia. VEC-162 demonstrated statistically significant improvement in several parameters used to measure the efficacy of insomnia therapies, including reduced duration of wake after sleep onset, improved sleep efficiency and shortened time to persistent sleep. In addition, VEC-162 also appeared to be safe and well-tolerated in the trial.

From inception to March 31, 2007 we incurred approximately \$23.8 million in direct research and development costs of VEC-162. We believe that we will have to conduct additional trials to receive FDA approval of VEC-162. In April 2007, we held our End of Phase II meeting with the FDA to discuss future clinical trial designs and our path to an NDA filing for VEC-162 in sleep disorders. We expect to initiate our next trial in the third quarter of 2007.

### ***VSF-173***

We have recently announced the initiation of a Phase II clinical trial for our product candidate VSF-173 in excessive sleepiness. The trial is a randomized, double-blind, placebo-controlled study to investigate the efficacy and safety of three oral doses of VSF-173 for the treatment of induced excessive sleepiness. We anticipate that approximately 60 healthy male and female subjects will participate in the study. The primary endpoint of the study is the difference from placebo on the Maintenance of Wakefulness Test (MWT), a standard measure of sleepiness.

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, and Alzheimer's disease.

From inception to March 31, 2007 we incurred approximately \$4.1 million in direct research and development costs related to VSF-173, including a milestone license fee of \$1.0 million paid upon the initiation of our first Phase II clinical trial.

### ***Revenues***

We have not generated any other operating revenue since our inception. Any revenue that we may receive in the near future is expected to consist primarily of license fees, milestone payments and research and development

reimbursement payments to be received from partners. If our development efforts result in clinical success, regulatory approval and successful commercialization of our products, we could generate revenue from sales of our products and from receipt of royalties on sales of licensed products.



**Research and development expenses**

The Company's research and development expenses consist primarily of fees paid to third parties in connection with the services they provide for our clinical trials, costs of contract manufacturing services, license fees, 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 they are incurred, including payments made to date under our license agreements. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to realize the potential of our product candidates and pharmacogenetics and pharmacogenomics expertise. From inception through March 31, 2007 we incurred research and development expenses in the aggregate of approximately \$89.0 million, including stock-based compensation expenses of approximately \$2.5 million. We expect our research and development expenses to increase as we continue to develop our product candidates. We also expect to incur substantial licensing costs in the future, as we continue our efforts to develop our product candidates and to evaluate potential in-license product candidates.

The following table summarizes our product development initiatives for the three months ended March 31, 2007, three months ended March 31, 2006 and the period from March 13, 2003 (inception) to March 31, 2007. 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.

	<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>	<b>From March 13, 2003 (Inception) to March 31, 2007</b>
Direct Project Costs(1)			
Iloperidone	\$ 5,322,000	\$ 11,671,000	\$ 50,698,000
VEC-162	2,796,000	2,753,000	23,815,000
VSF-173	1,484,000	299,000	4,053,000
Other Product Candidates	459,000	291,000	3,493,000
Total Direct Product Costs	10,061,000	15,014,000	82,059,000
Indirect Project Costs(1)			
Facility	131,000	173,000	1,215,000
Depreciation	110,000	102,000	1,373,000
Other Indirect Overhead	290,000	199,000	4,360,000
Total Indirect Expenses	\$ 531,000	\$ 474,000	\$ 6,948,000
Total Research & Development Expenses	\$ 10,592,000	\$ 15,488,000	\$ 89,007,000

(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, other related costs and stock-based compensation expenses for personnel serving executive, finance, accounting, information technology and human resource functions, facility costs not otherwise included in research and development expenses, insurance costs and professional fees for legal, accounting and other professional services. General and administrative costs also include third party expenses incurred to support business development, marketing and other business activities related to our product candidate iloperidone in anticipation of its commercial launch. We expect that our general and administrative expenses will increase as we continue to prepare the commercial

launch of our lead product candidates, add personnel and fulfill our reporting obligations applicable to public companies. From inception through March 31, 2007, we incurred general and administrative expenses in the aggregate of approximately \$30.4 million, including stock-based compensation expenses of approximately \$12.7 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, 2006 included in our annual report on the 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 report.

#### ***Accrued expenses***

As part of the process of preparing financial statements we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include professional service fees, such as lawyers and accountants, and contract service fees such as amounts paid to clinical monitors, data management organizations and investigators in conjunction with clinical trials, and fees paid to contract manufacturers in conjunction with the production of clinical materials. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. 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. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often subject to our judgment. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

#### ***Employee stock-based compensation***

We adopted SFAS 123(R) *Share Based Payment*, on January 1, 2006 using the modified prospective transition method of implementation. Accordingly, compensation costs for all stock-based awards to employees are measured based on the grant date fair value of those awards and recognized over the period during which the employee is required to perform service in exchange for the award. The Company generally recognizes the expense over the award's vesting period, as to date the Company granted no awards with market or performance conditions. For stock awards granted in 2006 and 2007, 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.

Factors which affect charges or credits to operations related to stock-based compensation expense are the fair value of the common stock underlying stock options for which stock-based compensation is recorded, the volatility of such fair value, risk-free rate and expected dividend yield used in the calculation of the fair value of the stock option. If our estimates of the fair value of these equity instruments are too high or too low, it

would have the effect of overstating or understating expenses. The stock-based compensation expense for a period is based on awards ultimately expected to vest and it is reduced for estimated forfeitures. If our estimated forfeiture rate is too high or too low, it would have the effect of overstating or understating expenses for the period.

Total employee stock-based compensation expense recognized during the first three months of 2007 and 2006 was comprised of the following:

	<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>
Research and development	\$ 1,003,000	\$ 143,000
General and administrative	2,996,000	1,344,000
Stock-based compensation expense	\$ 3,999,000	\$ 1,487,000

## 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 March 31, 2007, we had a deficit accumulated during the development stage of approximately \$115.2 million. We anticipate incurring additional losses, which may increase, for the foreseeable future.

### *Three months ended March 31, 2007 compared to three months ended March 31, 2006*

*Research and development expenses.* Research and development expenses decreased by approximately \$4.9 million, or 32%, to approximately \$10.6 million for the three months ended March 31, 2007 compared to approximately \$15.5 million for the three months ended March 31, 2006.

The following table discloses the components of research and development expenses reflecting all of our project expenses:

	<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>
Direct project costs:		
Clinical trials	\$ 2,762,000	\$ 11,566,000
Contract research and development, consultants, materials and other costs	4,242,000	1,569,000
Salaries, benefits and related costs	1,054,000	736,000
License fee expense	1,000,000	1,000,000

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Stock-based compensation	1,003,000	143,000
Total direct costs	10,061,000	15,014,000
Indirect project costs	531,000	474,000
Total	\$ 10,592,000	\$ 15,488,000

Direct costs decreased approximately \$5.0 million for the three months ended March 31, 2007 compared to the three months ended March 31, 2006 primarily as a result of lower clinical trial expenses for the Company's iloperidone and VEC-162 Phase III trials that were completed in 2006, offset by continuing clinical manufacturing activities for both iloperidone and VEC-162. Clinical trials expense decreased approximately \$8.8 million for the three months ended March 31, 2007 compared to the three months ended

March 31, 2006 primarily due to the cost incurred during the three months ended March 31, 2006 in our Phase III iloperidone and VEC-162 clinical trials that were initiated in the fourth quarter of 2005 and in the first quarter of 2006, respectively. Contract research and development, consulting, materials and other direct costs increased approximately \$2.7 million for the three months ended March 31, 2007 relative to the three months ended March 31, 2006, primarily as a result of increased regulatory and manufacturing-related development costs incurred in connection with the manufacturing of clinical supply materials for the iloperidone and the VEC-162 programs. Prior to FDA approval of our products, manufacturing-related costs are included in research and development expense. During the three months ended March 31, 2007 we met the requirement for a \$1.0 million milestone payment to Novartis under our license agreement for VSF-173, and during the three months ended March 31, 2006 we met the requirements for a \$1.0 million milestone payment to BMS under our license agreement for VEC-162. Salaries, benefits and related costs increased approximately \$318,000 for the three months ended March 31, 2007 relative to the three months ended March 31, 2006 due to an increase in personnel to support the development and clinical trial activities for iloperidone, VEC-162 and VSF-173. Stock-based compensation expense increased by approximately \$860,000 compared to the three months ended March 31, 2006 as a result of options granted in 2007 and the higher fair value of options granted during 2007 compared to options granted in prior periods.

We expect to continue to incur substantial research and development expenses due to our on-going research and development efforts and as our existing and future product candidates proceed through clinical trials.

*General and administrative expenses.* General and administrative expenses increased approximately \$3.3 million, or 113%, to approximately \$6.2 million for the three months ended March 31, 2007 from approximately \$2.9 million for the three months ended March 31, 2006.

The following table discloses the components of our general and administrative expenses:

	<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>
Salaries, benefits and related costs	\$ 785,000	\$ 589,000
Stock-based compensation	2,996,000	1,345,000
Marketing and related consulting services	1,017,000	
Legal, accounting and other professional expenses	701,000	256,000
Other expenses	735,000	735,000
<b>Total</b>	<b>\$ 6,234,000</b>	<b>\$ 2,925,000</b>

Salaries, benefits and related costs increased approximately \$196,000 for the three months ended March 31, 2007 compared to the three months ended March 31, 2006 due to an increase in personnel as we continued to develop the administrative structure to support the development and clinical trial activities for iloperidone, VEC-162 and our other product candidates. Stock-based compensation expense increased by approximately \$1.7 million as a result of options granted in January 2007 and the higher fair value of options granted during 2007 compared options granted in prior periods. Marketing and related consulting services expenses increased by approximately \$1.0 million due to increased business and marketing activity related to our anticipated commercial launch of iloperidone. These increased expenses included market research, branding, medical community cultivation and publication planning costs. Legal, accounting and other professional costs increased approximately \$445,000 for the three months ended March 31, 2007 compared

to the three months ended March 31, 2006 due primarily to a higher level of consulting activity in 2007 in support of business development and higher costs associated with our reporting and other regulatory obligations applicable to public companies.

In 2007 and thereafter we expect our general and administrative expenses to increase substantially. These increased expenses are expected to be necessary to support our discovery and development efforts and our commercial development activities.



*Interest income, net.* Net interest income in the three months ended March 31, 2007 was approximately \$1.4 million compared to net interest income of approximately \$291,000 in the three months ended March 31, 2006. Interest income was higher in 2007 due to higher average cash balances for the year and higher short-term interest rates which generated substantially higher interest income than in 2006.

### Liquidity and Capital Resources

We have funded our operations through March 31, 2007 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.

At March 31, 2007, cash and cash equivalents and marketable securities were approximately \$129.9 million compared to approximately \$31.9 million at December 31, 2006. Our cash and cash equivalents are highly liquid investments with a 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. At March 31, 2007 the Company also held a non-current deposit of \$430,000 that is used to collateralize a letter a credit issued for its current office lease expiring in 2016.

As of March 31, 2007 and December 31, 2006, our liquidity resources are summarized as follows:

	<b>March 31, 2007</b>	<b>December 31, 2006</b>
Cash and cash equivalents	\$ 64,221,000	\$ 30,929,000
U.S. Treasury and government agencies	16,792,000	
U.S. corporate debt securities	45,450,000	942,000
U.S. asset-backed securities	456,000	
Marketable securities, short-term	62,698,000	942,000
U.S. Treasury and government agencies	3,000,000	
Marketable securities, long-term	3,000,000	
	\$ 129,919,000	\$ 31,871,000
Restricted cash	\$ 430,000	\$ 430,000

We maintain cash balances with financial institutions in excess of insured limits, but do not anticipate any losses with respect to such cash balances.

### Cash Flow

<b>Three Months Ended March 31,</b>	<b>Three Months Ended March 31,</b>
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	2007	2006
Net cash (used in) provided by Operating activities	\$ (13,405,000)	\$ (10,719,000)
Investing activities	(64,646,000)	2,272,000
Financing activities	111,348,000	(46,000)
Exchange rate effect on cash and equivalents	(5,000)	
Net increase (decrease) in cash and cash equivalents	\$ 33,292,000	\$ (8,493,000)

Net cash used in operations was approximately \$13.4 million and approximately \$10.7 million for the three months ended March 31, 2007 and 2006, respectively. The net loss for the three months ended March 31, 2007 of approximately \$15.4 million was offset primarily by non-cash charges for depreciation and amortization of approximately \$149,000, stock-based compensation of approximately \$4.1 million, a decrease in accrued expenses and accounts payable of approximately \$2.2 million, principally related to clinical trial expenses, and other net changes in working capital. Net cash used in investing activities for the three months

ended March 31, 2007 was approximately \$64.6 million and consisted primarily of purchases of marketable securities of approximately \$65.5 million. Net cash provided by financing activities for the three months ended March 31, 2007 was approximately \$111.3 million, consisting primarily of net proceeds from our follow-on offering.

### **Contractual Obligations and Commitments**

The following table summarizes our long-term contractual cash obligations as of March 31, 2007:

		Cash Payments Due by Period					
	Total	April to December 2007	2008	2009	2010	2011	After 2011
		(In thousands)					
Operating leases	\$ 4,784	\$ 534	\$ 612	\$ 521	\$ 441	\$ 454	\$ 2,222

#### ***Operating leases***

Our commitments under operating leases shown above consist of payments relating to our real estate leases for our current and former headquarters located in Rockville, Maryland, expiring in 2016 and 2008, respectively, and for our research facility in Singapore expiring in 2009.

#### ***Clinical research organization contracts and other contracts***

We entered into agreements with clinical research organizations responsible for conducting and monitoring our clinical trials for iloperidone, VEC-162 and VSF-173. These contractual obligations are not reflected in the table above because we may terminate them on no more than 60 days notice without incurring additional charges (other than charges for work completed but not paid for through the effective date of termination and other costs incurred by our contractors in closing out work in progress as of the effective date of termination). We also entered into agreements with clinical manufacturing organizations and other outside contractors who will be responsible for additional services supporting our on-going 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 VEC-162 in March 2006 we met the first milestone specified in our licensing agreement with Bristol-Myers Squibb and recorded a related license expense

of \$1,000,000 during the three months ended March 31, 2006. 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 recorded a license fee expense of \$1,000,000 during the three months ended March 31, 2007. We may meet another milestone in 2007 under the license agreement with Novartis for iloperidone, for which we would be obligated to make a license payment of \$5,000,000. No 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 March 31, 2007, 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 report.

### **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 Regulations S-K.

### **Item 3. *Quantitative and Qualitative Disclosure About Market Risk***

#### **Foreign exchange**

We currently incur a portion of our operating expenses in Singapore. The reporting currency for our consolidated financial statements is U.S. Dollars. To date, we have determined operating expenses incurred outside of the United States have not been significant. 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 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 positions and do not intend to do so for the foreseeable future.

#### **Interest rates**

Our exposure to market risk is currently confined to our cash and cash equivalents, restricted cash and marketable securities that have maturities of less than 12 months. 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, restricted cash and marketable securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments.

#### **Effects of inflation**

Our most liquid assets are cash and cash equivalents and marketable securities. Because of their liquidity, these assets are not directly affected by inflation. We also believe that we have intangible assets in the value of our intellectual property. In accordance with generally accepted accounting principles, we have not capitalized the value of this intellectual property on our balance sheet. Due to the nature of this intellectual property, we believe that these intangible assets are not affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

### **Item 4. *Controls And Procedures***

#### **a) Evaluation of Disclosure Controls and Procedures**

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of March 31, 2007. Based upon this evaluation, management has concluded that, as of March 31, 2007, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified under

applicable rules of the Securities and Exchange Commission.

**b) Changes in Internal Controls**

There have been no changes in our internal controls over financial reporting, identified in connection with the evaluation of such internal controls that have occurred during the quarter ended March 31, 2007 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**Part II OTHER INFORMATION**

**Item 1A. Risk Factors**

*Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this report, including the consolidated financial statements and the related notes contained in this quarterly report on Form 10-Q, before deciding to invest in shares of our common stock. If any of the following risks is actually realized, 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**

***Our success is dependent on the success of our three product candidates in clinical development: iloperidone, VEC-162 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 recently completed Phase III trials for iloperidone and VEC-162, 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 successfully complete one or more clinical trials for any of our product candidates, we may not receive the regulatory approvals needed to market that product candidate. 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 tests 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 regulations 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 safe or effective

- they may interpret data from pre-clinical and clinical testing in different ways than we do

- they may not approve our manufacturing process

- they may change their approval policies or adopt new regulations

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

Moreover, if and when our products do obtain such approval or clearances, 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 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.

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 comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing, 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.***

Based on our current operating plans, we believe that our existing cash, cash equivalents and marketable securities, including the proceeds from the follow-on offering we completed in January 2007, will be sufficient to meet our anticipated operating needs through early 2008, and after that time we will require additional capital. In budgeting for our activities, we have relied on a number of assumptions, including assumptions that we will file an NDA for iloperidone in schizophrenia with the FDA by the end of 2007, that we will continue to expend funds in preparation of a commercial launch of iloperidone, that we will expend funds on the extended-release injectable formulation of iloperidone, that we will initiate another VEC-162 trial in the third quarter of 2007 and that this trial will be conducted in accordance with our expectations, that we will conduct our VSF-173 Phase II trial for excessive sleepiness in accordance with our expectations, that we will not engage in further in-licensing activities, that we will not receive any proceeds from potential partnerships, that we will not expend funds on the bipolar indication for iloperidone, that we will continue to evaluate pre-clinical compounds for potential development, that we will be able to continue the manufacturing of our product candidates at commercially reasonable prices, that we will be able to retain our key personnel, and that we will not incur any significant contingent liabilities. We may need to raise additional funds more quickly if one or more of our assumptions proves to be incorrect or if we choose to expand our product development efforts more rapidly than presently anticipated or seek to acquire additional product candidates, and we may also decide to raise additional funds even before they are needed if the conditions for raising capital are favorable.

We may seek to sell additional equity or debt securities or obtain a bank credit facility. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations.

We cannot assure you that additional funds will be available when we need them on terms that are acceptable to us, or at all. The unavailability of financing may require us to delay, scale back or eliminate expenditures for our research, development and marketing activities necessary to commercialize our potential biopharmaceutical products. If we are unable to secure sufficient capital to fund our research and development activities, we may not be able to continue operations or we may have to enter into collaboration agreements that could require us to share commercial rights to our products to a greater extent or at earlier stages in the drug development process than we currently intend. Collaborations that are consummated by us prior to proof-of-efficacy and safety of a product candidate could impair our ability to realize value from that product candidate.

We have engaged an investment bank to provide strategic and financial advisory services to the Company, which may lead to one or more possible transactions, including the acquisition, licensing or sale by the Company of one or more product candidates, or the acquisition of the Company. However, we can not assure you that we will complete any acquisitions, sales or licenses or that, if completed, any acquisition, sale or license will be successful or on attractive terms.



***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, marketing 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 March 31, 2007, we have accumulated net losses of approximately \$115.2 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 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.

***If our Common Technical Dossier (CTD) contractors do not successfully carry out their duties or if we lose our relations with our CTD contractors, our NDA for iloperidone could be delayed.***

We are dependent on third-party vendors for assistance in the preparation of the Common Technical Dossier (CTD) related to the NDA we expect to file for iloperidone by the end of 2007. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our program. If they fail to devote sufficient time and resources to our NDA preparation or if their performance is substandard, it will delay the approval of iloperidone.

If we lose our relationship with any one or more of these third 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. Consequently, the NDA and commercialization of iloperidone 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 pre-market 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 VEC-162 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<sup>®</sup> (risperidone) by Johnson & Johnson (including the depot formulation Risperdal<sup>®</sup> Consta<sup>®</sup>), Zyprexa<sup>®</sup> (olanzapine) by Eli Lilly and Company, Seroquel<sup>®</sup> (quetiapine) by AstraZeneca PLC, Abilify<sup>®</sup> (aripiprazole) by Bristol-Myers Squibb Company/Otsuka Pharmaceutical Co., Ltd., Geodon<sup>®</sup> (ziprasidone) by Pfizer Inc., Invega<sup>®</sup> (paliperidone) by Johnson & Johnson, 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 (Wyeth/Solvay S.A./Lundbeck A/S), and asenapine (Schering-Plough Corporation).

For VEC-162 in the treatment of insomnia, Rozerem<sup>™</sup> (ramelteon) by Takeda Pharmaceuticals Company Limited, hypnotics such as Ambien<sup>®</sup> (zolpidem) by sanofi-aventis (including Ambien CR<sup>®</sup>), Lunesta<sup>®</sup> (eszopiclone) by Sepracor Inc. and Sonata<sup>®</sup> (zaleplon) by King Pharmaceuticals, Inc., generic compounds such as trazodone and doxepin, and over-the-counter remedies such as Benadryl<sup>®</sup> and Tylenol PM<sup>®</sup>. In addition to the approved products, compounds in Phase III trials for insomnia include indiplon (Neurocrine Biosciences, Inc.) and low-dose doxepin (Silenor<sup>™</sup>, Somaxon Pharmaceuticals, Inc.).

For VEC-162 in the treatment of depression, antidepressants such as Paxil<sup>®</sup> (paroxetine) by GlaxoSmithKline (GSK), Zoloft<sup>®</sup> (sertraline) by Pfizer, Prozac<sup>®</sup> (fluoxetine) by Eli Lilly, Lexapro (escitalopram) by Lundbeck A/S /Forest Pharmaceuticals Inc., and Effexor<sup>®</sup> (venlafaxine) by Wyeth as well as other compounds such as Wellbutrin<sup>®</sup> (bupropion) by GSK and Cymbalta<sup>®</sup> (duloxetine) by Eli Lilly. In addition to the approved products, compounds in Phase III trials for depression include agomelatine (Novartis and Les Laboratoires Servier).

For VSF-173 in the treatment of excessive sleepiness, Provigil<sup>®</sup> (modafinil) and NuVigil<sup>®</sup> (armodafinil) by Cephalon Inc., and Xyrem<sup>®</sup> (sodium oxybate) by Jazz Pharmaceuticals, Inc.

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

At present, we have limited marketing and no sales personnel. In order for us to commercialize any of our product candidates, we must either acquire or internally develop sales, marketing and distribution capabilities, or enter into collaborations with partners to perform these services for us. We may 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 March 31, 2007, we had 45 full-time employees. We will need to continue 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

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 by using 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 six 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.

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

We expect our operating results 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 VEC-162 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 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.

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). Following the completion of the entire Phase III program for VEC-162, which may consist of several Phase III trials, and in the event that we have not entered into one or more development and commercialization agreements with one or more third parties covering certain significant markets, BMS has retained an option to reacquire the rights it has licensed to us to exclusively develop and commercialize VEC-162 on pre-determined financial terms, including the payment of royalties and milestone payments to 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 VEC-162 (including any intellectual property we develop with respect to VEC-162) 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 VEC-162, 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 December 31, 2006, we owned 27 pending provisional patent applications in the United States and three pending Patent Cooperation Treaty applications, which permit the pursuit of patents outside of the United States, 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 VEC-162'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 VEC-162's European new chemical entity patents until 2022 and to VSF-173's European new chemical entity patents until 2017. Additionally, a recent 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 EU countries, 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 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. 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 or 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

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 March 31, 2007 there were a total of 2,769,711 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. Additionally, the sale of additional equity securities at prices below the current market price of our common stock could result in dilution to our stockholders' interest.

***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***

### ***Use of Proceeds from Registered Securities***

We registered shares of our common stock in connection with our initial public offering under the Securities Act. Our Registration Statement on Form S-1 (Reg. No. 333-130759) in connection with our initial public offering was declared effective by the SEC on April 12, 2006. The offering was consummated on April 18, 2006 with respect to 5,750,000 shares of our common stock, and on April 25, 2006 with respect to 214,188 shares pursuant to the exercise by the underwriters of their over-allotment option. The managing underwriters of the offering were J.P. Morgan Securities Inc., Banc of America Securities LLC and Thomas Weisel Partners LLC.

All 5,964,188 shares of our common stock sold in the offering were sold to the public at the initial public offering price of \$10.00 per share. The aggregate price of the offering was approximately \$59.6 million. The net offering proceeds to us after deducting underwriting discounts and commissions, as well as offering expenses, were approximately \$53.3 million. We incurred total expenses in connection with the offering of approximately \$6.3 million, which consisted of approximate direct payments of:

- (i) \$1,861,000 in legal, accounting and printing fees
- (ii) \$4,175,000 in underwriters' discounts, fees and commissions and
- (iii) \$276,000 in miscellaneous expenses.

We also 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) \$45,000 in miscellaneous expenses

We have used a portion of, and intend to continue to use, the proceeds of our initial public offering and our follow-on offering for general corporate and research and development expenses, including for our clinical trials for iloperidone and VEC-162, the generation and submission of an NDA for iloperidone, the initiation of commercialization strategy of iloperidone, and clinical manufacturing expenses relating to the development of our lead product candidates. The unused net proceeds from the initial public and follow-on offerings 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 initial public offering and 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 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 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)**

May 8, 2007

/s/ Steven A. Shallcross

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

May 8, 2007

**VANDA PHARMACEUTICALS INC.**

**EXHIBIT INDEX**

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