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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**Form 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2006

OR

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

Commission File Number: 000-51863

**VANDA PHARMACEUTICALS INC.**

*(Exact name of registrant as specified in its charter)*

**Delaware**

*(State or Other Jurisdiction of  
Incorporation or Organization)*

**9605 Medical Center Drive, Suite 300**

**Rockville, Maryland**

*(Address of Principal Executive Offices)*

**03-0491827**

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

**20850**

*(Zip Code)*

**(240) 599-4500**

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 November 1, 2006, there were 21,907,188 shares of the Registrant's Common Stock issued and outstanding.

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

**Form 10-Q Index**

**For the Three and Nine Months Ended September 30, 2006**

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## PART I — FINANCIAL INFORMATION

## Item 1. Financial Statements (Unaudited)

VANDA PHARMACEUTICALS INC.  
(A Development Stage Company)  
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	September 30, 2006	December 31, 2005
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 31,899,979	\$ 21,012,815
Marketable securities	11,096,506	10,141,189
Prepaid expenses and other current assets	1,827,513	2,217,960
Total current assets	44,823,998	33,371,964
Property and equipment, net	1,848,270	1,110,576
Deposits	180,000	840,000
Restricted cash	430,230	430,230
Total assets	\$ 47,282,498	\$ 35,752,770
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,112,395	\$ 2,254,897
Accrued expenses	7,839,431	2,528,091
Current portion of long-term debt	374	142,461
Deferred grant revenue	136,251	129,950
Deferred rent	—	8,131
Total current liabilities	10,088,451	5,063,530
Deferred rent and other long-term liabilities	242,415	24,433
Total liabilities	10,330,866	5,087,963
Commitments and contingencies (Note 10)		
Stockholders' equity		
Common stock, \$0.001 par value, 150,000,000 and 70,000,000 shares authorized as of September 30, 2006 and December 31, 2005, respectively; and 21,907,188 and 98,945 shares issued and outstanding as of September 30, 2006 and December 31, 2005, respectively	21,907	99
Series A and Series B convertible preferred stock	—	61,795,187
Additional paid-in capital	124,893,956	23,982,981
Deferred stock-based compensation	—	(18,766,443)
Accumulated other comprehensive loss	(15,130)	(17,609)
Deficit accumulated during the development stage	(87,949,101)	(36,329,408)
Total stockholders' equity	36,951,632	30,664,807
Total liabilities and stockholders' equity	\$ 47,282,498	\$ 35,752,770

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

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

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

	Three Months Ended		Nine Months Ended		Period from
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005	March 13, 2003 (Inception) to September 30, 2006
Revenues from services	\$ —	\$ —	\$ —	\$ —	\$ 81,545
Operating expenses:					
Research and development	9,542,385	4,092,240	44,130,788	11,641,565	70,474,919
General and administrative	3,264,849	1,664,902	9,170,439	5,587,147	19,738,530
Total operating expenses	12,807,234	5,757,142	53,301,227	17,228,712	90,213,449
Loss from operations	(12,807,234)	(5,757,142)	(53,301,227)	(17,228,712)	(90,131,904)
Other income (expense):					
Interest income	683,469	57,259	1,686,363	208,763	2,275,280
Interest expense	(396)	(5,005)	(4,829)	(20,568)	(80,481)
Other income	—	—	—	93	602
Total other income	683,073	52,254	1,681,534	188,288	2,195,401
Loss before tax expense	(12,124,161)	(5,704,888)	(51,619,693)	(17,040,424)	(87,936,503)
Income tax provision	—	—	—	—	12,598
Net loss	(12,124,161)	(5,704,888)	(51,619,693)	(17,040,424)	(87,949,101)
Beneficial conversion feature — deemed dividend to preferred stockholders	—	(18,500,005)	—	(18,500,005)	(33,486,623)
Net loss attributable to common stockholders	\$ (12,124,161)	\$ (24,204,893)	\$ (51,619,693)	\$ (35,540,429)	\$ (121,435,724)
Basic and diluted net loss per share applicable to common stockholders	\$ (0.55)	\$ (1,308.87)	\$ (3.72)	\$ (3,094.51)	
Shares used in calculation of basic and diluted net loss per share applicable to common stockholders	21,871,542	18,493	13,862,613	11,485	

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

VANDA PHARMACEUTICALS INC.  
(A Development Stage Company)

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

	Series A and B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Comprehensive Loss	Total
	Shares	Par value	Shares	Par value						
<b>Balances at December 31, 2005</b>	52,276,437	\$ 61,795,187	98,945	\$ 99	\$ 23,982,981	\$ (18,766,443)	\$ (17,609)	\$ (36,329,408)		\$ 30,664,807
Elimination of deferred stock-based compensation due to adoption of SFAS 123(R)	—	—	—	—	(18,766,443)	18,766,443	—	—	—	—
Exercise of stock options	—	—	887	1	293	—	—	—	—	294
Initial public offering of common stock, net of issuance costs	—	—	5,964,188	5,964	53,323,987	—	—	—	—	53,329,951
Conversion of preferred stock upon initial public offering	(52,276,437)	( 61,795,187)	15,794,632	15,795	61,779,392	—	—	—	—	—
Exercise of warrants	—	—	48,536	48	48,544	—	—	—	—	48,592
Employee stock-based compensation	—	—	—	—	4,488,909	—	—	—	—	4,488,909
Non-employee stock-based compensation	—	—	—	—	36,293	—	—	—	—	36,293
Comprehensive loss:										
Net loss	—	—	—	—	—	—	—	(51,619,693)	\$ (51,619,693)	
Cumulative translation adjustment	—	—	—	—	—	—	3,645	—	3,645	
Net unrealized losses on marketable securities	—	—	—	—	—	—	(1,166)	—	(1,166)	
Comprehensive loss	—	—	—	—	—	—	—	—	\$ (51,617,214)	(51,617,214)
<b>Balances at September 30, 2006</b>	—	—	21,907,188	\$ 21,907	\$ 124,893,956	—	\$ (15,130)	\$ (87,949,101)		\$ 36,951,632

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

VANDA PHARMACEUTICALS INC.  
(A Development Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Nine Months Ended		Period from
	September 30, 2006	September 30, 2005	March 13, 2003 (Inception) to September 30, 2006
Cash flows from operating activities			
Net loss	\$ (51,619,693)	\$ (17,040,424)	\$ (87,949,101)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	415,197	316,435	1,295,480
Employee and non-employee stock-based compensation	4,525,202	4,090,301	9,706,086
Loss on disposal of assets	29,528	—	29,528
Accretion of discount on investments	(301,293)	(15,800)	(343,629)
Changes in assets and liabilities:			
Prepaid expenses and other current assets	391,559	(335,615)	(1,826,980)
Deposits	660,000	—	(180,000)
Accounts payable	(143,303)	(134,948)	2,027,896
Accrued expenses	5,329,690	1,179,697	7,726,200
Deferred grant revenue	—	127,866	130,603
Other liabilities	209,851	(370)	242,415
Net cash used in operating activities	<u>(40,503,262)</u>	<u>(11,812,858)</u>	<u>(69,141,502)</u>
Cash flows from investing activities			
Purchases of property and equipment	(1,187,295)	(96,341)	(2,872,784)
Purchases of marketable securities	(101,313,078)	(1,734,200)	(113,159,254)
Sales of marketable securities	82,137,888	1,750,000	82,137,888
Maturities of marketable securities	18,520,000	—	20,270,000
Investment in restricted cash	—	(430,230)	(430,230)
Net cash used in investing activities	<u>(1,842,485)</u>	<u>(510,771)</u>	<u>(14,054,380)</u>
Cash flows from financing activities			
Proceeds from borrowings on credit facility	—	—	515,147
Principal payments on obligations under capital lease	(1,071)	(51,246)	(94,097)
Principal payments on credit facility	(141,074)	(127,858)	(515,147)
Proceeds from issuance of preferred stock, net of issuance costs	—	18,500,005	61,795,187
Proceeds from exercise of stock options and warrants	48,886	14,076	80,640
Proceeds from issuance of common stock, net of issuance costs	53,329,951	—	53,333,950
Net cash provided by financing activities	<u>53,236,692</u>	<u>18,334,977</u>	<u>115,115,680</u>
Effect of foreign currency translation	(3,781)	(6,198)	(19,819)
Net increase in cash and cash equivalents	<u>\$ 10,887,164</u>	<u>\$ 6,005,150</u>	<u>\$ 31,899,979</u>
Cash and cash equivalents			
Beginning of period	<u>\$ 21,012,815</u>	<u>\$ 16,259,770</u>	<u>\$ —</u>
End of period	<u>\$ 31,899,979</u>	<u>\$ 22,264,920</u>	<u>\$ 31,899,979</u>

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

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

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

**1. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of Vanda Pharmaceuticals Inc. have been prepared in accordance with generally accepted accounting principles and the rules and regulations of the Securities and Exchange Commission, or 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, 2005 included in the Company's Registration Statement on Form S-1, as amended (Registration No. 333-130759), which was declared effective by the SEC on April 12, 2006. The financial information as of September 30, 2006 and for the periods of the three and nine months ended September 30, 2006 and September 30, 2005 and for the period from March 13, 2003 (inception) to September 30, 2006, 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 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. Initial Public Offering and Reverse Stock Split**

On April 18, 2006, the Company consummated its initial public offering, consisting of 5,750,000 shares of common stock. On April 21, 2006 the underwriters exercised an over-allotment option to purchase additional 214,188 shares of the Company's common stock. Including the over-allotment shares, the offering totaled 5,964,188 shares at a public offering price of \$10.00, resulting in net proceeds to the Company of approximately \$53.3 million (after deducting payment of underwriters' discounts and commissions and offering expenses).

In connection with the initial public offering, the Company effected a 1-for-3.309755 reverse stock split of the issued and outstanding common stock. Information relating to common stock and common stock-equivalents set forth in this report (including the share numbers in the preceding paragraph) has been restated to reflect this split for all periods presented. Upon consummation of the initial public offering, 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.

**3. Capital Resources and Liquidity**

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 and raising capital. Accordingly, the Company is considered to be in the development stage as defined in Statement of Financial Accounting Standards (SFAS) No. 7, *Accounting and Reporting by Development Stage Enterprises*.

The Company's activities will necessitate significant uses of working capital throughout 2006 and beyond. The Company plans to continue financing its operations with the cash received from financing activities, including its initial public offering. The Company believes that its current capital resources will be sufficient to meet the Company's operating needs through mid-2007, and after that time the Company will require additional capital.



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

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

In budgeting for its activities, the Company has relied on a number of assumptions, including assumptions that:

- the Company will not initiate a Phase II VSF-173 trial for excessive sleepiness with its current capital resources,
- its clinical trials will be conducted in accordance with the Company's expectations,
- the Company will not expend significant funds on the four week injectable formulation of, or bipolar indication for, iloperidone or on a Phase II or Phase III trial of VEC-162 for depression,
- the Company will be able to continue the manufacturing of its product candidates at commercially reasonable prices,
- the Company will be able to retain its key personnel, and
- the Company will not incur any significant contingent liabilities.

The Company may need to raise additional funds more quickly if one or more of its assumptions proves to be incorrect, if the Company chooses to expand its product development efforts more rapidly than presently anticipated or if it seeks to acquire additional product candidates. The Company does not plan to initiate a Phase II VSF-173 trial for excessive sleepiness with its current capital resources and has also delayed other non-priority manufacturing activities as a result of completing the enrollment for its iloperidone and VEC-162 Phase III trials significantly ahead of schedule. The Company expects these actions to allow the Company to focus its currently available resources on the Company's two lead product candidates. However, the Company does not expect these actions to result in any significant delays in the Company's overall clinical development results, including with respect to VSF-173.

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 the commercialization of its product candidates or its other research and development activities, it may not be able to continue operations, or it may have to enter into strategic collaborations that could require the Company to share commercial rights to its products to a greater extent or at earlier stages in the drug development process than is currently intended. These collaborations, if consummated prior to proof-of-efficacy or safety of a given product candidate, could impair the Company's ability to realize value from that product candidate. In the absence of the ability to raise additional equity capital, the Company is also prepared and believes it has the ability to curtail its existing clinical trial commitments and extend them in such a manner so that the Company has operating funds through the third quarter of 2007.

#### **4. Summary of Significant Accounting Policies**

##### ***Use of Estimates***

The preparation of condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates based upon current assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual conditions may differ materially from management's current assumptions. This may result in the estimates being incorrect and may require the Company to record additional charges or benefits from operations.

VANDA PHARMACEUTICALS INC.  
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

**Cash and Cash Equivalents**

For purposes of the condensed consolidated balance sheet and condensed consolidated statement of cash flows, cash equivalents represent all highly-liquid investments with an original maturity date of three months or less. At September 30, 2006, 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 cash balances.

**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.

**Restricted Cash**

During 2005, in conjunction with the lease of the office and laboratory space building, the Company provided the landlord with a letter of credit, which was collateralized with a restricted cash deposit in the amount of \$430,230.

**Stock-Based Compensation**

In December 2004, the Financial Accounting Standards Board ("FASB") revised Statement of Accounting Standards No. 123 ("SFAS 123(R)"), *Share-Based Payment*. On April 14, 2005, the SEC adopted a new rule amending the effective dates for SFAS 123(R).

Effective January 1, 2006 and for all periods subsequent to that date, SFAS 123(R) supersedes the previous accounting under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"). In March 2005, the SEC issued Staff Accounting Bulletin No. 107 ("SAB 107") relating to SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

In accordance with the new rule, the Company adopted the provisions of SFAS 123(R) on January 1, 2006. 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 (generally over the vesting period of the award). The Company has not granted any awards with market or performance conditions.

The Company adopted SFAS 123(R) using the modified prospective transition method. The valuation provisions of SFAS 123(R) apply to new awards and to awards that are outstanding at the effective date and subsequently modified or cancelled. Estimated compensation expense for awards outstanding at the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FASB Statement No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123"). In accordance with the modified prospective transition method, the Company's condensed consolidated financial statements for prior periods were not restated to reflect, and do not include, the impact of SFAS 123(R).

Stock-based compensation expense, which is a non-cash charge, results from estimating the fair value of employee stock options granted. On April 12, 2006, the Company completed its initial public offering and

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

began trading on the NASDAQ National Market. Prior to April 12, 2006, given the absence of an active market for our common stock, the exercise price of the stock options on the date of grant was determined by the board of directors using several factors, including progress and milestones achieved in the Company's business development and performance, the price per share of its convertible preferred stock offerings, the perspectives provided by the underwriters regarding estimates of a potential price per share in an initial public offering of the Company's common stock and general industry and economic trends. In establishing the estimated fair value of the common stock, the Company considered the guidance set forth in the AICPA Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issues as Compensation* and made retrospective determination of fair value. The exercise price for employee option grants issued subsequent to April 12, 2006 is based on the closing market value of the Company's common stock at the date of grant.

Stock-based compensation expense recognized during the three and nine months ended September 30, 2006 is based on the value of the portion of stock-based payment awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized in the Company's condensed consolidated statements of operations includes:

- compensation expense for stock-based payment awards granted prior to, but not yet vested as of, December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and
- compensation expense for stock-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with SFAS 123(R).

For stock awards granted in 2006, expenses are amortized under the accelerated attribution method. For stock awards granted prior to fiscal 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 statement of operations for the three and nine months ended September 30, 2006 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 the first nine months of 2006 have been estimated to be approximately 2% based on the Company's historical experience. In the pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred. The cumulative effect adjustment of adopting the change in estimating forfeitures was not considered material to the Company's financial statements for periods prior to January 1, 2006 upon implementation of SFAS 123(R) as of January 1, 2006.

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

Total stock-based compensation expense, related to all of the Company's stock-based awards to employees, recognized during the first three and nine months of 2006 and 2005 under SFAS 123(R) and APB 25, respectively, was comprised of the following:

	Three Months Ended		Nine Months Ended		Period from
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005	March 13, 2003 (Inception) to September 30, 2006
Research and development	\$ 184,789	\$ 16,700	\$ 475,563	\$ 658,529	\$ 1,266,526
General and administrative	1,321,008	766,316	4,013,347	3,431,772	8,362,694
Stock-based compensation expense	<u>\$ 1,505,797</u>	<u>\$ 783,016</u>	<u>\$ 4,488,910</u>	<u>\$ 4,090,301</u>	<u>\$ 9,629,220</u>
Stock-based compensation expense per basic and diluted share of common stock	<u>\$ 0.07</u>	<u>\$ 42.34</u>	<u>\$ 0.32</u>	<u>\$ 356.14</u>	

For the three months ended September 30, 2006, the adoption of SFAS 123R had the following effect on reported amounts that would have been reported using the intrinsic value method under APB No. 25:

	Three Months Ended September 30, 2006		
	Using APB No. 25 Accounting	SFAS 123R Adjustments	As Reported
Net loss	\$ (11,929,729)	\$ (194,432)	\$ (12,124,161)
Basic and diluted earnings per share	<u>\$ (0.54)</u>	<u>\$ (0.01)</u>	<u>\$ (0.55)</u>

For the nine months ended September 30, 2006, the adoption of SFAS 123R had the following effect on reported amounts that would have been reported using the intrinsic value method under APB No. 25:

	Nine Months Ended September 30, 2006		
	Using APB No. 25 Accounting	SFAS 123R Adjustments	As Reported
Net loss	\$ (51,054,650)	\$ (565,043)	\$ (51,619,693)
Basic and diluted earnings per share	<u>\$ (3.68)</u>	<u>\$ (0.04)</u>	<u>\$ (3.72)</u>

Since the Company had a net operating loss carryforward as of September 30, 2006, no excess tax benefits for the tax deductions related to stock-based awards were recognized in the condensed consolidated statements of operations. Additionally, no incremental tax benefits were recognized from stock options exercised in the three and nine months ended September 30, 2006 which would have resulted in a reclassification to reduce net cash used in operating activities with an offsetting increase in net cash provided by financing activities.

As of September 30, 2006, the Company had two equity incentive plans, the Second Amended and Restated Management Equity Plan (the "2004 Plan") and 2006 Equity Incentive Plan (the "2006 Plan") that were adopted in December 2004 and April 2006, respectively. An aggregate of 1,569,669 shares were subject to outstanding options granted under the 2004 Plan as of September 30, 2006, and no additional options will be granted under this plan. Reserved under the 2006 Plan are 1,500,000 shares of the Company's common stock of which 103,692 shares were subject to outstanding options as of September 30, 2006. On January 1 of each year starting with the year 2007, the number of shares reserved under the 2006 Plan will automatically

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**(A Development Stage Company)**

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

increase by 4% of the total number of shares of common stock that are outstanding at that time, or, if less, by 1,500,000 shares (or such lesser number as may be approved by the Company's board of directors).

Options are subject to terms and conditions established by the compensation committee of the board of directors. None of the stock-based awards are classified as a liability as of September 30, 2006. Option awards have 10-year contractual terms and 25% of the option shares typically vest and become exercisable on the first anniversary of the grant date and the remaining 75% of the option shares typically vest and become exercisable monthly in equal installments thereafter over three years. Certain option awards provide for accelerated vesting if there is a change in control (as described in these plans).

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. The expected term of options granted is based on the transition approach provided by SAB 107. 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. Assumptions used in the Black-Scholes model for the nine months ended September 30, 2006 were as follows:

	<b>Nine Months Ended September 30, 2006</b>
Expected dividend yield	0%
Expected volatility	70 - 73%
Expected term (years)	5.0 - 6.25
Weighted average risk-free interest rate	4.84%
Expected forfeiture rate	2%

A summary of option activity during the nine months ended September 30, 2006 is presented below.

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price at Grant Date</b>	<b>Weighted Average Remaining Term (Years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2005	1,532,542	\$ 1.39		
Granted	141,706	7.99		
Exercised	(887)	0.33		
Outstanding at September 30, 2006	1,673,361	\$ 1.95	8.77	\$ 12,301,503
Exercisable at September 30, 2006	419,500	\$ 0.36	8.03	\$ 3,751,202

The weighted average grant date fair value of options granted during the nine months ended September 30, 2006 was \$7.56 per share. The total intrinsic value of options exercised during the nine months ended September 30, 2006 was \$14,955. The Company received a total of \$294 in cash from the exercises of options during the nine months ended September 30, 2006. As of September 30, 2006, approximately \$16.2 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.

In conjunction with the 1-for-3.309755 reverse stock split of its common stock the Company also effected the reverse stock split of outstanding option grants using the same ratio. This modification has not resulted in any additional compensation expense.

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

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

*Pro Forma Information under SFAS 123 for Periods Prior to January 1, 2006*

Through fiscal year 2005, the Company accounted for stock-based awards to employees using the intrinsic value method in accordance with APB 25 and related interpretations and provided the required pro forma disclosures of SFAS 123. Under APB 25 the compensation expense is calculated as the difference between the fair value of the common stock on the date such options were granted and their exercise price.

The following table summarizes the pro forma effect on the net loss and per share data if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation for the three and nine-month periods ended September 30, 2005.

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net loss attributable to common stockholders	\$ (24,204,893)	\$ (35,540,429)
Add: Stock-based employee compensation expense included in net loss	783,016	4,090,301
Less: Stock-based employee compensation expense determined under SFAS 123	(661,381)	(4,012,441)
Pro forma net loss applicable to common stockholders	<u>\$ (24,083,258)</u>	<u>\$ (35,462,569)</u>
Net loss per share:		
Basic and diluted, net loss attributed to common stockholders as reported	\$ (1,308.87)	\$ (3,094.51)
Pro forma basic and diluted, net loss attributed to common stockholders	<u>\$ (1,302.29)</u>	<u>\$ (3,087.73)</u>

For employee stock options granted during the nine months ended September 30, 2005, the Company determined pro forma compensation expense under the provisions of SFAS 123 using the Black-Scholes model and the following assumptions:

	Nine Months Ended September 30, 2005
Expected dividend yield	0%
Expected volatility	67 - 68%
Expected term (years)	5
Weighted average risk-free interest rate	3.44%

The weighted average fair value of options granted during the nine months ended September 30, 2005 was \$15.03 per share.

**Equity Instruments Issued to Non-Employees**

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123, as amended by SFAS No. 148, *Accounting for Stock-based Compensation — Transition and Disclosure — An Amendment of SFAS No. 123* and EITF Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, which require such equity instruments to be recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest. The Company amortizes compensation expense related to non-employee stock options in

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

accordance with FIN No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans*.

On January 19, 2006, the Company granted to one of its consultants an option to purchase 3,625 shares of common stock with an exercise price of \$4.73 per share. The option was vested with respect to 2,190 shares as of January 19, 2006. The balance of the option will vest ratably over 19 months. The option expires on January 19, 2016 and for the nine months ended September 30, 2006 the Company recognized \$36,293 in consulting expense relating to this option.

During the three months ended September 30, 2006 the Company entered into two consulting agreements that will require the Company to grant options to purchase up to 20,000 shares of common stock to these consultants subject to certain performance criteria. The terms of the stock option grants will be finalized upon their issuance.

***Research and Development Expenses***

Research and development expenses include the cost of salaries, building costs, utilities, allocation of indirect costs, and expenses to third parties who conduct research and development, pursuant to development and consulting agreements, on behalf of the Company. Costs related to the acquisitions of intellectual property are 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. Research and development expenses are charged to operations as they are incurred.

***Recognition of Expenses in Outsourced Contracts***

Pursuant to the Company's assessment of the services that have been performed on clinical trials and other contracts, the Company recognizes expenses as the services are provided. Such 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.

***General and Administrative Expenses***

General and administrative costs are expensed as incurred and consist primarily of salaries and other related costs for personnel serving executive, finance, accounting, information technology and human resource functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal and accounting services.

***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.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

**Segment Information**

Management has determined that the Company operates in one business segment which is the development and commercialization of pharmaceutical products.

**New Accounting Standards**

In July 2006, the Financial Accounting Standard Board ("FASB") issued FASB Interpretation No. 48 ("FIN 48") *Accounting for Uncertainty in Income Taxes — and interpretation of FASB Statement No. 109*, to clarify certain aspects of accounting for uncertain tax positions, including issues related to the recognition and measurement of these tax positions. This interpretation is effective for fiscal years beginning after December 15, 2006. The Company is currently evaluating the impact of FIN 48 on its results of operations and financial condition.

In September 2006, the FASB issued FASB Statement No. 157, *Fair Value Measurements* ("FAS 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 (GAAP). FAS 157 outlines a common definition of fair value to be used throughout GAAP and the new standard intends to make the measurement of fair value more consistent and comparable and improve disclosures about those measures. Companies will need to adopt FAS 157 for financial statements issued for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of FAS 157 on its results of operations and financial condition.

In September 2006, the Staff of the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of determining whether the current year's financial statements are materially misstated. SAB 108 is effective for fiscal years beginning after November 15, 2006. The Company is currently evaluating the requirements of SAB 108; however, the Company does not believe that its adoption will have a material effect on its financial statements.

**5. 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.  
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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

	Three Months Ended		Nine Months Ended	
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
<b>Numerator:</b>				
Net loss attributable to common stockholders	\$ (12,124,161)	\$ (24,204,893)	\$ (51,619,693)	\$ (35,540,429)
<b>Denominator:</b>				
Weighted average shares of common stock outstanding	21,907,188	23,876	13,904,719	11,745
Weighted average unvested shares of common stock subject to repurchase	(35,646)	(5,383)	(42,106)	(260)
Denominator for basic and diluted net loss per share	21,871,542	18,493	13,862,613	11,485
Basic and diluted net loss per share applicable to common stockholders	\$ (0.55)	\$ (1,308.87)	\$ (3.72)	\$ (3,094.51)
<b>Anti-dilutive securities not included in diluted net loss per share calculation:</b>				
Series A and B Preferred Stock	—	12,110,038	—	12,110,038
Options to purchase common stock	1,673,361	1,143,111	1,673,361	1,143,111
Warrants to purchase common stock	—	50,335	—	50,335
	1,673,361	13,303,484	1,673,361	13,303,484

**6. Marketable Securities**

The following is a summary of the Company's available-for-sale marketable securities as of September 30, 2006:

	Amortized Cost	Net Unrealized Gains	Net Unrealized Losses	Fair Market Value
U.S. government agencies	\$ 6,763,476	\$ 1,037	\$ (70)	\$ 6,764,443
U.S. corporate debt	4,331,518	545	—	4,332,063
	\$ 11,094,994	\$ 1,582	\$ (70)	\$ 11,096,506

The following is a summary of the Company's available-for-sale marketable securities as of December 31, 2005:

	Amortized Cost	Net Unrealized Gains	Net Unrealized Losses	Fair Market Value
U.S. government agencies	\$ 6,054,023	\$ 847	\$ —	\$ 6,054,870
U.S. corporate debt	4,084,488	1,831	—	4,086,319
	\$ 10,138,511	\$ 2,678	\$ —	\$ 10,141,189

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

**7. Prepaid Expenses and Other Current Assets**

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

	September 30, 2006	December 31, 2005
Current deposits with vendors	\$ 790,000	\$ 220,000
Prepaid insurance	449,154	194,418
Accrued interest income	130,495	81,557
Other prepaid expenses	433,446	911,943
Prepaid initial public offering costs	—	794,099
Other receivables	24,418	15,943
	<u>\$ 1,827,513</u>	<u>\$ 2,217,960</u>

**8. Property and Equipment**

Property and equipment — at cost:

	Estimated Useful Life (Years)	September 30, 2006	December 31, 2005
Laboratory equipment	5	\$ 1,550,906	\$ 1,102,270
Computer equipment	3	691,378	366,963
Furniture and fixtures	7	163,973	101,556
Leasehold improvements	10	727,727	302,228
Construction in progress		—	120,851
		<u>3,133,984</u>	<u>1,993,868</u>
Less — accumulated depreciation and amortization		<u>(1,285,714)</u>	<u>(883,292)</u>
		<u>\$ 1,848,270</u>	<u>\$ 1,110,576</u>

Depreciation and amortization expense for the nine months ended September 30, 2006 and 2005 was \$415,197 and \$316,435, respectively, and \$1,295,480 for the period from March 13, 2003 (inception) to September 30, 2006.

**9. Accrued Expenses**

Accrued expenses consist of the following:

	September 30, 2006	December 31, 2005
Accrued research and development expenses	\$ 6,609,494	\$ 1,862,288
Bonus accrual	542,878	530,311
Accrued professional fees	180,863	71,000
Employee benefits	172,098	46,063
Other accrued expenses	334,098	18,429
Total accrued expenses	<u>\$ 7,839,431</u>	<u>\$ 2,528,091</u>

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

**10. 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 2006. The Company intends to renew its Singapore lease by the end of 2006 under similar terms.

The Company vacated its previous headquarters in January 2006. According to SFAS 146, Accounting for Costs Associated with Exit or Disposal Activities, a liability for costs that will continue to be incurred under a lease for its remaining term without economic benefit to the company shall be recognized and measured when the company ceases using the right conveyed by the lease, reduced by estimated sublease rentals that could be reasonably obtained. In accordance with SFAS 146 the Company has recorded non-cash charges relating to the abandonment of its former office of approximately \$267,000 during the nine months ended September 30, 2006.

*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 has no liabilities recorded for these agreements as of September 30, 2006, as the Company believes the fair value of these indemnification agreements is minimal.

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 these indemnification agreements is minimal, and accordingly the Company has not recognized any liabilities relating to these agreements as of September 30, 2006.

**11. 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

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

consideration for this sublicense, the Company paid Novartis an initial license fee of \$500,000 and is obligated to make future milestone payments to Novartis of less than \$100 million in the aggregate (the majority of which are tied to sales milestones), as well as royalty payments to Novartis at a rate which, as a percentage of net sales, is in the mid-twenties. 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 (New Drug Application) 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. If the Company does not cure any breaches by Novartis or Titan of their respective obligations under their agreements with Titan and Sanofi-Aventis, respectively, the Company's rights to develop and commercialize iloperidone may revert back to Novartis, although the Company is not aware of any such breaches by Titan or Novartis.

**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 recorded an expense of \$1,000,000 as it met its first milestone relating to the initiation of the Phase III clinical trial for VEC-162.

BMS holds certain rights with respect to VEC-162 in the license agreement. For example, BMS has a right of first negotiation to enter into a commercialization and development agreement with the Company after the completion of the first Phase III trial. Additionally, 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 entire Phase III program, which may consist of several Phase III trials, BMS has the option to exclusively develop and commercialize VEC-162 on its own on pre-determined financial terms, including milestone and royalty payments.

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.

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

**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. Novartis has the right to co-develop and exclusively commercialize VSF-173 on its own after Phase II and Phase III 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.

**12. Income Taxes**

The Company has not recorded any tax provision or benefit for the three and nine months ended September 30, 2006 or September 30, 2005. 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 reasonably assured at September 30, 2006 and December 31, 2005.

**13. Warrants**

In 2003, in connection with entering into the line of credit facility to finance the purchase of equipment, the Company granted to the lender a freely exercisable warrant to purchase 13,626 shares of the Company's common stock (the "Lender Warrant") at an exercise price of \$1.32 per share. The Lender Warrant was valued using the Black-Scholes option pricing model at \$0.93 per share and the aggregate value was \$12,628, which was recorded as general and administrative for the period from March 13, 2003 through December 31, 2003.

In February 2004, the Company issued a warrant to a consultant to purchase 36,709 shares of the Company's common stock (the "Consultant Warrant") at an exercise price of \$1.32 per share. The Consultant Warrant was valued using the Black-Scholes option pricing model at \$0.76 per share and the aggregate value was \$27,945, which was recorded as general and administrative for the year ended December 31, 2004.

In connection with the Company's initial public offering, the holder of the Lender Warrant exercised the warrant in full by using the warrant's net exercise feature, such that 11,827 shares of the Company's common stock were issued to the lender upon exercise. Additionally, in connection with the Company's initial public offering, the holder of the Consultant Warrant exercised the warrant in full.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

**14. Beneficial Conversion Feature**

In September 2005, the Company completed the sale of an additional 15,040,654 shares of Series B Preferred Stock for proceeds of approximately \$18.5 million. After evaluating the fair value of the Company's common stock obtainable upon conversion by the stockholders, the Company determined that the issuance of the Series B Preferred Stock sold in September 2005 resulted in a beneficial conversion feature calculated in accordance with EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*, (EITF 98-5) as interpreted by EITF Issue No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*, (EITF 00-27) of approximately \$18.5 million which was fully accreted in September 2005 and was recorded as a deemed dividend to preferred stockholders during the three and nine months ended September 30, 2005.

In December 2005, the Company closed an additional private placement of 12,195,129 shares of Series B Preferred Stock for proceeds of approximately \$15.0 million. The Company evaluated the fair value of the Company's common stock obtainable upon conversion by the stockholders using EITF 98-5 and EITF 00-27 and determined that the issuance of the Series B Preferred Stock sold in December 2005 resulted in a beneficial conversion feature of approximately \$15.0 million that was fully accreted in December 2005 and was recorded as a deemed dividend to preferred stockholders for the year ended December 31, 2005.

## **Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

### **Forward Looking Statements**

Various statements in this report on Form 10-Q, including the notes to the financial statements above, 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**

Vanda Pharmaceuticals Inc. ("Vanda" or the "Company") was founded in November 2002 and commenced its operations on March 13, 2003. We are 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. Our lead product candidate, iloperidone, is a compound for the treatment of schizophrenia and bipolar disorder and is in a Phase III trial for schizophrenia. Our second product candidate, VEC-162, is a compound for the treatment of sleep and mood disorders which is currently in a Phase III trial for transient insomnia. VEC-162 is also ready for Phase II trials for the treatment of depression. Our third product candidate, VSF-173, is a compound for the treatment of excessive sleepiness and is ready for a Phase II trial.

We concluded enrollment of our current Phase III trial for iloperidone on August 29, 2006 and we expect to report the top-line results for this trial in December 2006. If this trial is successful, we expect to file a New Drug Application (NDA) for iloperidone in schizophrenia with the Food and Drug Administration (FDA) by the end of 2007. We concluded enrollment of our Phase III trial of VEC-162 on August 21, 2006 and we expect to announce the top-line results for this trial in November 2006. We also expect to begin a Phase II trial of VSF-173 for excessive sleepiness in late 2007. Assuming successful outcomes of our clinical trials and approval by the FDA, we expect to commercialize iloperidone and VSF-173 with our own sales force in the U.S. and 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 company and have accumulated an aggregate deficit of approximately \$87.9 million since the inception of our operations. We have no product revenues to date and have no approved products for sale. Since we began our operations in March 2003, we have devoted substantially all of our resources to the in-licensing and clinical development of our product candidates. Our future operating results will depend largely on our ability to successfully develop and commercialize our lead product candidate, iloperidone and on the progress of other product candidates currently in our research and development pipeline. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks which are detailed in the section "Risk Factors" set forth as Item 1A of Part II of this report.

On April 18, 2006, we consummated our initial public offering, consisting of 5,750,000 shares of common stock. On April 21, 2006 the underwriters exercised an over-allotment option to purchase additional 214,188 shares of our common stock. Including the over-allotment shares, the offering totaled 5,964,188 shares of common stock at a public offering price of \$10.00, resulting in net proceeds to the Company of approximately \$53.3 million (after deducting underwriters' discounts and commissions as well as offering expenses).

In connection with the initial public offering, the Company effected a 1-for-3.309755 reverse stock split of the issued and outstanding common stock. Information in this report relating to common stock and common stock-equivalents (including the share numbers in the preceding paragraph) has been restated to reflect this split for all periods presented. Upon completion of the initial public offering, all shares of the Company's Series A Preferred Stock and B Preferred Stock were converted into an aggregate of 15,794,632 shares of common stock.

#### ***Phase III trial for iloperidone***

On August 29, 2006, we concluded the patient enrollment of our Phase III trial to evaluate iloperidone for the treatment of patients with schizophrenia with 604 patients. The trial is a randomized, double-blind, placebo- and active-controlled Phase III trial and it has been conducted at investigator sites in the U.S. and in India. To have a successful clinical trial, we need to demonstrate that iloperidone has statistically significant efficacy better than placebo. The active control is present to validate the design of the trial and to increase the chances that trial participant will receive some form of treatment while participating in the trial. Patients have been receiving four weeks of inpatient treatment in the trial. We expect to complete the study and to report its top-line results in December 2006.

Prior to September 30, 2006, we incurred approximately \$30.2 million in clinical costs related to this trial. We currently expect that between October 1, 2006 and December 31, 2006, we will incur approximately \$2.0 million in additional clinical costs related to the trial. In 2007, we expect that we will incur approximately \$2.0 million to \$3.0 million in costs related to the trial and for services rendered to us in connection with the analysis of trial data and the preparation of regulatory filings. Assuming that the outcome of this trial is sufficient to support the filing of an NDA, we expect to make such a filing by the end of 2007. We would then expect to launch iloperidone commercially in early 2009. However, the timing and costs of our iloperidone trial, and 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, our trial may be delayed due to a failure of our clinical services provider to perform services in a timely or proper manner or the trial may be unsuccessful in proving iloperidone's efficacy and safety, which would cause the filing of an NDA to be delayed indefinitely. Additionally, even if our trial is successful, 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 set forth as Item 1A of Part II of this report for a more detailed discussion of these and other risks.

***Phase III trial for VEC-162***

On August 21, 2006, we concluded the patient enrollment of our Phase III trial to evaluate the safety and efficacy of VEC-162 for the treatment of transient insomnia with 412 patients. The trial is a randomized, double-blind, placebo-controlled trial conducted with healthy volunteers at investigator sites in the U.S. The trial measures sleep efficiency and time to fall asleep, as well as next-day performance and mood. Participants receive one day of inpatient treatment. We expect to complete the study and to report its top-line results in November 2006.

Prior to September 30, 2006, we incurred approximately \$6.0 million in clinical costs related to this trial. We expect that between October 1, 2006 and December 31, 2006, we will incur approximately \$1.0 million in clinical costs related to the trial, related administrative services and for services rendered to us in connection with the analysis of trial data. In 2007, we expect that we will incur less than \$0.5 million in costs related to the trial. We believe that we will need to conduct additional trials beyond this Phase III trial to receive FDA approval.

***Research and development expenses***

The Company's research and development expenses consist primarily of fees paid to third-party professional service providers in connection with the services they provide for our clinical trials, costs of contract manufacturing services, costs of materials used in clinical trials and research and development, depreciation of capital resources used to develop our products, and all related facilities costs. We expense research and development costs as incurred, including payments made to date under our license agreements. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to realize the potential of our product candidates and pharmacogenetics and pharmacogenomics expertise. From inception through September 30, 2006, we incurred research and development expenses in the aggregate of approximately \$70.5 million, including stock-based compensation expenses of approximately \$1.3 million. We expect our research and development expenses to increase as we continue to develop our product candidates and we also expect to incur licensing costs in the future that could be substantial, as we continue our efforts to evaluate potential in-license product candidates.

The following table summarizes our product development initiatives for the three months ended September 30, 2006 and September 30, 2005, and nine months ended September 30, 2006 and September 30, 2005, and the period from March 13, 2003 (inception) to September 30, 2006. Included in this table are the research and development expenses recognized in connection with our product candidates in clinical development. Included in "Other product candidates" are the costs directly related to research initiatives for all other product candidates.

	Three Months Ended		Nine Months Ended		Period from March 13, 2003 (Inception) to September 30, 2006
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005	
<b>Direct Project Costs(1)</b>					
Iloperidone	\$ 5,195,000	\$ 2,535,000	\$ 31,478,000	\$ 4,423,000	\$ 40,398,000
VEC-162	3,512,000	1,133,000	9,559,000	5,057,000	18,912,000
VSF-173	214,000	37,000	849,000	707,000	2,360,000
Other Product Candidates	228,000	118,000	873,000	608,000	2,810,000
<b>Total Direct Product Costs</b>	<b>9,149,000</b>	<b>3,823,000</b>	<b>42,759,000</b>	<b>10,795,000</b>	<b>64,480,000</b>
<b>Indirect Project Costs(1)</b>					
Facility	129,000	59,000	447,000	185,000	952,000
Depreciation	125,000	94,000	350,000	281,000	1,139,000
Other Indirect Overhead	139,000	116,000	575,000	380,000	3,904,000
<b>Total Indirect Expenses</b>	<b>393,000</b>	<b>269,000</b>	<b>1,372,000</b>	<b>846,000</b>	<b>5,995,000</b>
<b>Total Research &amp; Development Expenses</b>	<b>\$ 9,542,000</b>	<b>\$ 4,092,000</b>	<b>\$ 44,131,000</b>	<b>\$ 11,641,000</b>	<b>\$ 70,475,000</b>

(1) Many of our research and development costs are not attributable to any individual project because we share resources across several development projects. We record direct costs, including personnel costs and related benefits and stock-based compensation, on a project-by-project basis. We record indirect costs that support a number of our research and development activities in the aggregate.

#### **General and administrative expenses**

General and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, accounting, information technology, marketing and human resource functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal and accounting services. We expect that our general and administrative expenses will increase as we add personnel and fulfill our reporting obligations applicable to public companies, including the compliance with Section 404 of Sarbanes-Oxley Act. From inception through September 30, 2006, we incurred general and administrative expenses in the aggregate of approximately \$19.7 million, including stock-based compensation expenses of approximately \$8.4 million.

#### **Critical Accounting Policies**

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

Our significant accounting policies are described in the notes to our audited consolidated financial statements for the year ended December 31, 2005 included in the final prospectus relating to our initial public offering. 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.

#### **Stock-based compensation**

We adopted SFAS 123(R) — *Share Based Payment*, on January 1, 2006 using the modified prospective method of implementation and adopted the accelerated vesting method. Prior to January 1, 2006 we followed APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation*. In the notes to our financial statements we provide pro forma disclosures in accordance with SFAS No. 123 and related pronouncements.

Factors which affect charges or credits to operations related to stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded, the volatility of such fair value, and risk-free rate, expected dividend yield and expected life of the option used in the calculation of the fair value of the stock option. The stock-based compensation expense for a period is also affected by expected forfeiture rate for the respective option grants. If our estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating expenses.

On April 12, 2006, our common stock began trading on the NASDAQ National Market. Prior to April 12, 2006, given the absence of an active market for our common stock, the exercise price of our stock options on the date of grant was determined by our board of directors using several factors, including progress and milestones achieved in our business development and performance, the price per share of our convertible preferred stock offerings, the perspectives provided by our underwriters regarding estimates of a potential price per share in an initial public offering of our common stock and general industry and economic trends. In establishing our estimates of fair value, we considered the guidance set forth in the AICPA Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* and made a retrospective determination of fair value. The exercise price for employee options granted after April 12, 2006 is based on the market price of our common stock.

Stock-based compensation expense recognized during the three months ended September 30, 2006 is based on the value of the portion of stock-based payment awards that is ultimately expected to vest during the

period. Stock-based compensation expense recognized in the Company's condensed consolidated statement of operations includes:

- compensation expense for stock-based payment awards granted prior to, but not yet vested as of, December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123, and
- compensation expense for stock-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with SFAS 123(R).

Total stock-based compensation expense, related to all of the Company's stock-based awards, recognized during the three months ended September 30, 2006 and September 30, 2005, and also during the nine months ended September 30, 2006 and September 30, 2005, under SFAS 123(R) and APB 25, respectively, was comprised of the following:

	Three Months Ended		Nine Months Ended	
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
Research and development	\$ 185,000	\$ 17,000	\$ 476,000	\$ 659,000
General and administrative	1,321,000	766,000	4,013,000	3,431,000
Stock-based compensation expense	\$ 1,506,000	\$ 783,000	\$ 4,489,000	\$ 4,090,000

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

We account for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS No. 123 and EITF Issue No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. On January 19, 2006, the Company issued one of our consultants a grant to purchase 3,625 shares of our common stock with the exercise price of \$4.73, of which 2,190 were fully vested as of January 19, 2006 and the balance will vest ratably over 19 months. The option expires on January 19, 2016 and for the nine months ended September 30, 2006 we recorded a consulting expense of approximately \$36,000 relating to this option.

During the three months ended September 30, 2006 the Company entered into two consulting agreements that will require the Company to grant options to purchase up to 20,000 shares of common stock to these consultants subject to certain performance criteria. The terms of the stock option grants will be finalized upon their issuance.

#### **Income taxes**

As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. We account for income taxes by the liability method. Under this method, deferred income taxes are recognized for tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some of all of the deferred tax assets will not be realized. We have not recorded any tax provision or benefit for the three and nine-month periods ended September 30, 2006. We have provided a valuation allowance for the full amount of our net deferred tax assets since the likelihood of realization of any future benefit from deductible temporary differences and net operating loss carry forwards cannot be determined at September 30, 2006 and December 31, 2005.

### ***New Accounting Standards***

In July 2006, the Financial Accounting Standard Board ("FASB") issued FASB Interpretation No. 48 ("FIN 48") *Accounting for Uncertainty in Income Taxes — and interpretation of FASB Statement No. 109*, to clarify certain aspects of accounting for uncertain tax positions, including issues related to the recognition and measurement of these tax positions. This interpretation is effective for fiscal years beginning after December 15, 2006. While we are currently evaluating FIN 48, this pronouncement is not currently expected to have significant impact on our results of operations and financial condition.

In September 2006, the FASB issued FASB Statement No. 157, *Fair Value Measurements* ("FAS 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 (GAAP). FAS 157 outlines a common definition of fair value to be used throughout GAAP and the new standard intends to make the measurement of fair value more consistent and comparable and improve disclosures about those measures. Companies will need to adopt FAS 157 for financial statements issued for fiscal years beginning after November 15, 2007. We are currently evaluating the impact of FAS 157 on our results of operations and financial condition.

In September 2006, the Staff of the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of determining whether the current year's financial statements are materially misstated. SAB 108 is effective for fiscal years beginning after November 15, 2006. We are currently evaluating the requirements of SAB 108; however, we do not believe that its adoption will have a material effect on our financial statements.

### **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 September 30, 2006, we had a deficit accumulated during the development stage of approximately \$87.9 million. We anticipate incurring additional losses, which may increase, for the foreseeable future.

#### ***Three months ended September 30, 2006 compared to three months ended September 30, 2005***

*Research and development expenses.* Research and development expenses increased by approximately \$5.5 million, or 134%, to approximately \$9.5 million for the three months ended September 30, 2006 compared to approximately \$4.1 million for the three months ended September 30, 2005. Research and development expense consists of direct costs which include salaries and related costs of research and development personnel, stock-based compensation, and the costs of consultants, materials and supplies associated with research and development projects, as well as clinical activities. Indirect research and development costs include facilities, depreciation, and other indirect overhead costs.

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

	Three Months Ended	
	September 30, 2006	September 30, 2005
Direct project costs:		
Clinical trials	\$ 5,774,000	\$ 1,054,000
Contract research and development, consultants, materials and other costs	2,265,000	2,044,000
Salaries, benefits and related costs	925,000	708,000
Stock-based compensation	185,000	17,000
Total direct costs	9,149,000	3,823,000
Indirect project costs	393,000	269,000
Total	<u>\$ 9,542,000</u>	<u>\$ 4,092,000</u>

Direct costs increased approximately \$5.3 million primarily as a result of clinical development activities for iloperidone and VEC-162. Clinical trials expense increased approximately \$4.7 million for the three months ended September 30, 2006 primarily due to the cost incurred in our Phase III iloperidone and VEC-162 clinical trials that began 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 by approximately \$221,000 for the three month period ended September 30, 2006 and reflect the continuing regulatory and manufacturing related development costs incurred in connection with the manufacturing of clinical supply materials for the iloperidone and the VEC-162 clinical trial programs. Prior to FDA approval of our products, manufacturing-related costs are included in research and development expense. Salaries, benefits and related costs increased approximately \$217,000 for the three months ended September 30, 2006 due to an increase in personnel to support the development and clinical trial activities for iloperidone and VEC-162. Indirect project costs also increased by approximately \$124,000 for the three months ended September 30, 2006 due primarily to the increase in facility rent expense.

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

*General and administrative expenses.* General and administrative expenses increased approximately \$1.6 million, or 96%, to approximately \$3.3 million for the three months ended September 30, 2006 from approximately \$1.7 million for the three months ended September 30, 2005.

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

	Three Months Ended	
	September 30, 2006	September 30, 2005
Salaries, benefits and related costs	\$ 610,000	\$ 367,000
Stock-based compensation	1,321,000	766,000
Legal, consulting and other professional expenses	641,000	352,000
Other expenses	693,000	180,000
Total	<u>\$ 3,265,000</u>	<u>\$ 1,665,000</u>

General and administrative expenses consist of professional fees, salaries and related costs for executive and other administrative personnel and facility costs. Salaries, benefits and related costs increased approximately \$243,000 for the three months ended September 30, 2006 due to an increase in personnel as we continued to develop the administrative, business development and other functions required to support the development and clinical trial activities for iloperidone, VEC-162 and our other product candidates.

Legal, consulting and other professional costs increased approximately \$289,000 for the three months ended September 30, 2006 due primarily to a higher level of consulting activity in 2006 in support of business development and market research activities related to our lead product candidates and also the increased expenses associated with being a public company. Other expenses increased approximately \$513,000 for the three months ended September 30, 2006, due to an increase in expenses relating to our new office facilities of approximately \$100,000, an increase in insurance costs of approximately \$251,000 and an increase in other general and administrative expenses.

We expect our general and administrative expenses to continue to increase as we support our discovery and development efforts, form our commercial development activities and fulfill our reporting and other regulatory obligations applicable to public companies, including the compliance with Section 404 of the Sarbanes-Oxley Act.

*Interest income, net.* Net interest income in the three months ended September 30, 2006 was approximately \$683,000 compared to net interest income of approximately \$52,000 in the three months ended September 30, 2005. Interest income was higher in 2006 due to higher average cash balances for the quarter, primarily resulting from the proceeds from our initial public offering in April 2006, and higher short-term interest rates which generated substantially higher interest income than in 2005.

Our interest income and expense for the three months ended September 30, 2006 and the three months ended September 30, 2005 are disclosed on the following table:

	Three Months Ended	
	September 30, 2006	September 30, 2005
Interest income	\$ 683,000	\$ 57,000
Interest expense	—	(5,000)
Total, net	<u>\$ 683,000</u>	<u>\$ 52,000</u>

***Nine months ended September 30, 2006 compared to nine months ended September 30, 2005***

*Research and development expenses.* Research and development expenses increased by approximately \$32.5 million, or 279%, to approximately \$44.1 million for the nine months ended September 30, 2006 compared to approximately \$11.6 million for the nine months ended September 30, 2005. Research and development expense consists of direct costs which include salaries and related costs of research and development personnel, stock-based compensation, the costs of consultants, materials and supplies associated with research and development projects, as well as clinical activities. Indirect research and development costs include facilities, depreciation, and other indirect overhead costs.

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

	Nine Months Ended	
	September 30, 2006	September 30, 2005
Direct project costs:		
Clinical trials	\$ 33,055,000	\$ 4,101,000
Contract research and development, consultants, materials and other costs	6,855,000	4,496,000
Salaries, benefits and related costs	2,373,000	1,539,000
Stock-based compensation	476,000	659,000
Total direct costs	<u>42,759,000</u>	<u>10,795,000</u>
Indirect project costs	1,372,000	846,000
Total	<u>\$ 44,131,000</u>	<u>\$ 11,641,000</u>

Direct costs increased approximately \$32.0 million primarily as a result of clinical development activities for iloperidone and VEC-162. Clinical trials expense increased approximately \$29.0 million for the nine months ended September 30, 2006 primarily due to the cost incurred in our Phase III iloperidone and VEC-162 clinical trials that began 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 \$2.4 million for the nine months ended September 30, 2006, primarily as a result of a \$1.0 million milestone payment under our license agreement for VEC-162 with Bristol-Myers Squibb and due to increased regulatory and manufacturing-related development costs incurred in connection with the manufacturing of clinical supply materials for the iloperidone and the VEC-162 clinical trial programs. Prior to FDA approval of our products, manufacturing-related costs are included in research and development expense. Salaries, benefits and related costs increased approximately \$834,000 for the nine months ended September 30, 2006 due to an increase in personnel to support the development and clinical trial activities for iloperidone and VEC-162. Indirect project costs also increased by approximately \$526,000 for the nine months ended September 30, 2006 due primarily to the increase in facility rent expense.

We expect to continue to incur substantial research and development expenses due to our ongoing 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 \$3.6 million, or 64%, to approximately \$9.2 million for the nine months ended September 30, 2006 from approximately \$5.6 million for the nine months ended September 30, 2005.

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

	Nine Months Ended	
	September 30, 2006	September 30, 2005
Salaries, benefits and related costs	\$ 1,746,000	\$ 946,000
Stock-based compensation	4,013,000	3,431,000
Legal, consulting and other professional expenses	1,363,000	680,000
Other expenses	2,048,000	530,000
<b>Total</b>	<b>\$ 9,170,000</b>	<b>\$ 5,587,000</b>

General and administrative expenses consist of professional fees, salaries and related costs for executive and other administrative personnel and facility costs. Salaries, benefits and related costs increased approximately \$0.8 million for the nine months ended September 30, 2006 due to an increase in personnel as we continued to develop the administrative, business development and other functions required to support the development and clinical trial activities for iloperidone, VEC-162 and our other product candidates.

Legal, consulting and other professional costs increased approximately \$683,000 for the nine months ended September 30, 2006 due primarily to a higher level of consulting activity in 2006 in support of business development and market research activities related to our lead product candidates as well as the increased legal, accounting and other professional expenses associated with being a public company. Other expenses increased approximately \$1.5 million for the nine months ended September 30, 2006, due to an increase in facilities expenses of approximately \$429,000, which includes expenses relating to abandonment of our former office facilities of approximately \$267,000, an increase in insurance expenses of approximately \$515,000, primarily due to an increase in directors' and officers' and clinical trial insurance and an increase in other general and administrative expenses.

We expect our general and administrative expenses to continue to increase as we support our discovery and development efforts, form our commercial development activities and fulfill our reporting and other regulatory obligations applicable to public companies, including the compliance with Section 404 of the Sarbanes-Oxley Act.



*Interest income, net.* Net interest income in the nine months ended September 30, 2006 was approximately \$1.7 million compared to net interest income of approximately \$188,000 in the nine months ended September 30, 2005. Interest income was higher in 2006 due to higher average cash balances for the period and higher short-term interest rates which generated substantially higher interest income than in 2005.

Our interest income and expense for the nine months ended September 30, 2006 and the nine months ended September 30, 2005 are disclosed on the following table:

	Nine Months Ended	
	September 30, 2006	September 30, 2005
Interest income	\$ 1,686,000	\$ 209,000
Interest expense	(5,000)	(21,000)
<b>Total, net</b>	<b>\$ 1,681,000</b>	<b>\$ 188,000</b>

#### Liquidity and Capital Resources

We have funded our operations through September 30, 2006 principally with the net proceeds from private preferred stock offerings and initial public offering, totaling approximately \$61.8 million and \$53.3 million, respectively.

At September 30, 2006, cash and cash equivalents, marketable securities and restricted cash were approximately \$43.4 million compared to approximately \$31.6 million at December 31, 2005. 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.

As of September 30, 2006 and December 31, 2005, our liquidity resources are summarized as follows:

	September 30, 2006	December 31, 2005
Cash and cash equivalents	\$ 31,900,000	\$ 21,013,000
U.S. government agencies securities	6,765,000	6,055,000
U.S. corporate debt securities	4,332,000	4,086,000
Marketable securities	11,097,000	10,141,000
Restricted cash	430,000	430,000
	<b>\$ 43,427,000</b>	<b>\$ 31,584,000</b>

We maintained all of our cash and cash equivalents in four financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits, but do not anticipate any losses with respect to such cash balances.

Our activities will necessitate significant uses of working capital throughout 2006 and beyond. We plan to continue financing our operations with the cash received from financing activities, including the initial public offering of our common stock. We believe that our current capital resources will be sufficient to meet our operating needs through mid-2007, 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 initiate a Phase II VSF-173 trial for excessive sleepiness with our current capital resources,
- the clinical trials will be conducted in accordance with our expectations,
- we will not expend significant funds on the four week injectable formulation of, or bipolar indication for, iloperidone or on a Phase II or Phase III trial of VEC-162 for depression,

- we will be able to continue the manufacturing of our product candidates at commercially reasonable prices,
- we will be able to retain its key personnel, and
- we will not incur any significant contingent liabilities.

We may need to raise additional funds more quickly if one or more of its assumptions proves to be incorrect, if we choose to expand our product development efforts more rapidly than presently anticipated or if we seek to acquire additional product candidates. We do not plan to initiate a Phase II VSF-173 trial for excessive sleepiness until late 2007 and we have also delayed certain other non-priority manufacturing activities as a result of completing the enrollment for our iloperidone and VEC-162 Phase III trials significantly ahead of schedule. We expect that these actions will allow us to focus our currently available resources on our two lead product candidates. However, we do not currently expect these actions to result in any significant delays in the Company's overall clinical development results, including with respect to VSF-173.

We may decide to raise additional funds even before they are needed if the conditions for raising capital are favorable. However, we may not be able to raise additional funds on acceptable terms, or at all. If we are unable to secure sufficient capital to fund our research and development activities, we may not be able to continue operations, or we may have to enter into strategic collaborations that could require us to share commercial rights to our products to a greater extent or at earlier stages in the drug development process than is currently intended. These collaborations, if consummated prior to proof-of-efficacy or safety of a given product candidate, could impair our ability to realize value from that product candidate. In the absence of the ability to raise additional equity capital, we are also prepared and have the ability to curtail our existing clinical trial commitments and extend them in such a manner so that we have operating funds through the third quarter of 2007.

In 2003, we entered into a \$515,147 credit facility to finance the purchase of specified equipment based on lender-approved schedules. The interest rate was fixed at 9.3% per annum. In September 2006 we settled this obligation in full. The total indebtedness relating to this credit facility was approximately \$142,000 as of December 31, 2005.

#### Cash Flow

	Nine Months Ended	
	September 30, 2006	September 30, 2005
Net cash provided by (used in)		
Operating activities	\$ (40,503,000)	\$ (11,813,000)
Investing activities	(1,843,000)	(511,000)
Financing activities	53,237,000	18,335,000
Exchange rate effect on cash and equivalents	(4,000)	(6,000)
Net increase in cash and cash equivalents	<u>\$ 10,887,000</u>	<u>\$ 6,005,000</u>

Net cash used in operations was approximately \$40.5 million and approximately \$11.8 million for the nine months ended September 30, 2006 and 2005, respectively. The net loss for the nine months ended September 30, 2006 of approximately \$51.6 million was offset primarily by non-cash charges for depreciation and amortization of approximately \$415,000, stock-based compensation of approximately \$4.5 million, an increase of accrued expenses of approximately \$5.3 million, principally related to clinical trial expenses, and other net changes in working capital. Net cash used in investing activities for the nine months ended September 30, 2006 was approximately \$1.8 million and consisted primarily of net purchases of marketable securities of approximately \$0.6 million and purchases of property and equipment of approximately \$1.2 million. Net cash provided by financing activities for the nine months ended September 30, 2006 was

approximately \$53.2 million, consisting primarily of net proceeds from the initial public offering of our common stock of \$53.3 million.

### Contractual Obligations and Commitments

The following table summarizes our long-term contractual cash obligations as of September 30, 2006:

	Total	October to December 2006	Cash Payments Due by Period				After 2010
			2007 (In thousands)	2008	2009	2010	
Operating leases	\$ 4,848	\$ 127	\$ 642	\$ 536	\$ 427	\$ 440	\$ 2,676

#### 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 2006. We intend to renew the Singapore lease by the end of 2006 under similar terms.

We vacated our previous headquarters in January 2006. According to SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*, a liability for costs that will continue to be incurred under a lease for its remaining term without economic benefit to the company shall be recognized and measured when the company ceases using the right conveyed by the lease, reduced by estimated sublease rentals that could be reasonably obtained. In accordance with SFAS 146 we have recorded non-cash charges relating to the abandonment of our former office of approximately \$267,000 during the nine months ended September 30, 2006.

#### Credit facility

In 2003, we entered into a \$515,147 credit facility to finance the purchase of specified equipment based on lender-approved schedules. The facility was paid in full in September 2006.

#### Clinical research organization contracts and other contracts

We have entered into agreements with clinical research organizations responsible for conducting and monitoring our clinical trials for iloperidone and VEC-162, and have also entered into agreements with clinical supply manufacturing organizations and other outside contractors who will be responsible for additional services supporting our ongoing clinical development processes. These contractual obligations are not reflected in the table above because we may terminate them on no more than 60 days' notice without incurring additional charges (other than charges for work completed but not paid for through the effective date of termination and other costs incurred by our contractors in closing out work in progress as of the effective date of termination).

Assuming that our ongoing Phase III trials for iloperidone and VEC-162 are completed in accordance with our expectations, we will incur approximately \$3.0 million in costs from October 1 to December 31, 2006, and approximately \$2.5 million to \$3.5 million in costs in 2007, for clinical trial services rendered in connection with these trials.

#### License agreements

In February 2004 and September 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. In partial consideration for these rights, we paid a \$500,000 non-refundable fee for each compound. We are obligated to make additional payments under the conditions in the agreements upon the achievement of specified clinical, regulatory and commercial milestones. We met a clinical milestone

earlier in 2006 under the VEC-162 agreement with BMS and made an associated milestone payment and recorded an expense of \$1,000,000. We may meet other milestones in 2007 under our license agreements with Novartis for iloperidone and VSF-173, for which we would be obligated to make license payments. 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 Note 11 to the financial statements included with this report for a more detailed description of these license agreements.

We have not included any contractual obligations relating to our license agreements in the above table, since the amount, 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 and growth in product sales. 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" at Item 1A of Part II of this report.

#### **Prospective Information**

We expect to incur losses from operations for the foreseeable future. We expect to incur increasing research and development expenses, including expenses related to additions to personnel and clinical trials. We expect that our general and administrative expenses will increase in the future as we expand our business development, legal and accounting staff, add infrastructure and incur additional costs related to being a public company, including directors' and officers' insurance, investor relations programs and increased professional fees. Our future capital requirements will depend on a number of factors, including our continued progress of our research and development of product candidates, the timing and outcome of regulatory approvals, payments received or made under potential collaborative agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the acquisition of licenses to new products or compounds, the status of competitive products, the availability of financing and our or our potential partners' success in developing markets for our product candidates. Based on our current operating plans, we believe that our existing cash, restricted cash and cash equivalents, including the proceeds from our initial public offering will be sufficient to complete and report the results from our ongoing iloperidone and VEC-162 Phase III clinical trials that are both expected to be completed by the end of 2006 and to continue additional development and clinical activities for our product candidates.

#### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements, as defined in Item 303(a)(4) of the Securities and Exchange Commission's Regulation S-K.

#### **Item 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 condensed consolidated financial statements is U.S. Dollar. 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. We do not currently hedge foreign currency fluctuations 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, restricted cash and cash equivalents. 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) of the Securities Exchange Act of 1934) as of September 30, 2006. Based upon this evaluation, management has concluded that, as of September 30, 2006, 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 September 30, 2006 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

In addition to the other information set forth in this report, the following factors should be considered carefully in evaluating our business and us.

#### 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, our business will be materially harmed.***

We are uncertain whether any of our current product candidates in clinical development will prove effective and safe in humans or meet applicable regulatory standards. To date, the data supporting our product candidates is derived solely from laboratory and pre-clinical studies and limited clinical trials. However, for each of our product candidates we must provide the FDA and similar foreign regulatory authorities with more extensive clinical data for a defined indication of the product candidate before these regulatory authorities can approve the product candidate for commercial sale. Frequently, product candidates that have shown promising results in early clinical trials have suffered significant setbacks in later clinical trials. Future clinical trials involving our product candidates may reveal that those candidates are ineffective, are unacceptably toxic, have other undesirable side effects or are otherwise unfit for future development. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. If we are unable to discover and develop products that are effective and safe in humans, 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; and
- governmental or regulatory delays and changes in regulatory requirements and guidelines.

It is possible that none of our product candidates will complete clinical trials in any of the markets in which we intend to sell those product candidates. Accordingly, we may not receive the regulatory approvals needed to market our product candidates in any markets. Any failure or delay in commencing or completing clinical trials or obtaining regulatory approvals for our product candidates would severely harm our business.

***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; and
- 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. We plan to use appropriate statistical methods for analysis of our data. In addition to conventional statistical models, we may be using a “mixed-method repeated measures” statistical model to analyze data from our Phase III trial for iloperidone, as we believe that this model will reduce certain biases that can be associated with other statistical models. We have discussed the use of this statistical model with the FDA in an August 2005 guidance meeting, and they have agreed that the model is valid. However, to our knowledge, the “mixed-method repeated measures” statistical model has not been previously used as the primary basis for judging efficacy in a clinical trial by the FDA. If the FDA does not approve of our findings based on our “mixed-method repeated measures” model, our clinical trial for iloperidone may not be successful.

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; or
- withdrawal of approvals and 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, either alone or with a commercial partner. 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 materially adversely affect our business, financial condition and results of operations.

***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; and
- 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 on, among other things, 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 will be sufficient to meet our anticipated operating needs through mid-2007, 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 delay a Phase II VSF-173 trial for excessive sleepiness until late 2007, and that our clinical trials will generally be conducted in accordance with our expectations, that we will not expend significant funds on the four week injectable formulation of, or bipolar indication for, iloperidone or on a Phase II or Phase III trial of VEC-162 for depression, that we will be able to continue the manufacturing



of our product candidates at commercially reasonable prices, that we will be able to retain 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.

The Company does not plan to initiate the Phase II VSF-173 trial for excessive sleepiness until late 2007 and may delay other non-priority manufacturing activities as a result of its iloperidone and VEC-162 Phase III trials being completed ahead of schedule. The Company expects that these actions will focus the Company's currently available resources on the Company's two lead product candidates. However, these actions are not expected to result in any significant delays in the Company's overall clinical development results, including with respect to VSF-173.

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. 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 strategic collaborations 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 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 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 and development, clinical trial and administrative activity. 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 September 30, 2006, we have accumulated net losses of approximately \$87.9 million. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, conduct clinical trials, 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 approval of our products. The parties with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our products. Moreover,

these parties may also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors it could harm our competitive position.

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

***If our CTD contractors do not successfully carry out their duties or if we lose our relations with our CTD contractors, our NDA could be delayed.***

We are dependent on third-party vendors for the preparation of the Common Technical Dossier (CTD) for 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 our products.

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. Consequently, the NDA and commercialization of our product candidates could be delayed.

***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 the manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce the compounds for our clinical trials. Suppliers may not sell these materials to our manufacturers at the time 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 would be delayed, significantly affecting our ability to develop our product candidates. If our manufacturers or we 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 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 products. We do not have long-term agreements with any of these third parties, and if they are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers or formulators or enter into favorable agreements with them. Any inability to acquire sufficient quantities of our compounds 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 compounds 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 processes for VEC-162 and VSF-173 have not been tested in quantities needed for continued clinical trials or commercial sales, and delays in scale-up to commercial quantities could delay clinical trials, regulatory submissions and commercialization of our compounds;
- 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; and
- 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.

***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 products 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; and
- manufacturing and marketing products.

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

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

- For iloperidone in the treatment of schizophrenia, the atypical antipsychotics Risperdal® (risperidone) by Johnson & Johnson (including the depot formulation Risperdal® Consta®), Zyprexa® (olanzapine) by Eli Lilly and Company, Seroquel® (quetiapine) by AstraZeneca PLC, Abilify® (aripiprazole) by Bristol-Myers Squibb Company/Otsuka Pharmaceutical Co., Ltd., and Geodon® (ziprasidone) by Pfizer Inc., and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine and sulpiride (all of which are generic). In addition to the approved products, compounds in Phase III trials for the treatment of schizophrenia include bifeprunox (Wyeth/Solvay S.A./Lundbeck A/S), paliperidone (Johnson & Johnson), and asenapine (Pfizer).
- For VEC-162 in the treatment of insomnia, Rozerem™ (ramelteon) by Takeda Pharmaceuticals Company Limited, hypnotics such as Ambien® (zolpidem) by Sanofi-Aventis (including Ambien CR®), Lunesta® (eszopiclone) by Sepracor Inc. and Sonata® (zaleplon) by King Pharmaceuticals, Inc., generic benzodiazepines such as trazodone and doxepin, and over-the-counter remedies such as Benadryl® and Tylenol PM®. In addition to the approved products, compounds in Phase III trials for insomnia include

indiplon (Neurocrine Biosciences, Inc.) gaboxadol (Merck & Co., Inc./Lundbeck A/S), and low-dose doxepin (Silenor™, Somaxon Pharmaceuticals, Inc.).

- For VEC-162 in the treatment of depression, agomelatine (Les Laboratoires Servier), antidepressants such as Paxil® (paroxetine) by GSK, Zoloft® (sertraline) by Pfizer, Prozac® (fluoxetine) by Eli Lilly, and Lexapro (escitalopram) by Lundbeck/Forest Pharmaceuticals Inc., Effexor® (venlafaxine) by Wyeth as well as other compounds such as Wellbutrin® (bupropion) by GlaxoSmithKline (GSK) and Cymbalta® (duloxetine) by Eli Lilly.
- For VSF-173 in the treatment of excessive sleepiness, Provigil® (modafinil) by Cephalon Inc. and Xyrem® (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 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 strategic 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; and
- 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 October 31, 2006, we had 45 full-time employees. We will need to continue to expand our managerial, operational, financial and other resources in order 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; and
- 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; and
- 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. 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 intellectual property through a further sublicense from Novartis. Our rights with respect to this 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). BMS has a right of first negotiation to enter into a commercialization and development agreement with us prior to the completion of our Phase III program. Additionally, following the completion of our Phase III program for VEC-162, and in the event that we have not entered into one or more development and commercialization agreement 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. If we seek a co-promotion agreement for VEC-162, BMS has a right of first negotiation to enter into such an agreement with us. BMS may terminate our license if we fail to meet certain milestones or if we otherwise breach our royalty or other obligations in the agreement. In the event that we terminate our license, or if BMS terminates our license due to our breach, all of our rights to 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 meet certain development and commercialization milestones described in our license agreement, 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 October 31, 2006, we owned fourteen 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 may be volatile 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 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 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; and
- 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.***

If our existing stockholders sell a large number of our common stock or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. All of the shares sold in our initial public offering in April 2006 are freely tradable without restriction or further registration under the federal securities laws, unless purchased by an "affiliate" as that term is used in Rule 144 under the Securities Act of 1933, as amended. As of October 31, 2006,

approximately 12,178,110 additional shares of our common stock may be immediately resold by their holders pursuant to and subject to the provisions of Rule 144 under the Securities Act of 1933, as amended (including restrictions imposed on our affiliates by Rule 144). An additional 3,684,594 shares of common stock will be eligible for resale by their holders on or about December 9, 2006, pursuant to and subject to the provisions of Rule 144 (including restrictions imposed on our affiliates by Rule 144). By December 31, 2006, an additional 3,151 shares of our currently outstanding common stock will become vested to their respective holders by the terms of our Second Amended and Restated Management Equity Plan, and will be eligible for resale by their holders pursuant to and subject to the provisions of Rule 144 (including restrictions imposed on our affiliates pursuant to Rule 144).

Also, holders of 15,797,652 shares of our common stock have rights with respect to the registration of the sale of their shares of common stock with the SEC.

We have registered 1,569,667 shares of common stock that we are obligated to issue upon the exercise of currently outstanding options granted under, our Second Amended and Restated Management Equity 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.

We have also registered 1,500,000 shares of common stock that are authorized for issuance under our 2006 Equity Incentive Plan. The shares authorized for issuance under our 2006 Equity Incentive Plan can be freely sold in the public market upon issuance, subject to the restrictions imposed on our affiliates under Rule 144. We have granted options to purchase 103,692 shares under our 2006 Equity Incentive Plan as of September 30, 2006, none of which are vested.

***Existing stockholders may significantly influence us, which could delay or prevent an acquisition by a third party or result in the entrenchment of management or the board of directors.***

As of September 30, 2006 the executive officers, key employees and directors and their affiliates beneficially owned, in the aggregate, approximately 72% of our outstanding common stock. As a result, these stockholders, if acting together, may be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, which could have the effect of delaying or preventing either a third party from acquiring control over us or any changes to our management or board of directors.

***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 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 by laws 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; and
- 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**

**Unregistered Sales of Equity Securities**

During the three months ended September 30, 2006, we granted options to purchase an aggregate of 100,978 shares of our common stock to our employees under our 2006 Stock Plan.

**Use of Proceeds from Registered Securities**

We registered shares of our common stock in connection with our initial public offering under the Securities Act of 1933, as amended. 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 21, 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. and 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 per share of \$10.00. The aggregate price of the offering was \$59,641,880. The net offering proceeds to us after deducting underwriting discounts and commissions, as well as estimated offering expenses, were approximately \$53,330,000. We incurred total expenses in connection with the offering of approximately \$6,312,000, 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.

No payments for such expenses were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

We have used a portion of , and intend to continue to use, these proceeds for general corporate and research and development expenses, including for our current clinical trials for iloperidone and VEC-162 and clinical manufacturing expenses relating to the development of our lead product candidates. The unused net proceeds from the initial public offering are invested in investment grade securities. The use of proceeds is not materially different from the use of proceeds described in the final prospectus for our initial public offering, except that we will not initiate a Phase II trial for VSF-173 with these proceeds as we plan to focus our currently available resources on our two lead product candidates.

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 5. Other Information**

(a) On November 9, 2006, we entered into indemnification agreements with each of Dr. Paolo Baroldi, our Chief Medical Officer, and H. Thomas Watkins, one of our directors. The indemnification agreements with Dr. Baroldi and Mr. Watkins are in the form attached as Exhibit 10.11 to the Company's final registration statement on Form S-1 relating to its initial public offering.

**Item 6. Exhibits**

<u>Exhibit Number</u>	<u>Description</u>
3.6*	Amended and Restated Bylaws
3.8*	Amended and Restated Certificate of Incorporation
4.1*	2004 Securityholder Agreement (as amended)
4.4*	Specimen certificate representing the common stock of the registrant
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	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

# Application has been made to the Securities and Exchange Commission to seek confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.

\* Incorporated herein by reference to the exhibit of the same number in the Company's Registration Statement on Form S-1 (Commission File No. 333-130759).

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.

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

November 9, 2006

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

November 9, 2006

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

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

I, Mihael H. Polymeropoulos, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vanda Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. [Paragraph omitted in accordance with SEC Release 34-47986]
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2006

/s/ Mihael H. Polymeropoulos

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

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

I, Steven A. Shallcross, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vanda Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. [Paragraph omitted in accordance with SEC Release 34-47986]
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2006

/s/ Steven A. Shallcross

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



**Certification****Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002****(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)**

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

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) and 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2006

/s/ Mihael H. Polymeropoulos

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

Date: November 9, 2006

/s/ Steven A. Shallcross

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

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