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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, 2007

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 5, 2007, there were 26,650,634 shares of the Registrant's Common Stock issued and outstanding.

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Vanda Pharmaceuticals Inc.  
(A Development Stage Enterprise)

Form 10-Q Index

For the Three and Nine Months Ended September 30, 2007

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Part I — FINANCIAL INFORMATION ITEM

1. FINANCIAL STATEMENTS (UNAUDITED)

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

|   | September 30,<br>2007 | December 31,<br>2006 |
|---|-----------------------|----------------------|
| <b>ASSETS</b>   |                       |                      |
| Current assets:   |                       |                      |
| Cash and cash equivalents   | \$ 59,954,473         | \$ 30,928,895        |
| Marketable securities   | 45,474,370            | 941,981              |
| Prepaid expenses, deposits and other current assets   | 3,439,284             | 1,949,466            |
| Total current assets  | 108,868,127           | 33,820,342           |
| Marketable securities, long-term  | 3,992,347             | —                    |
| Property and equipment, net   | 1,444,925             | 1,859,704            |
| Deposits  | 150,000               | 150,000              |
| Restricted cash   | 430,230               | 430,230              |
| Total assets  | <u>\$ 114,885,629</u> | <u>\$ 36,260,276</u> |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                       |                      |
| Current liabilities:  |                       |                      |
| Accounts payable  | \$ 3,446,423          | \$ 2,783,249         |
| Accrued expenses  | 11,868,130            | 6,322,808            |
| Total current liabilities   | 15,314,553            | 9,106,057            |
| Deferred rent   | 280,655               | 238,413              |
| Deferred grant revenue  | —                     | 129,950              |
| Other long-term liabilities   | —                     | 28,984               |
| Total liabilities   | 15,595,208            | 9,503,404            |
| Commitments and contingencies   |                       |                      |
| Stockholders' equity  |                       |                      |
| Common stock, \$0.001 par value, 150,000,000 shares authorized as of September 30, 2007 and December 31, 2006; and 26,643,487 and 22,128,534 shares issued and outstanding as of September 30, 2007 and December 31, 2006, respectively | 26,643                | 22,129               |
| Additional paid-in capital  | 252,412,208           | 126,578,588          |
| Accumulated other comprehensive gain (loss)   | 13,430                | (3,269)              |
| Deficit accumulated during the development stage  | (153,161,860)         | (99,840,576)         |
| Total stockholders' equity  | 99,290,421            | 26,756,872           |
| Total liabilities and stockholders' equity  | <u>\$ 114,885,629</u> | <u>\$ 36,260,276</u> |

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

VANDA PHARMACEUTICALS INC.  
(A Development Stage Enterprise)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

|  | Three Months Ended    |                       | Nine Months Ended     |                       | Period from  |
|--|-----------------------|-----------------------|-----------------------|-----------------------|--|
|  | September 30,<br>2007 | September 30,<br>2006 | September 30,<br>2007 | September 30,<br>2006 | March 13,<br>2003<br>(Inception) to<br>September 30,<br>2007 |
| Revenues from services   | \$ —                  | \$ —                  | \$ —                  | \$ —                  | \$ 81,545  |
| Operating expenses:  |                       |                       |                       |                       |  |
| Research and development   | 13,874,248            | 9,542,385             | 34,660,132            | 44,130,788            | 113,075,038  |
| General and administrative   | 9,647,646             | 3,264,849             | 23,330,570            | 9,170,439             | 47,536,325   |
| Total operating expenses   | 23,521,894            | 12,807,234            | 57,990,702            | 53,301,227            | 160,611,363  |
| Loss from operations   | (23,521,894)          | (12,807,234)          | (57,990,702)          | (53,301,227)          | (160,529,818)  |
| Other income (expense):  |                       |                       |                       |                       |  |
| Interest income  | 1,514,708             | 683,469               | 4,608,143             | 1,686,363             | 7,399,713  |
| Interest expense   | —                     | (396)                 | —                     | (4,829)               | (80,485)   |
| Other income   | 71,345                | —                     | 71,345                | —                     | 71,947   |
| Total other income, net  | 1,586,053             | 683,073               | 4,679,488             | 1,681,534             | 7,391,175  |
| Loss before tax provision  | (21,935,841)          | (12,124,161)          | (53,311,214)          | (51,619,693)          | (153,138,643)  |
| Income tax provision   | 7,660                 | —                     | 10,070                | —                     | 23,217   |
| Net loss   | (21,943,501)          | (12,124,161)          | (53,321,284)          | (51,619,693)          | (153,161,860)  |
| Beneficial conversion feature — deemed dividend to preferred stockholders                            | —                     | —                     | —                     | —                     | (33,486,623)   |
| Net loss attributable to common stockholders   | \$ (21,943,501)       | \$ (12,124,161)       | \$ (53,321,284)       | \$ (51,619,693)       | \$ (186,648,483)   |
| Basic and diluted net loss per share applicable to common stockholders                               | \$ (0.82)             | \$ (0.55)             | \$ (2.03)             | \$ (3.72)             |  |
| Shares used in calculation of basic and diluted net loss per share applicable to common stockholders | 26,612,853            | 21,871,542            | 26,223,151            | 13,862,613            |  |

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

VANDA PHARMACEUTICALS INC.  
(A Development Stage Enterprise)

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

|   | Common Stock      |                  | Additional<br>Paid-In<br>Capital | Accumulated<br>Other<br>Comprehensive<br>Gain (Loss) | Deficit<br>Accumulated<br>During the<br>Development<br>Stage | Comprehensive<br>Loss | Total                |
|---|-------------------|------------------|----------------------------------|--|--|-----------------------|----------------------|
|   | Shares            | Par Value        |                                  |  |  |                       |                      |
| <b>Balances at December 31, 2006</b>                      | 22,128,534        | \$ 22,129        | \$ 126,578,588                   | \$ (3,269)   | \$ (99,840,576)  |                       | \$ 26,756,872        |
| Follow-on offering of common stock, net of issuance costs | 4,370,000         | 4,370            | 111,250,480                      | —  | —  | —                     | 111,254,850          |
| Employee stock-based compensation                         | —                 | —                | 14,301,976                       | —  | —  | —                     | 14,301,976           |
| Exercise of stock options                                 | 144,953           | 144              | 103,032                          | —  | —  | —                     | 103,176              |
| Non-employee stock-based compensation                     | —                 | —                | 178,132                          | —  | —  | —                     | 178,132              |
| Comprehensive loss:                                       |                   |                  |                                  |  |  |                       |                      |
| Net loss  | —                 | —                | —                                | —  | (53,321,284)   | \$ (53,321,284)       |                      |
| Cumulative translation adjustment                         | —                 | —                | —                                | (26,792)   | —  |                       | (26,792)             |
| Net unrealized gains on marketable securities             | —                 | —                | —                                | 43,491   | —  |                       | 43,491               |
| Comprehensive loss  | —                 | —                | —                                | —  | —  | \$ (53,304,585)       | (53,304,585)         |
| <b>Balances at September 30, 2007</b>                     | <u>26,643,487</u> | <u>\$ 26,643</u> | <u>\$ 252,412,208</u>            | <u>\$ 13,430</u>                                     | <u>\$ (153,161,860)</u>                                      |                       | <u>\$ 99,290,421</u> |

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

VANDA PHARMACEUTICALS INC.  
(A Development Stage Enterprise)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

|   | Nine Months Ended     |                       | Period from  |
|---|-----------------------|-----------------------|--|
|   | September 30,<br>2007 | September 30,<br>2006 | March 13,<br>2003<br>(Inception) to<br>September 30,<br>2007 |
| <b>Cash flows from operating activities</b>                                 |                       |                       |  |
| Net loss  | \$ (53,321,284)       | \$ (51,619,693)       | \$ (153,161,860)   |
| Adjustments to reconcile net loss to net cash used in operating activities: |                       |                       |  |
| Depreciation and amortization   | 446,806               | 415,197               | 1,865,659  |
| Employee and non-employee stock-based compensation                          | 14,480,108            | 4,525,202             | 25,792,817   |
| Loss on disposal of assets  | 27,017                | 29,528                | 56,545   |
| Accretion of discount on investments  | (1,315,609)           | (301,293)             | (1,736,683)  |
| Changes in assets and liabilities:  |                       |                       |  |
| Prepaid expenses, deposits and other current assets                         | (1,414,371)           | 391,559               | (3,360,162)  |
| Deposits  | —                     | 660,000               | (150,000)  |
| Accounts payable  | 660,697               | (143,303)             | 3,435,841  |
| Accrued expenses  | 5,544,227             | 5,329,690             | 11,863,292   |
| Deferred grant revenue  | (140,599)             | —                     | —  |
| Other liabilities   | 13,258                | 209,851               | 280,655  |
| Net cash used in operating activities                                       | <u>(35,019,750)</u>   | <u>(40,503,262)</u>   | <u>(115,113,896)</u>   |
| <b>Cash flows from investing activities</b>                                 |                       |                       |  |
| Purchases of property and equipment   | (249,728)             | (1,187,295)           | (3,441,225)  |
| Proceeds from sales of property and equipment                               | 119,054               | —                     | 119,054  |
| Purchases of marketable securities  | (107,570,370)         | (101,313,078)         | (221,649,154)  |
| Proceeds from sales of marketable securities                                | —                     | 82,137,888            | 82,137,888   |
| Maturities of marketable securities   | 60,395,000            | 18,520,000            | 91,815,000   |
| Investment in restricted cash   | —                     | —                     | (430,230)  |
| Net cash used in investing activities                                       | <u>(47,306,044)</u>   | <u>(1,842,485)</u>    | <u>(51,448,667)</u>  |
| <b>Cash flows from financing activities</b>                                 |                       |                       |  |
| Proceeds from borrowings on note payable                                    | —                     | —                     | 515,147  |
| Principal payments on obligations under capital lease                       | —                     | (1,071)               | (91,691)   |
| Principal payments on note payable  | —                     | (141,074)             | (515,147)  |
| Proceeds from issuance of preferred stock, net of issuance costs            | —                     | —                     | 61,795,187   |
| Proceeds from exercise of stock options and warrants                        | 103,176               | 48,886                | 262,046  |
| Proceeds from issuance of common stock, net of issuance costs               | 111,254,850           | 53,329,951            | 164,588,801  |
| Net cash provided by financing activities                                   | <u>111,358,026</u>    | <u>53,236,692</u>     | <u>226,554,343</u>   |
| Effect of foreign currency translation                                      | (6,654)               | (3,781)               | (37,307)   |
| Net increase in cash and cash equivalents                                   | <u>29,025,578</u>     | <u>10,887,164</u>     | <u>59,954,473</u>  |
| <b>Cash and cash equivalents</b>  |                       |                       |  |
| Beginning of period   | 30,928,895            | 21,012,815            | —  |
| End of period   | <u>\$ 59,954,473</u>  | <u>\$ 31,899,979</u>  | <u>\$ 59,954,473</u>   |

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

VANDA PHARMACEUTICALS INC.  
(A Development Stage Enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

**1. Business Organization and Presentation**

**Business organization**

Vanda Pharmaceuticals Inc. (Vanda or the Company) is a biopharmaceutical company focused on the development and commercialization of small molecule therapeutics, with exclusive worldwide commercial rights to three product candidates in clinical development for various central nervous system disorders. Vanda commenced its operations on March 13, 2003. The Company's lead product candidate, iloperidone, is a compound for the treatment of schizophrenia and bipolar disorder. The Company submitted a New Drug Application (NDA) for iloperidone in schizophrenia to the United States Food and Drug Administration (FDA) on September 27, 2007. The Company's second product candidate, VEC-162, is a compound for the treatment of sleep and mood disorders, which previously demonstrated positive results from a Phase III clinical trial in transient insomnia. VEC-162 is also ready for Phase II trials for the treatment of depression. The Company recently initiated a Phase III trial of VEC-162 in chronic primary insomnia. The Company's third product candidate, VSF-173, is a compound for the treatment of excessive sleepiness. On October 30, 2007 the Company reported the top-line results of its first Phase II trial of VSF-173 for the treatment of excessive sleepiness.

**Initial public and follow-on offerings**

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

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

**Capital resources**

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, raising capital and market research. Accordingly, the Company is considered to be in the development stage as defined in Statement of Financial Accounting Standards (SFAS) No. 7, *Accounting and Reporting by Development Stage Enterprises*.

The Company's activities will necessitate significant uses of working capital throughout 2007 and beyond. Additionally, the Company's capital requirements will depend on many factors, including the success of the Company's research and development efforts, payments received under contractual agreements with other parties, if any, and the status of competitive products. The Company plans to continue financing its operations with cash received from financing activities and believes that its current capital resources will be sufficient to meet its anticipated operating needs into mid-2008 and, after that time, the Company will require additional capital. In budgeting for its activities, the Company has relied on a number of assumptions, including assumptions that the Company will continue to expend funds in preparation of a commercial launch of iloperidone, that it will conduct the Phase III trial of VEC-162 in chronic primary insomnia in accordance with its expectations, that it will not engage in further in-licensing activities, that it will not receive any proceeds from potential partnerships, that it will not expend funds on the bipolar indication for iloperidone, that it will continue to evaluate pre-clinical compounds for potential development, that it will be able to continue the manufacturing of our product candidates at commercially reasonable prices, that it will be able to retain its key personnel, and that it will not incur any significant contingent liabilities.



VANDA PHARMACEUTICALS INC.  
(A Development Stage Enterprise)

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

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

**Basis of presentation**

The accompanying unaudited condensed consolidated financial statements of Vanda Pharmaceuticals Inc. have been prepared in accordance with accounting principles generally accepted in the United States and the rules and regulations of the Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all the information and footnotes required by generally accepted accounting principles for complete financial statements and should be read in conjunction with the Company's consolidated financial statements for the year ended December 31, 2006 included in the Company's annual report on the Form 10-K. The financial information as of September 30, 2007 and for the periods of the three and nine months ended September 30, 2007 and 2006 and for the period from March 13, 2003 (inception) to September 30, 2007, is unaudited, but in the opinion of management all adjustments, consisting only of normal recurring accruals, considered necessary for a fair statement of the results of these interim periods have been included. The condensed consolidated balance sheet data as of December 31, 2006 was derived from audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States.

The results of the Company's operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year. The financial information included herein should be read in conjunction with the consolidated financial statements and notes in the Company's annual report incorporated by reference in the Form 10-K for the year ended December 31, 2006. The condensed consolidated financial statements include the accounts of the Company and its wholly-owned Singapore subsidiary. All inter-company balances and transactions have been eliminated.

**2. Summary of Significant Accounting Policies**

*Use of estimates*

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

*Cash and cash equivalents*

For purposes of the condensed consolidated balance sheets and condensed consolidated statements of cash flows, cash equivalents represent highly-liquid investments with a maturity of three months or less at the date of purchase.

VANDA PHARMACEUTICALS INC.  
(A Development Stage Enterprise)

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

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

**Restricted cash**

During 2005, in conjunction with the lease of the office and laboratory space in Rockville, MD, the Company provided the landlord with a letter of credit, which was collateralized with a deposit in the amount of \$430,230. The deposit is recorded as non-current restricted cash at September 30, 2007 since the letter of credit is required until the lease expires in 2016.

**Concentrations of credit risk**

Financial instruments which potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. The Company places its cash and cash equivalents and marketable securities with highly-rated financial institutions. At September 30, 2007, the Company maintained all of its cash, cash equivalents and marketable securities in three financial institutions. Deposits held with these institutions may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand, and the Company believes there is minimal risk of losses on such balances.

**Stock-based compensation**

The Company accounts for the stock-based compensation expenses in accordance with the Financial Accounting Standards Board (FASB) revised SFAS No. 123, *Share-Based Payment* (SFAS 123(R)). Accordingly, compensation costs for all stock-based awards to employees and directors are measured based on the grant date fair value of those awards and recognized over the period during which the employee or director is required to perform service in exchange for the award. The Company generally recognizes the expense over the award's vesting period.

For stock awards granted in 2006 and 2007, expenses are amortized under the accelerated attribution method. For stock awards granted prior to January 1, 2006, expenses are amortized under the accelerated attribution method for options that were modified after the original grant date and under the straight-line attribution method for all other options. As stock-based compensation expense recognized in the condensed consolidated statements of operations for the three and nine months ended September 30, 2006 and 2007 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures on the options granted during 2006 and 2007 were estimated to be approximately 2% based on the Company's historical experience.

VANDA PHARMACEUTICALS INC.  
(A Development Stage Enterprise)

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

Total stock-based compensation expense recognized during the three and nine months ended September 30, 2007 and 2006 comprised of the following:

|  | Three Months Ended    |                       | Nine Months Ended     |                       | Period from<br>March 13,<br>2003<br>(Inception) to<br>September 30,<br>2007 |
|--|-----------------------|-----------------------|-----------------------|-----------------------|---|
|  | September 30,<br>2007 | September 30,<br>2006 | September 30,<br>2007 | September 30,<br>2006 |   |
| Research and development   | \$ 1,097,577          | \$ 184,789            | \$ 3,292,944          | \$ 475,563            | \$ 4,825,955  |
| General and administrative   | 4,059,822             | 1,321,008             | 11,009,038            | 4,013,347             | 20,749,243  |
| Stock-based compensation expense   | \$ 5,157,399          | \$ 1,505,797          | \$ 14,301,982         | \$ 4,488,910          | \$ 25,575,198   |
| Stock-based compensation expense per basic and diluted share of common stock | \$ 0.19               | \$ 0.07               | \$ 0.55               | \$ 0.32               |   |
| Shares used in calculation of stock-based compensation expense per share     | 26,612,853            | 21,871,542            | 26,223,151            | 13,862,613            |   |

As of September 30, 2007, approximately \$29.8 million of total unrecognized compensation costs related to non-vested awards are expected to be recognized over a weighted average period of 2.8 years.

As of September 30, 2007, the Company had two equity incentive plans, the Second Amended and Restated Management Equity Plan (the 2004 Plan) and the 2006 Equity Incentive Plan (the 2006 Plan) that were adopted in December 2004 and April 2006, respectively. An aggregate of 1,195,577 shares were subject to outstanding options granted under the 2004 Plan as of September 30, 2007, and no additional options will be granted under this plan. As of September 30, 2007 there are 2,385,141 shares of the Company's common stock reserved under the 2006 Plan of which 1,651,608 shares were subject to outstanding options to employees and non-employees.

Options are subject to terms and conditions established by the compensation committee of the board of directors. None of the stock-based awards are classified as a liability as of September 30, 2007. Option awards have 10-year contractual terms and all options granted prior to December 31, 2006 and options granted to new employees vest and become exercisable on the first anniversary of the grant date with respect to the 25% of the option awards. The remaining 75% of the option awards vest and become exercisable monthly in equal installments thereafter over three years. Option awards granted to existing employees after December 31, 2006 vest and become exercisable monthly in equal installments over four years. The initial stock options granted to directors upon their election vest and become exercisable in equal monthly installments over a period of four years, while the subsequent annual stock option grants to directors vest and become exercisable in equal monthly installments over a period of one year. Certain option awards to executives provide for accelerated vesting if there is a change in control of the Company.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model that uses the assumptions noted in the following table. Expected volatility rates are based on historical volatility of the common stock of comparable entities and other factors due to the lack of historic information of the Company's publicly traded common stock. The expected term of options granted is based on the transition approach provided by Staff Accounting Bulletin ("SAB") No. 107 as the options meet the "plain vanilla" criteria required by this method. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The

VANDA PHARMACEUTICALS INC.  
(A Development Stage Enterprise)

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

Company has not paid dividends to its stockholders since its inception and does not plan to pay dividends in the foreseeable future.

Assumptions used in the Black-Scholes-Merton option pricing model for employee and director stock options granted during the nine months ended September 30, 2007 and 2006 were as follows:

|  | Nine Months Ended     |                       |
|--|-----------------------|-----------------------|
|  | September 30,<br>2007 | September 30,<br>2006 |
| Expected dividend yield                | 0%                    | 0%                    |
| Weighted average expected volatility   | 71%                   | 71%                   |
| Weighted average expected term (years) | 6.25                  | 5.56                  |
| Weighted average risk-free rate        | 4.66%                 | 4.84%                 |

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

|                                   | Number of<br>Shares | Weighted<br>Average<br>Exercise Price<br>at Grant Date | Weighted<br>Average<br>Remaining Term<br>(Years) | Aggregate<br>Intrinsic Value |
|-----------------------------------|---------------------|--|--|------------------------------|
| Outstanding at December 31, 2006  | 1,347,205           | \$ 1.69  |  |                              |
| Forfeited                         | (6,580)             | 2.77   |  |                              |
| Exercised                         | (145,048)           | 0.71   |  | \$ 3,168,427                 |
| Outstanding at September 30, 2007 | 1,195,577           | 1.80   | 8.00   | 14,476,815                   |
| Exercisable at September 30, 2007 | 523,075             | 1.72   | 7.81   | 6,521,261                    |

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

|                                   | Number of<br>Shares | Weighted<br>Average<br>Exercise Price<br>at Grant Date | Weighted<br>Average<br>Remaining Term<br>(Years) | Aggregate<br>Intrinsic Value |
|-----------------------------------|---------------------|--|--|------------------------------|
| Outstanding at December 31, 2006  | 359,527             | \$ 20.21   |  |                              |
| Granted                           | 1,317,301           | 29.01  |  |                              |
| Forfeited                         | (72)                | 30.65  |  |                              |
| Cancelled                         | (25,148)            | 27.91  |  |                              |
| Outstanding at September 30, 2007 | 1,651,608           | 27.11  | 9.33   | \$ 536,616                   |
| Exercisable at September 30, 2007 | 250,463             | 26.66  | 9.31   | 150,027                      |

The weighted average grant-date fair value of options granted during the nine months ended September 30, 2007 was \$20.03 per share. For the nine months ended September 30, 2007 and 2006 the Company received a total of \$103,176 and \$294, respectively, in cash from options exercised under the stock-based arrangements.

**Equity instruments issued to non-employees**

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

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As of September 30, 2007, an aggregate of 35,625 shares were subject to outstanding options granted to non-employees under the 2004 Plan and 2006 Plan of which 28,187 options are subject to vesting. Total non-employee equity-based compensation expense, recognized during the three and nine months ended September 30, 2007 and 2006 was comprised of the following:

|                            | Three Months Ended    |                       | Nine Months Ended     |                       | Period from<br>March 13,<br>2003<br>(Inception) to<br>September 30,<br>2007 |
|----------------------------|-----------------------|-----------------------|-----------------------|-----------------------|---|
|                            | September 30,<br>2007 | September 30,<br>2006 | September 30,<br>2007 | September 30,<br>2006 |   |
| Research and development   | \$ 465                | \$ 1,528              | \$ 90,262             | \$ 36,292             | \$ 129,755  |
| General and administrative | (1,418)               | —                     | 87,864                | —                     | 87,864  |
|                            | <u>\$ (953)</u>       | <u>\$ 1,528</u>       | <u>\$ 178,126</u>     | <u>\$ 36,292</u>      | <u>\$ 217,619</u>   |

**Accrued expenses**

Management is required to estimate accrued expenses as part of the process of preparing financial statements. The estimation of accrued expenses involves identifying services that have been performed on the Company's behalf, and then estimating the level of service performed and the associated cost incurred for such services as of each balance sheet date in the financial statements. Accrued expenses include professional service fees, such as lawyers and accountants, contract service fees, such as those under contracts with clinical monitors, data management organizations and investigators in conjunction with clinical trials, fees to contract manufacturers in conjunction with the production of clinical materials, and fees for marketing and other commercialization activities. Pursuant to management's assessment of the services that have been performed on clinical trials and other contracts, the Company recognizes these expenses as the services are provided. Such management assessments include, but are not limited to: (1) an evaluation by the project manager of the work that has been completed during the period, (2) measurement of progress prepared internally and/or provided by the third-party service provider, (3) analyses of data that justify the progress, and (4) management's judgment.

**Research and development expenses**

The Company's research and development expenses consist primarily of fees for services provided by third parties in connection with the clinical trials, costs of contract manufacturing services, license fees, costs of materials used in clinical trials and research and development, depreciation of capital resources used to develop products, all related facilities costs, and salaries, other employee related costs and stock-based compensation related to the research and development personnel. The Company expenses research and development costs as they are incurred, including payments made to date under the license agreements. Manufacturing-related costs are also included in research and development expenses as the Company does not yet have FDA approval for any of its product candidates. Costs related to the acquisitions of intellectual property have been expensed as incurred since the underlying technology associated with these acquisitions were made in connection with the Company's research and development efforts and have no alternative future use. Milestone payments are accrued when it is deemed probable that the milestone event will be achieved.

**General and administrative expenses**

General and administrative costs consist primarily of salaries, other employee related costs and stock-based compensation for personnel serving executive, business development, marketing, finance, accounting, information technology and human resource functions, facility costs not otherwise included in research and development expenses, insurance costs and professional fees for legal, accounting and other professional

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services. General and administrative costs also include third party expenses incurred to support business development, marketing and other business activities related to our product candidate iloperidone, in anticipation of its commercial launch.

**Income taxes**

The Company accounts for income taxes under the liability method in accordance with the provisions of SFAS No. 109, *Accounting for Income Taxes* (SFAS 109), which requires companies to account for deferred income taxes using the asset and liability method. Under the asset and liability method, current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credits and loss carryforwards. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Tax rate changes are reflected in income during the period such changes are enacted. Changes in ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

On January 1, 2007, the Company adopted the provisions of Financial Standards Accounting Board Interpretation ("FIN") No. 48, *Accounting for Uncertainty in Income Taxes*. The adoption of FIN No. 48 did not have a material effect on the Company's financial position or results of operations.

**Segment information**

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

**Recent accounting pronouncements**

In September 2006, the FASB issued FASB Statement No. 157, *Fair Value Measurements* (SFAS 157), which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under generally accepted accounting principles. SFAS 157 outlines a common definition of fair value and the new standard intends to make the measurement of fair value more consistent and comparable and improve disclosures about those measures. The Company will need to adopt SFAS 157 for financial statements issued for fiscal years beginning after November 15, 2007. While the Company continues to evaluate the impact of SFAS 157, this pronouncement is not expected to have significant impact on its results of operations and financial condition.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115* (SFAS 159). According to this standard the entities will now be permitted to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis (the fair value option). SFAS 159 is effective for fiscal years beginning after November 15, 2007. While the Company continues to evaluate the impact of SFAS 159, this pronouncement is not expected to have significant impact on its results of operations and financial condition.

In June 2007, the Emerging Issues Task Force issued EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3), which provides guidance to research and development companies on how to account for the nonrefundable portion of an advance payment made for research and development activities. The Company will be required to adopt EITF 07-3 for the year beginning after December 15, 2007. The Company is

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currently assessing EITF 07-3 and does not expect the pronouncement to have a significant impact on its future condensed consolidated financial statements upon its adoption.

**3. Earnings per Share**

Net loss attributable to common stockholders per share is calculated in accordance with SFAS No. 128, *Earnings per Share* and SAB No. 98. Basic earnings per share (EPS) is calculated by dividing the net income or loss attributable to common stockholders by the weighted average number of shares of common stock outstanding, reduced by the weighted average unvested shares of common stock subject to repurchase.

Diluted EPS is computed by dividing the net income or loss attributable to common stockholders by the weighted average number of other potential common stock outstanding for the period. Other potential common stock includes 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 effect, resulting in dilutive loss per share attributable to common stockholders and basic loss per share attributable to common stockholders being equivalent.

|  | Three Months Ended    |                       | Nine Months Ended     |                       |
|--|-----------------------|-----------------------|-----------------------|-----------------------|
|  | September 30,<br>2007 | September 30,<br>2006 | September 30,<br>2007 | September 30,<br>2006 |
| <b>Numerator:</b>  |                       |                       |                       |                       |
| Net loss   | \$ (21,943,501)       | \$ (12,124,161)       | \$ (53,321,284)       | \$ (51,619,693)       |
| <b>Denominator:</b>  |                       |                       |                       |                       |
| Weighted average shares of common stock outstanding                              | 26,629,637            | 21,907,188            | 26,243,793            | 13,904,719            |
| Weighted average unvested shares of common stock subject to repurchase           | (16,784)              | (35,646)              | (20,642)              | (42,106)              |
| Denominator for basic and diluted net loss per share                             | \$ 26,612,853         | \$ 21,871,542         | \$ 26,223,151         | \$ 13,862,613         |
| Basic and diluted net loss per share applicable to common stockholders           | \$ (0.82)             | \$ (0.55)             | \$ (2.03)             | \$ (3.72)             |
| Anti-dilutive securities not included in diluted net loss per share calculation: |                       |                       |                       |                       |
| Options to purchase common stock   | 2,847,185             | 1,673,361             | 2,847,185             | 1,673,361             |

Upon consummation of the initial public offering on April 12, 2006, all shares of the Company's Series A Preferred Stock and Series B Preferred Stock were converted into an aggregate of 15,794,632 shares of common stock. Additionally, the holders of the warrants to purchase 50,335 shares of common stock exercised their warrants upon the Company's initial public offering.

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4. Marketable Securities

The following is a summary of the Company's available-for-sale marketable securities as of September 30, 2007:

|                                       | Amortized<br>Cost    | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses | Fair Market<br>Value |
|---------------------------------------|----------------------|------------------------------|-------------------------------|----------------------|
| <b>Short-term :</b>                   |                      |                              |                               |                      |
| U.S. Treasury and government agencies | \$ 6,477,825         | \$ 5,332                     | \$ —                          | \$ 6,483,157         |
| U.S. corporate debt                   | 36,160,430           | 37,805                       | (12,902)                      | 36,185,333           |
| U.S. asset-based securities           | 2,803,806            | 2,074                        | —                             | 2,805,880            |
|                                       | <u>\$ 45,442,061</u> | <u>\$ 45,211</u>             | <u>\$ (12,902)</u>            | <u>\$ 45,474,370</u> |
| <b>Long-term:</b>                     |                      |                              |                               |                      |
| U.S. corporate debt                   | \$ 1,986,513         | \$ 1,049                     | —                             | \$ 1,987,562         |
| U.S. asset-based securities           | 2,004,375            | 410                          | —                             | 2,004,785            |
|                                       | <u>\$ 3,990,888</u>  | <u>\$ 1,459</u>              | <u>—</u>                      | <u>\$ 3,992,347</u>  |

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

|                     | Amortized<br>Cost | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses | Fair Market<br>Value |
|---------------------|-------------------|------------------------------|-------------------------------|----------------------|
| <b>Short-term :</b> |                   |                              |                               |                      |
| U.S. corporate debt | \$ 941,970        | \$ 36                        | \$ (25)                       | \$ 941,981           |
|                     | <u>\$ 941,970</u> | <u>\$ 36</u>                 | <u>\$ (25)</u>                | <u>\$ 941,981</u>    |

5. Prepaid Expenses, Deposits and Other Current Assets

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

|   | September 30,<br>2007 | December 31,<br>2006 |
|---|-----------------------|----------------------|
| Deposits with vendors                     | \$ 790,000            | \$ 820,000           |
| Prepaid insurance                         | 455,202               | 337,332              |
| Prepaid research and development expenses | 737,742               | 185,229              |
| Accrued interest income                   | 417,338               | 97,575               |
| Other prepaid expenses                    | 1,035,225             | 332,400              |
| Prepaid follow-on offering costs          | —                     | 69,064               |
| Other receivables                         | 3,777                 | 107,866              |
|   | <u>\$ 3,439,284</u>   | <u>\$ 1,949,466</u>  |



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6. **Property and Equipment**

Property and equipment — at cost:

|  | Estimated Useful Life<br>(Years) | September 30,<br>2007 | December 31,<br>2006 |
|--|----------------------------------|-----------------------|----------------------|
| Laboratory equipment                             | 5                                | \$ 1,285,107          | \$ 1,675,375         |
| Computer equipment                               | 3                                | 762,755               | 741,404              |
| Furniture and fixtures                           | 7                                | 187,317               | 169,549              |
| Leasehold improvements                           | 10                               | 485,506               | 736,518              |
|  |                                  | 2,720,685             | 3,322,846            |
| Less — accumulated depreciation and amortization |                                  | (1,275,760)           | (1,463,142)          |
|  |                                  | <u>\$ 1,444,925</u>   | <u>\$ 1,859,704</u>  |

Depreciation and amortization expense for the nine months ended September 30, 2007 was \$446,806, for the nine months ended September 30, 2006 was \$415,197 and for the period from March 13, 2003 (inception) to September 30, 2007 was \$1,865,659.

7. **Accrued Expenses**

Accrued expenses consist of the following:

|   | September 30,<br>2007 | December 31,<br>2006 |
|---|-----------------------|----------------------|
| Accrued research and development expenses | \$ 3,923,252          | \$ 4,552,050         |
| Accrued license fee                       | 5,000,000             | —                    |
| Bonus accrual                             | 695,650               | 1,084,512            |
| Accrued professional fees                 | 1,825,693             | 329,177              |
| Employee benefits                         | 248,763               | 78,656               |
| Lease abandonment                         | 124,267               | 232,388              |
| Other accrued expenses                    | 50,505                | 46,025               |
|   | <u>\$ 11,868,130</u>  | <u>\$ 6,322,808</u>  |

8. **Commitments and Contingencies**

*Singapore research facility*

In May 2007, the Company initiated a plan to move all of its operations out of Singapore and to consolidate all of its discovery research activities in its Rockville, Maryland facility. The consolidation was completed as of September 30, 2007, and all expenses of the consolidation, including employee severance, loss on the sale of fixed assets and other related costs were recorded in the condensed consolidated financial statements as of September 30, 2007. Total expenses relating to the consolidation of the discovery research activities were not significant to the Company's condensed consolidated financial statements.

In 2004 the Company's subsidiary in Singapore entered into an agreement with the Economic Development Board of Singapore (EDB) to provide a grant for a development project. During 2005, the Company received a payment from the EDB that was recorded as deferred grant revenue since under certain conditions the EDB could have reclaimed these funds. On September 19, 2007 the Company agreed with the EDB to pay

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back 50% of the grant and the remaining 50%, or \$71,345, was recognized as other income during the three months ended September 30, 2007.

**Operating leases**

The Company has commitments totaling approximately \$6.5 million under operating real estate leases for its current and former headquarters located in Rockville, Maryland, expiring in 2016 and 2008. In September 2007, the Company entered into an agreement to sublease its former headquarters for the remainder of the lease for approximately \$67,000.

**Guarantees and indemnifications**

The Company has entered into a number of standard intellectual property indemnification agreements in the ordinary course of its business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners or customers, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to the Company's products. The term of these indemnification agreements is generally perpetual from the date of execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Since inception, the Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements. The Company also indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes that the fair value of the indemnification agreements is minimal, and accordingly the Company has not recognized any liabilities relating to these agreements as of September 30, 2007.

**Licensing agreements**

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

*Iloperidone.* The Company acquired exclusive worldwide rights to patents for iloperidone through a sublicense agreement with Novartis. A predecessor company of sanofi-aventis, Hoechst Marion Roussel, Inc. (HMRI), discovered iloperidone and completed early clinical work on the compound. In 1996, following a review of its product portfolio, HMRI licensed its rights to the iloperidone patents to Titan Pharmaceuticals, Inc. on an exclusive basis. In 1997, soon after it had acquired its rights, Titan sublicensed its rights to iloperidone on an exclusive basis to Novartis. In June 2004, the Company acquired exclusive worldwide rights to these patents to develop and commercialize iloperidone through a sublicense agreement with Novartis. In partial consideration for this sublicense, the Company paid Novartis an initial license fee of \$500,000 and is obligated to make future milestone payments to Novartis of less than \$100 million in the aggregate (the majority of which are tied to sales milestones), as well as royalty payments to Novartis at a rate which, as a percentage of net sales, is in the mid-twenties. The Company expects to meet a milestone in 2007 under this license agreement relating to the filing of the NDA for iloperidone in schizophrenia, for which the Company is obligated to make a license payment of \$5.0 million. The Company recorded an expense of \$5.0 million in September 2007 resulting from this milestone obligation.

The rights with respect to the patents to develop and commercialize iloperidone may terminate, in whole or in part, if the Company fails to meet certain development or commercialization milestones relating to the time it takes for the Company to launch iloperidone commercially following regulatory approval, and the time it takes for the Company to receive regulatory approval following the submission of an NDA or equivalent foreign filing. Additionally, the Company's rights may terminate in whole or in part if the Company does not meet certain other obligations under the sublicense agreement to make royalty and milestone payments, if the

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Company fails to comply with requirements in the sublicense agreement regarding its financial condition, or if the Company does not abide by certain restrictions in the sublicense agreement regarding other development activities.

*VEC-162.* In February 2004, the Company entered into a license agreement with Bristol-Myers Squibb (BMS) under which the Company received an exclusive worldwide license under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize VEC-162. In partial consideration for the license, the Company paid BMS an initial license fee of \$500,000 and is obligated to make future milestone payments to BMS of less than \$40 million in the aggregate (the majority of which are tied to sales milestones) as well as royalty payments based on the net sales of VEC-162 at a rate which, as a percentage of net sales, is in the low teens. The Company is also obligated under this agreement to pay BMS a percentage of any sublicense fees, upfront payments and milestone and other payments (excluding royalties) that the Company receives from a third party in connection with any sublicensing arrangement, at a rate which is in the mid-twenties. The Company has agreed with BMS in the license agreement for VEC-162 to use commercially reasonable efforts to develop and commercialize VEC-162 and to meet certain milestones in initiating and completing certain clinical work. During March 2006, the Company met its first milestone relating to the initiation of the Phase III clinical trial for VEC-162 and recorded a license fee expense of \$1,000,000.

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

Either party may terminate the VEC-162 license agreement under certain circumstances, including a material breach of the agreement by the other. In the event that BMS has not exercised its option to reacquire the rights to VEC-162 and the Company terminates the license, or if BMS terminates the license due to the Company's breach, all rights licensed and developed by the Company under this agreement will revert or otherwise be licensed back to BMS on an exclusive basis.

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

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

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an early termination of the license agreement, all rights licensed and developed by the Company under this agreement may revert back to Novartis.

*Future license payments.* Except for the accrued expense of \$5,000,000 in connection with the license fee payable upon the expected filing of the NDA by the FDA for iloperidone in schizophrenia, no other amounts were recorded as liabilities nor were any other contractual obligations relating to the license agreements included in the condensed consolidated financial statements as of September 30, 2007, since the amounts, timing and likelihood of these future payments are unknown and will depend on the successful outcome of future clinical trials, regulatory filings, favorable FDA regulatory approvals, growth in product sales and other factors.

**Research and development and marketing agreements**

The Company entered into agreements with several organizations to provide services relating to clinical development, clinical manufacturing activities and marketing services under fee service arrangements. The Company's current agreements for these services may be terminated on no more than 60 days notice without incurring additional charges, other than charges for work completed but not paid for through the effective date of termination and other costs incurred by the Company's contractors in closing out work in progress as of the effective date of termination.

**9. Income Taxes**

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

The Company has not recorded any tax provision or benefit for the nine months ended September 30, 2007 or 2006, except for an estimated tax expense resulting from the research and development agreement with the Company's subsidiary in Singapore. The Company has provided a valuation allowance for the full amount of its net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss cannot be sufficiently assured at September 30, 2007 and December 31, 2006. Under the Tax Reform Act of 1986, the amounts of and benefits from the operating loss carryforwards may be impaired in certain circumstances. Events which cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, over a three year period.

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

**Forward Looking Statements**

Various statements in this report are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," and "could," and similar expressions or words, identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Vanda is at an early stage of development and may not ever have any products that generate significant revenue. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements include, among others:

- delays in the completion of our clinical trials;
- a failure of our product candidates to be demonstrably safe and effective;
- a failure to obtain regulatory approval for our products or to comply with ongoing regulatory requirements;
- a lack of acceptance of our product candidates in the marketplace, or a failure to become or remain profitable;
- our inability to obtain the capital necessary to fund our research and development activities;
- our failure to identify or obtain rights to new product candidates;
- a failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage our growth;
- a loss of any of our key scientists or management personnel;
- losses incurred from product liability claims made against us;
- a loss of rights to develop and commercialize our products under our license and sublicense agreements; and
- the increased expenses and administrative workload associated with being a public company.

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

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

**Our Business**

We are a biopharmaceutical company focused on the development and commercialization of clinical-stage product candidates for central nervous system disorders, with exclusive worldwide commercial rights to three product candidates in clinical development. Our lead product candidate, iloperidone, is a compound for the treatment of schizophrenia and bipolar disorder and on September 27, 2007 we submitted a New Drug Application (NDA) for iloperidone in schizophrenia with the United States Food and Drug Administration (FDA). Our second product candidate, VEC-162, is a compound for the treatment of sleep and mood disorders, which previously demonstrated positive results in a Phase III clinical trial for transient insomnia. We will have to conduct additional trials prior to our filing of an NDA for VEC-162, and we recently initiated a Phase III trial of VEC-162 in chronic primary 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. On

October 30, 2007 we reported the top-line results of our first Phase II clinical trial of VSF-173 for the treatment of excessive sleepiness. We plan to conduct additional Phase II trials.

Assuming successful outcomes of our clinical trials and approval by the FDA, we plan to commercialize iloperidone and VSF-173 with our own sales force in the U.S., and we expect to commercialize VEC-162 through a partnership with a global pharmaceutical company, although we have not yet identified such a global partner.

We are a development stage enterprise and have accumulated net losses of approximately \$153.2 million since the inception of our operations through September 30, 2007. We have no product revenues to date and have no approved products for sale. Since inception we have devoted substantially all of our efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, raising capital and conducting market research. Our future operating results will depend largely on our ability to successfully develop and commercialize our lead product candidates, iloperidone and VEC-162, and on the progress of other product candidates currently in our research and development pipeline. The results of our operations will vary significantly from year-to-year and quarter-to-quarter and depend on a number of factors, including risks related to our business, risks related to our industry, and other risks which are detailed in the "Risk Factors" section of this quarterly report on Form 10-Q.

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

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

Based on our current operating plans, we believe that our existing cash, cash equivalents and marketable securities, will be sufficient to meet our anticipated operating needs into mid-2008, and after that time we will require additional capital. In budgeting for our activities, we have relied on a number of assumptions, including assumptions that we will continue to expend funds in preparation of a commercial launch of iloperidone, that we will conduct our VEC-162 Phase III trial in chronic primary insomnia in accordance with our expectations, that we will not engage in further in-licensing activities, that we will not receive any proceeds from potential partnerships, that we will not expend funds on the bipolar indication for iloperidone, that we will continue to evaluate clinical and pre-clinical compounds for potential development, that we will be able to continue the manufacturing of our product candidates at commercially reasonable prices, that we will be able to retain our key personnel, and that we will not incur any significant contingent liabilities. We may need to raise additional funds more quickly if one or more of our assumptions proves to be incorrect or if we choose to expand our product development efforts more rapidly than presently anticipated or seek to acquire additional product candidates, and we may also decide to raise additional funds even before they are needed if the conditions for raising capital are favorable.

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

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

### ***Iloperidone***

Iloperidone is our product candidate under development to treat schizophrenia and bipolar disorder. We submitted an NDA for iloperidone in schizophrenia to the FDA on September 27, 2007. We are also developing a 4-week injectable formulation of iloperidone, for which we already have early Phase II data from a study previously conducted by Novartis. From inception to September 30, 2007, we incurred approximately \$63.7 million in research and development costs directly attributable to our development of iloperidone, including a \$5.0 million milestone license fee payable to Novartis related to the filing of our NDA.

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

We also continue to progress with the development of our 4-week injectable formulation of iloperidone, for which we already have early Phase II data from a study previously conducted by Novartis. We are planning to conduct additional clinical work in 2008.

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

VEC-162 is our product candidate under development to treat sleep and mood disorders. VEC-162 is a melatonin receptor agonist that works by adjusting the human "body clock" of circadian rhythm. VEC-162 has successfully completed a Phase III trial in transient insomnia in November 2006. We initiated a Phase III trial of VEC-162 in chronic primary insomnia in October 2007.

From inception to September 30, 2007, we incurred approximately \$30.9 million in direct research and development costs directly attributable to our development of VEC-162. We believe that we will have to conduct additional trials to receive FDA approval of VEC-162. We have recently initiated a Phase III clinical trial to evaluate the safety and efficacy of VEC-162 in chronic primary insomnia. The trial is a randomized, double-blind, and placebo-controlled study, and will enroll approximately 400 patients. The trial will measure time to fall asleep and sleep maintenance, as well as next-day performance and mood. We expect to announce the results of this Phase III trial in the fourth quarter of 2008.

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

VSF-173 is an oral compound that has demonstrated effects on animal sleep/wake patterns and gene expression suggestive of a stimulant effect. In a recently completed Phase II trial of VSF-173 in excessive sleepiness, the compound demonstrated improvement compared to placebo on the Maintenance of Wakefulness Test (MWT), though not statistically significant, and dose-dependent, statistically significant improvements versus placebo on a number of secondary endpoints taken in the recovery sleep period after dosing, including number of awakenings, and sleep efficiency and wake after sleep onset in the first third of the recovery sleep period. VSF-173 was also demonstrated to be safe and well-tolerated. We expect to conduct additional Phase II trials.

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

From inception to September 30, 2007, we incurred approximately \$5.6 million in direct research and development costs directly attributable to our development of VSF-173, including a milestone license fee of \$1.0 million paid upon the initiation of our first Phase II clinical trial.

**Research and development expenses**

The Company's research and development expenses consist primarily of fees for services provided by third parties in connection with the clinical trials, costs of contract manufacturing services, license fees, costs of materials used in clinical trials and research and development, depreciation of capital resources used to develop products, all related facilities costs, and salaries, other employee related costs and stock-based compensation related to the research and development personnel. The Company expenses research and development costs as they are incurred, including payments made to date under the license agreements. Manufacturing-related costs are also included in research and development expenses as the Company does not yet have FDA approval for any of its product candidates. Costs related to the acquisitions of intellectual property have been expensed as incurred since the underlying technology associated with these acquisitions were made in connection with the Company's research and development efforts and have no alternative future use. Milestone payments are accrued when it is deemed probable that the milestone event will be achieved.

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, 2007, we incurred research and development expenses in the aggregate of approximately \$113.1 million, including employee stock-based compensation expenses of approximately \$4.8 million. We expect to continue to incur significant research and development expenses as we continue to develop our product candidates. We also expect to incur substantial licensing costs in the future, as we continue our efforts to develop our product candidates and to evaluate potential in-license product candidates.

The following table summarizes our product development initiatives for the three and nine months ended September 30, 2007 and 2006 and the period from March 13, 2003 (inception) to September 30, 2007. Included in this table are the research and development expenses recognized in connection with our product candidates in clinical development. Included in "Other product candidates" are the costs directly related to research initiatives for all other product candidates.

|  | Three Months Ended    |                       | Nine Months Ended     |                       | Period from<br>March 13,<br>2003<br>(Inception) to<br>September 30,<br>2007 |
|--|-----------------------|-----------------------|-----------------------|-----------------------|---|
|  | September 30,<br>2007 | September 30,<br>2006 | September 30,<br>2007 | September 30,<br>2006 |   |
| <b>Direct project costs(1)</b>                 |                       |                       |                       |                       |   |
| Iloperidone                                    | \$ 7,972,000          | \$ 5,195,000          | \$ 18,366,000         | \$ 31,478,000         | \$ 63,742,000   |
| VEC-162  | 3,894,000             | 3,512,000             | 9,922,000             | 9,559,000             | 30,941,000  |
| VSF-173  | 782,000               | 214,000               | 3,077,000             | 849,000               | 5,646,000   |
| Other product candidates                       | 653,000               | 228,000               | 1,559,000             | 873,000               | 4,593,000   |
| <b>Total direct product costs</b>              | <b>13,301,000</b>     | <b>9,149,000</b>      | <b>32,924,000</b>     | <b>42,759,000</b>     | <b>104,922,000</b>  |
| <b>Indirect project costs(1)</b>               |                       |                       |                       |                       |   |
| Facility                                       | 59,000                | 129,000               | 341,000               | 447,000               | 1,425,000   |
| Depreciation                                   | 108,000               | 125,000               | 333,000               | 350,000               | 1,596,000   |
| Other indirect overhead                        | 406,000               | 139,000               | 1,062,000             | 575,000               | 5,132,000   |
| <b>Total indirect expenses</b>                 | <b>573,000</b>        | <b>393,000</b>        | <b>1,736,000</b>      | <b>1,372,000</b>      | <b>8,153,000</b>  |
| <b>Total research and development expenses</b> | <b>\$ 13,874,000</b>  | <b>\$ 9,542,000</b>   | <b>\$ 34,660,000</b>  | <b>\$ 44,131,000</b>  | <b>\$ 113,075,000</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, other employee related costs and stock-based compensation expenses for personnel serving executive, finance, accounting, information technology and human resource functions, facility costs not otherwise included in research and development expenses, insurance costs and professional fees for legal, accounting and other professional services. General and administrative costs also include third party expenses incurred to support business development, marketing and other business activities related to our product candidate iloperidone in anticipation of its commercial launch. We expect that our general and administrative expenses will increase as we continue to prepare for the commercial launch of our lead product candidate, add sales personnel and continue to build our commercial infrastructure. From inception through September 30, 2007, we incurred general and administrative expenses in the aggregate of approximately \$47.5 million, including employee stock-based compensation expenses of approximately \$20.7 million.

### **Critical Accounting Policies**

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

Our significant accounting policies are described in the notes to our audited consolidated financial statements for the year ended December 31, 2006 included in our annual report on the Form 10-K. However, we believe that the following critical accounting policies relating to accrued expenses and stock-based compensation expense are important to understanding and evaluating our reported financial results, and we have accordingly included them in this report.

#### **Accrued expenses**

As part of the process of preparing financial statements we are required to estimate accrued expenses. The estimation of accrued expenses involves identifying services that have been performed on our behalf, and then estimating the level of service performed and the associated cost incurred for such services as of each balance sheet date in the financial statements. Accrued expenses include professional service fees, such as lawyers and accountants, contract service fees, such as those under contracts with clinical monitors, data management organizations and investigators in conjunction with clinical trials, fees to contract manufacturers in conjunction with the production of clinical materials, and fees for marketing and other commercialization activities. Pursuant to our assessment of the services that have been performed on clinical trials and other contracts, we recognize these expenses as the services are provided. Our assessments include, but are not limited to: (1) an evaluation by the project manager of the work that has been completed during the period, (2) measurement of progress prepared internally and/or provided by the third-party service provider, (3) analyses of data that justify the progress, and (4) management's judgment. In the event that we do not identify certain costs that have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high.

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

We adopted SFAS 123(R) — *Share Based Payment*, on January 1, 2006 using the modified prospective transition method of implementation. Accordingly, compensation costs for all stock-based awards to employees and directors are measured based on the grant date fair value of those awards and recognized over the service period. The Company generally recognizes the expense over the award's vesting period. For stock awards granted in 2006 and 2007, expenses are amortized under the accelerated attribution method. For stock awards granted prior to January 1, 2006, expenses are amortized under the accelerated attribution method for options

that were modified after the original grant date and under the straight-line attribution method for all other options.

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

Total employee stock-based compensation expense recognized during the three and nine months ending September 30, 2007 and 2006 was comprised of the following:

|                            | Three Months Ended    |                       | Nine Months Ended     |                       |
|----------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
|                            | September 30,<br>2007 | September 30,<br>2006 | September 30,<br>2007 | September 30,<br>2006 |
| Research and development   | \$ 1,097,000          | \$ 185,000            | \$ 3,293,000          | \$ 476,000            |
| General and administrative | 4,060,000             | 1,321,000             | 11,009,000            | 4,013,000             |
| Stock-based compensation   | \$ 5,157,000          | \$ 1,506,000          | \$ 14,302,000         | \$ 4,489,000          |

#### Recent accounting pronouncements

In September 2006, the FASB issued FASB Statement No. 157, *Fair Value Measurements* (SFAS 157), which addresses how companies should measure fair value when they are required to use a fair value measure for recognition or disclosure purposes under generally accepted accounting principles. SFAS 157 outlines a common definition of fair value and the new standard intends to make the measurement of fair value more consistent and comparable and improve disclosures about those measures. We will need to adopt SFAS 157 for financial statements issued for fiscal years beginning after November 15, 2007. While we continue to evaluate the impact of SFAS 157, this pronouncement is not expected to have significant impact on our results of operations and financial condition.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115* (SFAS 159). According to this standard the entities will now be permitted to measure many financial instruments and certain other assets and liabilities at fair value on an instrument-by-instrument basis (the fair value option). SFAS 159 is effective for fiscal years beginning after November 15, 2007. While we continue to evaluate the impact of SFAS 159, this pronouncement is not expected to have significant impact on our results of operations and financial condition.

In June 2007, the Emerging Issues Task Force issued EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3), which provides guidance to research and development companies on how to account for the nonrefundable portion of an advance payment made for research and development activities. We will be required to adopt EITF 07-3 for the year beginning after December 15, 2007. We are currently assessing EITF 07-3 and do not expect the pronouncement to have a significant impact on its future condensed consolidated financial statements upon its adoption.

#### 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, 2007, we had a deficit accumulated during the development stage of

approximately \$153.2 million. We anticipate incurring additional losses, which may increase, for the foreseeable future.

**Three months ended September 30, 2007 compared to three months ended September 30, 2006**

*Research and development expenses.* Research and development expenses increased by approximately \$4.3 million, or 45%, to approximately \$13.9 million for the three months ended September 30, 2007 compared to approximately \$9.5 million for the three months ended September 30, 2006.

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

|   | Three Months Ended    |                       |
|---|-----------------------|-----------------------|
|   | September 30,<br>2007 | September 30,<br>2006 |
| Direct project costs:   |                       |                       |
| Clinical trials   | \$ 2,444,000          | \$ 5,774,000          |
| Contract research and development, consultants, materials and other costs | 3,731,000             | 2,265,000             |
| License fees  | 5,000,000             | —                     |
| Salaries, benefits and related costs                                      | 1,029,000             | 925,000               |
| Stock-based compensation  | 1,097,000             | 185,000               |
| Total direct costs  | 13,301,000            | 9,149,000             |
| Indirect project costs  | 573,000               | 393,000               |
|   | <u>\$ 13,874,000</u>  | <u>\$ 9,542,000</u>   |

Direct costs increased approximately \$4.2 million for the three months ended September 30, 2007 compared to the three months ended September 30, 2006 as a result of the milestone fee and other expenses relating to our NDA for iloperidone, increase in clinical manufacturing activities for both iloperidone and VEC-162, offset by lower clinical trial expenses for the Company's iloperidone and VEC-162 Phase III trials that were primarily completed in 2006. Clinical trials expense decreased approximately \$3.3 million for the three months ended September 30, 2007 compared to the three months ended September 30, 2006 primarily due to the cost incurred during the three months ended September 30, 2006 in our Phase III iloperidone and VEC-162 clinical trials that were completed primarily in 2006. Contract research and development, consulting, materials and other direct costs increased approximately \$1.5 million for the three months ended September 30, 2007 relative to the three months ended September 30, 2006, primarily as a result of increased iloperidone NDA related expenses and manufacturing-related development costs incurred in connection with the manufacturing of clinical supply materials for the iloperidone and the VEC-162 programs. Prior to FDA approval of our products, manufacturing-related costs are included in research and development expense. Salaries, benefits and related costs increased approximately \$103,000 for the three months ended September 30, 2007 relative to the three months ended September 30, 2006 due to an increase in personnel to support the development and clinical trial activities for iloperidone, VEC-162 and VSF-173. Stock-based compensation expense increased by approximately \$913,000 compared to the three months ended September 30, 2006 as a result of options granted in 2007 and the higher fair value of options granted during 2007 compared to options granted in prior periods.

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

*General and administrative expenses.* General and administrative expenses increased approximately \$6.4 million, or 196%, to approximately \$9.6 million for the three months ended September 30, 2007 from approximately \$3.3 million for the three months ended September 30, 2006.

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

|   | Three Months Ended    |                       |
|---|-----------------------|-----------------------|
|   | September 30,<br>2007 | September 30,<br>2006 |
| Salaries, benefits and related costs              | \$ 760,000            | \$ 610,000            |
| Stock-based compensation                          | 4,060,000             | 1,321,000             |
| Marketing and related consulting services         | 3,369,000             | 235,000               |
| Legal, accounting and other professional expenses | 686,000               | 406,000               |
| Other expenses                                    | 773,000               | 693,000               |
|   | <u>\$ 9,648,000</u>   | <u>\$ 3,265,000</u>   |

Salaries, benefits and related costs increased approximately \$150,000 for the three months ended September 30, 2007 compared to the three months ended September 30, 2006 due to an increase in personnel as we continued to develop the administrative structure to support the development and clinical trial activities of our lead product candidates and to build our marketing capabilities in anticipation of the commercial launch of iloperidone. Stock-based compensation expense increased by approximately \$2.7 million as a result of options granted in 2007 and the higher fair value of options granted during 2007 compared to options granted in prior periods. Marketing and related consulting services expenses increased by approximately \$3.1 million due to the increase in marketing activity related to our anticipated commercial launch of iloperidone. These increased expenses included market research, branding, medical community cultivation and publication planning costs. Legal, accounting and other professional costs increased by approximately \$280,000 for the three months ended September 30, 2007 compared to the three months ended September 30, 2006 due primarily to a higher level of business development consulting activity and higher costs associated with our reporting and other regulatory obligations applicable to public companies.

We expect our general and administrative expenses to increase substantially, primarily to support our commercial development activities.

*Interest and other income.* Interest and other income in the three months ended September 30, 2007 was approximately \$1.6 million compared to approximately \$683,000 in the three months ended September 30, 2006. Interest income was higher in 2007 due to higher average cash balances for the quarter, primarily resulting from the proceeds from our public offerings and higher short-term interest rates which generated substantially higher interest income than in 2006. Other income for the three months ended September 30, 2007 includes approximately \$71,000 in revenue recognized from a grant from the Economic Development Board in Singapore. We do not expect to receive similar grants in the future.

Our interest and other income for the three months ended September 30, 2007 and 2006 are disclosed on the following table:

|                 | Three Months Ended    |                       |
|-----------------|-----------------------|-----------------------|
|                 | September 30,<br>2007 | September 30,<br>2006 |
| Interest income | \$ 1,515,000          | \$ 683,000            |
| Other income    | 71,000                | —                     |
|                 | <u>\$ 1,586,000</u>   | <u>\$ 683,000</u>     |

***Nine months ended September 30, 2007 compared to nine months ended September 30, 2006***

*Research and development expenses.* Research and development expenses decreased by approximately \$9.5 million, or 21%, to approximately \$34.7 million for the nine months ended September 30, 2007 compared to approximately \$44.1 million for the nine months ended September 30, 2006.

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

|   | Nine Months Ended     |                       |
|---|-----------------------|-----------------------|
|   | September 30,<br>2007 | September 30,<br>2006 |
| Direct project costs:   |                       |                       |
| Clinical trials   | \$ 7,323,000          | \$ 33,055,000         |
| Contract research and development, consultants, materials and other costs | 13,261,000            | 5,855,000             |
| License fees  | 6,000,000             | 1,000,000             |
| Salaries, benefits and related costs                                      | 3,047,000             | 2,373,000             |
| Stock-based compensation  | 3,293,000             | 476,000               |
| Total direct costs  | 32,924,000            | 42,759,000            |
| Indirect project costs  | 1,736,000             | 1,372,000             |
|   | <u>\$ 34,660,000</u>  | <u>\$ 44,131,000</u>  |

Direct costs decreased approximately \$9.8 million for the nine months ended September 30, 2007 compared to the nine months ended September 30, 2006 as a result of lower clinical trial expenses for the Company's iloperidone and VEC-162 Phase III trials that were primarily completed in 2006. These decreases were offset by the milestone fee that we expect to pay and other expenses relating to our NDA for iloperidone and clinical manufacturing activities for both iloperidone and VEC-162. Clinical trials expense decreased approximately \$25.7 million for the nine months ended September 30, 2007 compared to the nine months ended September 30, 2006 primarily due to the cost incurred during the nine months ended September 30, 2006 in our Phase III iloperidone and VEC-162 clinical trials. Contract research and development, consulting, materials and other direct costs increased approximately \$7.4 million for the nine months ended September 30, 2007 relative to the nine months ended September 30, 2006 primarily as a result of increased expenses related to the preparation of our NDA for iloperidone and the increased manufacturing of clinical supply materials for the iloperidone and the VEC-162 programs. Prior to FDA approval of our products, manufacturing-related costs are included in research and development expenses. During the nine months ended September 30, 2007 we met the requirements for a \$5.0 million milestone payment to Novartis under our license agreement for iloperidone and a \$1.0 million milestone payment to Novartis under our license agreement for VSF-173, and during the nine months ended September 30, 2006 we met the requirements for a \$1.0 million milestone payment to BMS under our license agreement for VEC-162. Salaries, benefits and related costs increased approximately \$674,000 for the nine months ended September 30, 2007 relative to the nine months ended September 30, 2006 due to an increase in personnel to support the development and clinical trial activities for iloperidone, VEC-162 and VSF-173. Stock-based compensation expense increased by approximately \$2.8 million compared to the nine months ended September 30, 2006 as a result of options granted in 2007 and the higher fair value of options granted during 2007 compared to options granted in prior periods.

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

*General and administrative expenses.* General and administrative expenses increased approximately \$14.2 million, or 154%, to approximately \$23.3 million for the nine months ended September 30, 2007 from approximately \$9.2 million for the nine months ended September 30, 2006.

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

|   | Nine Months Ended     |                       |
|---|-----------------------|-----------------------|
|   | September 30,<br>2007 | September 30,<br>2006 |
| Salaries, benefits and related costs              | \$ 2,319,000          | \$ 1,746,000          |
| Stock-based compensation                          | 11,009,000            | 4,013,000             |
| Marketing and related consulting services         | 5,373,000             | 385,000               |
| Legal, accounting and other professional expenses | 2,333,000             | 978,000               |
| Other expenses                                    | 2,297,000             | 2,048,000             |
|   | <u>\$ 23,331,000</u>  | <u>\$ 9,170,000</u>   |

Salaries, benefits and related costs increased approximately \$573,000 for the nine months ended September 30, 2007 compared to the nine months ended September 30, 2006 due to an increase in personnel as we continued to develop the administrative structure to support the development and clinical trial activities of our lead product candidates and to build our marketing capabilities in anticipation of the commercial launch of iloperidone. Stock-based compensation expense increased by approximately \$7.0 million as a result of options granted in 2007 and the higher fair value of options granted during 2007 compared to options granted in prior periods. Marketing and related consulting services expenses increased by approximately \$5.0 million due to the increase in marketing activities related to our anticipated commercial launch of iloperidone. These increased expenses included market research, branding, medical community cultivation and publication planning costs. Legal, accounting and other professional costs increased approximately \$1.4 million for the nine months ended September 30, 2007 compared to the nine months ended September 30, 2006 due primarily to a higher level of business developments consulting activity and higher costs associated with our reporting and other regulatory obligations applicable to public companies.

We expect our general and administrative expenses to increase substantially, primarily to support our commercial development activities.

*Interest and other income, net.* Net interest income in the nine months ended September 30, 2007 was approximately \$4.7 million compared to net interest income of approximately \$1.7 million in the nine months ended September 30, 2006. Interest income was higher in 2007 due to higher average cash balances for the period, primarily resulting from the proceeds from our public offerings and higher short-term interest rates which generated substantially higher interest income than in 2006. Other income for the nine months ended September 30, 2007 includes approximately \$71,000 in revenue recognized from a grant from the Economic Development Board in Singapore. We do not expect to receive similar grants in the future.

Our interest and other income for the nine months ended September 30, 2007 and the nine months ended September 30, 2006 are disclosed on the following table:

|                  | Nine Months Ended     |                       |
|------------------|-----------------------|-----------------------|
|                  | September 30,<br>2007 | September 30,<br>2006 |
| Interest income  | \$ 4,608,000          | \$ 1,686,000          |
| Other income     | 71,000                | —                     |
| Interest expense | —                     | (5,000)               |
|                  | <u>\$ 4,679,000</u>   | <u>\$ 1,681,000</u>   |

#### Liquidity and Capital Resources

We have funded our operations through September 30, 2007 principally with the net proceeds from private preferred stock offerings of approximately \$62.0 million, with net proceeds from our April 2006 initial public offering of approximately \$53.3 million and with net proceeds from our January 2007 follow-on offering of approximately \$111.3 million.

As of September 30, 2007, cash and cash equivalents and marketable securities were approximately \$109.4 million compared to approximately \$31.9 million at December 31, 2006. Our cash and cash equivalents are highly liquid investments with a maturity of 90 days or less at date of purchase and consist of time deposits, investments in money market funds with commercial banks and financial institutions, and commercial paper of high-quality corporate issuers. As of September 30, 2007 the Company also held a non-current deposit of \$430,000 that is used to collateralize a letter of credit issued for its current office lease expiring in 2016.

As of September 30, 2007 and December 31, 2006, our liquidity resources are summarized as follows:

|                                       | September 30,<br>2007 | December 31,<br>2006 |
|---------------------------------------|-----------------------|----------------------|
| Cash and cash equivalents             | \$ 59,954,000         | \$ 30,929,000        |
| U.S. Treasury and government agencies | 6,483,000             | —                    |
| U.S. corporate debt securities        | 36,185,000            | 942,000              |
| U.S. asset-backed securities          | 2,806,000             | —                    |
| Marketable securities, short-term     | 45,474,000            | 942,000              |
| U.S. corporate debt securities        | 1,988,000             | —                    |
| U.S. asset-backed securities          | 2,004,000             | —                    |
| Marketable securities, long-term      | 3,992,000             | —                    |
|                                       | <u>\$ 109,420,000</u> | <u>\$ 31,871,000</u> |
| Restricted cash                       | <u>\$ 430,000</u>     | <u>\$ 430,000</u>    |

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

#### Cash Flow

|  | Nine Months Ended     |                       |
|--|-----------------------|-----------------------|
|  | September 30,<br>2007 | September 30,<br>2006 |
| Net cash provided by (used in)               |                       |                       |
| Operating activities                         | \$ (35,020,000)       | \$ (40,503,000)       |
| Investing activities                         | (47,306,000)          | (1,843,000)           |
| Financing activities                         | 111,358,000           | 53,237,000            |
| Exchange rate effect on cash and equivalents | (6,000)               | (4,000)               |
| Net increase in cash and cash equivalents    | <u>\$ 29,026,000</u>  | <u>\$ 10,887,000</u>  |

Net cash used in operations was approximately \$35.0 million and approximately \$40.5 million for the nine months ended September 30, 2007 and 2006, respectively. The net loss for the nine months ended September 30, 2007 of approximately \$53.3 million was offset primarily by non-cash charges for stock-based compensation of approximately \$14.5 million, by depreciation and amortization of approximately \$447,000, by a decrease in prepaid expenses of approximately \$1.4 million, by an increase in accrued expenses and accounts payable of approximately \$6.2 million, and other net changes in working capital. Net cash used in investing activities for the nine months ended September 30, 2007 was approximately \$47.3 million and consisted primarily of net purchases of marketable securities of approximately \$47.2 million. Net cash provided by financing activities for the nine months ended September 30, 2007 was approximately \$111.4 million, consisting primarily of net proceeds from our follow-on offering.

**Contractual Obligations and Commitments**

The following table summarizes our long-term contractual cash obligations as of September 30, 2007:

|                  | Cash Payments Due by Period |                                |            |            |            |            |               |
|------------------|-----------------------------|--------------------------------|------------|------------|------------|------------|---------------|
|                  | Total                       | October to<br>December<br>2007 | 2008       | 2009       | 2010       | 2011       | After<br>2011 |
| Operating leases | \$ 6,497,000                | \$ 162,000                     | \$ 662,000 | \$ 685,000 | \$ 706,000 | \$ 727,000 | \$ 3,555,000  |

**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. 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 the sublease rentals. As of September 30, 2007, the balance of the lease abandonment accrual was approximately \$124,000.

During the second quarter of 2007, we exercised an option to lease additional space in our current headquarters in Rockville, Maryland and the additional commitment is reflected in the summary of operating lease commitments. In connection with the consolidation of our research activities, we terminated our Singapore lease, vacated the premises at the end of September 2007 and we have no other obligations in respect to the Singapore lease.

**Clinical research organization contracts and other contracts**

We entered into agreements with clinical research organizations responsible for conducting and monitoring our clinical trials for iloperidone, VEC-162 and VSF-173. These contractual obligations are not reflected in the table above because we may terminate them on no more than 60 days notice without incurring additional charges (other than charges for work completed but not paid for through the effective date of termination and other costs incurred by our contractors in closing out work in progress as of the effective date of termination). We also entered into agreements with clinical manufacturing organizations and other outside contractors who are responsible for additional services supporting our ongoing clinical development and commercialization processes. These contractual obligations are not reflected in the table above because we may terminate them on no more than 60 days notice without incurring additional charges (other than charges for work completed but not paid for through the effective date of termination and other costs incurred by our contractors in closing out work in progress as of the effective date of termination).

**License agreements**

In February 2004 and June 2004, we entered into separate licensing agreements with Bristol-Myers Squibb and Novartis, respectively, for the exclusive rights to develop and commercialize our three compounds in clinical development. We are obligated to make payments under the conditions in the agreements upon the achievement of specified clinical, regulatory and commercial milestones. If the products are successfully commercialized we will be required to pay certain royalties based on net sales for each of the licensed products. Please see the notes to the condensed consolidated financial statements included with this report for a more detailed description of these license agreements.

As a result of the successful commencement of the Phase III clinical study of VEC-162 in March 2006, we met the first milestone specified in our licensing agreement with Bristol-Myers Squibb and recorded a related license expense of \$1,000,000 during the three months ended March 31, 2006. During March 2007, we met our first milestone under the license agreement with Novartis for VSF-173 relating to the initiation of the Phase II clinical trial and recorded a license fee expense of \$1,000,000 during the three months ended March 31, 2007. As a result of the submission of our NDA for iloperidone in October 2007, we expect to meet another milestone under our license agreement with Novartis. During the three months ended September 30, 2007 we have recorded a \$5,000,000 milestone related charge, and expect to make this licensing payment to Novartis upon the successful filing of the NDA by the FDA. No other amounts were recorded as liabilities nor were any other contractual obligations relating to the license agreements included in



the condensed consolidated financial statements as of September 30, 2007, since the amounts, timing and likelihood of these payments are unknown and will depend on the successful outcome of future clinical trials, regulatory filings, favorable FDA regulatory approvals, growth in product sales and other factors. For a more detailed description of the risks associated with the outcome of such clinical trials, regulatory filings, FDA approvals and product sales, please see the section "Risk Factors" of this quarterly report on Form 10-Q.

**Off-Balance Sheet Arrangements**

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

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

**Foreign Exchange**

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

**Interest Rates**

Our exposure to market risk is currently confined to our cash, cash equivalents 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, cash equivalents and marketable securities, we do not believe that a change in market rates would have any significant impact on the realized value of our investments.

**Effects of Inflation**

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

**Item 4T. Controls and Procedures**

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

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of the Company's "disclosure controls and procedures" (as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of September 30, 2007. Based upon this evaluation, management has concluded that, as of September 30, 2007, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified under applicable rules of the Securities and Exchange Commission.

**b) Changes in Internal Controls**

There have been no changes in our internal controls over financial reporting, identified in connection with the evaluation of such internal controls that have occurred during the quarter ended September 30, 2007 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**Part II — OTHER INFORMATION****Item 1A. Risk Factors**

*Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this report, including the condensed consolidated financial statements and the related notes contained in this quarterly report on Form 10-Q, before deciding to invest in shares of our common stock. If any of the following risks is actually realized, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment.*

**Risks related to our business and industry**

***Our success is dependent on the success of our three product candidates: iloperidone, VEC-162 and VSF-173. If any of these product candidates are determined to be unsafe or ineffective in humans, whether in clinical trials or commercially, our business will be materially harmed.***

Despite the positive results of our completed trials, we are uncertain whether any of our current product candidates will ultimately prove to be effective and safe in humans. Frequently, product candidates that have shown promising results in clinical trials have suffered significant setbacks in later clinical trials or even after they are approved for commercial sale. Future uses of any of our product candidates, whether in clinical trials or commercially, may reveal that the product candidate is ineffective, unacceptably toxic, has other undesirable side effects or is otherwise not fit for further use. If we are unable to discover and develop products that are safe and effective, our business will be materially harmed.

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

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

- our inability to manufacture or obtain from third parties materials sufficient for use in pre-clinical studies and clinical trials
- delays in patient enrollment and variability in the number and types of patients available for clinical trials
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data
- poor effectiveness of product candidates during clinical trials
- unforeseen safety issues or side effects
- governmental or regulatory delays and changes in regulatory requirements and guidelines

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

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

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

The process of obtaining FDA and other required regulatory approvals and clearances will require us to expend substantial time and capital. Despite the time and expense expended, regulatory approval is never guaranteed. The number of pre-clinical and clinical tests that will be required for FDA approval varies

depending on the drug candidate, the disease or condition that the drug candidate is in development for, and the regulations applicable to that particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including that:

- a drug candidate may not be safe or effective
- they may interpret data from pre-clinical and clinical testing in different ways than we do
- they may not approve our manufacturing process
- they may change their approval policies or adopt new regulations

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

Moreover, if and when our products do obtain such approval or clearances, the marketing, distribution and manufacture of such products would remain subject to extensive ongoing regulatory requirements. Failure to comply with applicable regulatory requirements could result in:

- warning letters
- fines
- civil penalties
- injunctions
- recall or seizure of products
- total or partial suspension of production
- refusal of the government to grant approvals
- withdrawal of approvals
- criminal prosecution

Any delay or failure by us to obtain regulatory approvals for our product candidates could diminish competitive advantages that we may attain and would adversely affect the marketing of our products. We have not received regulatory approval to market any of our product candidates in any jurisdiction.

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

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

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

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

jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could harm our business materially.

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

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

In addition, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product, we could face one or more of the following:

- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication
- regulatory authorities may withdraw their approval of the product
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product
- our reputation may suffer

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

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

Even if we receive regulatory approvals for the sale of our product candidates, the commercial success of these products will depend, among other things, on their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. The degree of market acceptance of any of our product candidates will depend on a number of factors, including the demonstration of its safety and efficacy, its cost-effectiveness, its potential advantages over other therapies, the reimbursement policies of government and third-party payors with respect to the product candidates, 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 into mid-2008 and after that time we will require additional capital. In budgeting for our activities, we have relied on a number of assumptions, including assumptions that we will continue to expend funds in preparation of a commercial launch of iloperidone, that we will conduct our VEC-162 Phase III trial in chronic primary insomnia in accordance with

our expectations, that we will not engage in further in-licensing activities, that we will not receive any proceeds from potential partnerships, that we will not expend funds on the bipolar indication for iloperidone, that we will continue to evaluate pre-clinical compounds for potential development, that we will be able to continue the manufacturing of our product candidates at commercially reasonable prices, that we will be able to retain our key personnel, and that we will not incur any significant contingent liabilities. We may need to raise additional funds more quickly if one or more of our assumptions proves to be incorrect or if we choose to expand our product development efforts more rapidly than presently anticipated or seek to acquire additional product candidates, and we may also decide to raise additional funds even before they are needed if the conditions for raising capital are favorable.

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

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

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

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

We have a limited operating history. We have not generated any revenue from product sales to date and we cannot estimate with precision the extent of our future losses. We do not currently have any products that have been approved for commercial sale and we may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses for the foreseeable future, particularly as we increase our research, clinical development, marketing and administrative activities. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. We have been engaged in identifying and developing compounds and product candidates since March 2003. As of September 30, 2007, we have accumulated net losses of approximately \$153.2 million. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals, and have our products manufactured and marketed. We cannot assure you that we will be profitable even if we successfully commercialize our products. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

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

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

If we lose our relationship with any one or more of these parties, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to current Good Laboratory Practices (cGMP), 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.

***The FDA may refuse to file our NDA for iloperidone, which may delay or prevent the approval of iloperidone for commercial use.***

We submitted our New Drug Application (NDA) for iloperidone to the FDA on September 27, 2007. The FDA must inform us within 75 days of submission if it has accepted our NDA submission and filed it for regulatory review. If the FDA determines that our NDA submission is incomplete or insufficient for filing, the FDA may refuse to file the NDA. Any such refusal by the FDA could require us to expend additional time and resources to revise and resubmit our NDA, harm our business and reputation and cause the market price of our stock to decline. Furthermore, there is no guarantee that any revised or resubmitted NDA filing we make will be accepted by the FDA.

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

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

Our manufacturing strategy presents the following additional risks:

- the manufacturing process for VSF-173 has not been tested in quantities needed for continued clinical trials or commercial sales, and delays in scale-up to commercial quantities of VEC-162 and VSF-173 could delay clinical trials, regulatory submissions and commercialization of these product candidates
- because most of our third-party manufacturers and formulators are located outside of the United States, there may be difficulties in importing our compounds or their components into the United States as a

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

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

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

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

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

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

- developing products
- undertaking pre-clinical testing and clinical trials
- obtaining FDA and other regulatory approvals of products
- manufacturing and marketing products

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

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

- For iloperidone in the treatment of schizophrenia, the atypical antipsychotics Risperdal® (risperidone) (including the depot formulation Risperdal® Consta®) and Invega® (paliperidone) by Johnson & Johnson, Zyprexa® (olanzapine) by Eli Lilly and Company, Seroquel® (quetiapine) by AstraZeneca PLC, Abilify® (aripiprazole) by Bristol-Myers Squibb Company/Otsuka Pharmaceutical Co., Ltd., Geodon® (ziprasidone) by Pfizer Inc. and generic clozapine, as well as the typical antipsychotics haloperidol, chlorpromazine, thioridazine, and sulpiride (all of which are generic). In addition to the approved products, compounds in Phase III trials (or for which an NDA has been recently filed) for the treatment of schizophrenia include bifeprexon (Wyeth/Solvay S.A./Lundbeck A/S), and asenapine (Schering-Plough Corporation) and pimavanserin (Acadia Pharmaceuticals).
- 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 compounds such as trazodone and doxepin, and over-the-counter remedies such as Benadryl® and Tylenol PM®. In addition to the approved products, compounds in Phase III trials (or for which an

NDA has been recently filed) for insomnia include indiplon (Neurocrine Biosciences, Inc.) and low-dose doxepin (Silenor™, Somaxon Pharmaceuticals, Inc.).

- For VEC-162 in the treatment of depression, antidepressants such as Paxil® (paroxetine) by GlaxoSmithKline (GSK), Zoloft® (sertraline) by Pfizer, Prozac® (fluoxetine) by Eli Lilly, Lexapro (escitalopram) by Lundbeck A/S /Forest Pharmaceuticals Inc., and Effexor® (venlafaxine) by Wyeth as well as other compounds such as Wellbutrin® (bupropion) by GSK and Cymbalta® (duloxetine) by Eli Lilly. In addition to the approved products, compounds in Phase III trials for depression include agomelatine (Novartis and Les Laboratoires Servier).
- For VSF-173 in the treatment of excessive sleepiness, Provigil® (modafinil) and Nuvigil® (armodafinil) by Cephalon Inc., and Xyrem® (sodium oxybate) by Jazz Pharmaceuticals, Inc.

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

At present, we have limited marketing and no sales personnel. In order for us to commercialize any of our product candidates, we must either acquire or internally develop sales, marketing and distribution capabilities, or enter into collaborations with partners to perform these services for us. We may not be able to establish sales and distribution partnerships on acceptable terms or at all, and if we do enter into a distribution arrangement, our success will be dependent upon the performance of our partner. In the event that we attempt to acquire or develop our own in-house sales, marketing and distribution capabilities, factors that may inhibit our efforts to commercialize our products without partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our product
- the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage against companies with broader product lines
- unforeseen costs associated with creating our own sales and marketing team or with entering into a partnering agreement with an independent sales and marketing organization

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

As of September 30, 2007, we had 47 full-time employees. We will need to expand our managerial, operational, financial and other resources in order for us to manage and fund our operations, continue our development activities and commercialize our product candidates. Our current personnel, systems and facilities are not adequate to support this future growth. To manage our growth, we must:

- manage our clinical trials effectively
- manage our internal development efforts effectively
- improve our operational, financial, accounting and management controls, reporting systems and procedures
- 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 nine to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Our business could be materially harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

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

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007 or the FDAAA. The FDAAA grants a variety of new powers to the FDA, many of which are aimed at assuring drug safety and monitoring the safety of drug products after approval. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. While we expect the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry as well as our business will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute existing products.

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

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

- our addition or termination of development programs
- variations in the level of expenses related to our existing three product candidates or future development programs
- our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements
- any intellectual property infringement lawsuit in which we may become involved
- regulatory developments affecting our product candidates or those of our competitors

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

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

***Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of licenses or sublicenses granted to us by other pharmaceutical companies. With respect to VEC-162 and VSF-173, these terms and conditions include options in favor of these pharmaceutical companies to reacquire rights to commercialize and develop these product candidates in certain circumstances.***

Iloperidone is based in part on patents and other intellectual property owned by sanofi-aventis and Novartis. Titan Pharmaceuticals, Inc. (Titan) holds an exclusive license from sanofi-aventis to the intellectual property owned by sanofi-aventis, and Titan has sublicensed its rights under such license on an exclusive basis to Novartis. We have acquired exclusive rights to this and other intellectual property through a further sublicense from Novartis. Our rights with respect to the intellectual property to develop and commercialize iloperidone may terminate, in whole or in part, if we fail to meet certain milestones contained in our sublicense agreement with Novartis relating to the time it takes for us to launch iloperidone commercially following regulatory approval, and the time it takes for us to receive regulatory approval following our submission of an NDA or equivalent foreign filing. We may also lose our rights to develop and commercialize iloperidone if we fail to pay royalties to Novartis, if we fail to comply with certain requirements in the sublicense regarding our financial condition, or if we fail to comply with certain restrictions regarding our other development activities. Finally, our rights to develop and commercialize iloperidone may be impaired if

we do not cure breaches by Novartis and Titan of similar obligations contained in these sublicense and license agreements, although we are not aware of any such breach by Titan or Novartis. In the event of an early termination of our sublicense agreement, all rights licensed and developed by us under this agreement may be extinguished, which would have a material adverse effect on our business.

VEC-162 is based in part on patents that we have licensed on an exclusive basis and other intellectual property licensed from Bristol-Myers Squibb Company (BMS). Following the completion of the entire Phase III program for VEC-162, which may consist of several Phase III trials, and in the event that we have not entered into one or more development and commercialization agreements with one or more third parties covering certain significant markets, BMS has retained an option to reacquire the rights it has licensed to us to exclusively develop and commercialize VEC-162 on pre-determined financial terms, including the payment of royalties and milestone payments to us. BMS may terminate our license if we fail to meet certain milestones or if we otherwise breach our royalty or other obligations in the agreement. In the event that we terminate our license, or if BMS terminates our license due to our breach, all of our rights to VEC-162 (including any intellectual property we develop with respect to VEC-162) will revert back to BMS or otherwise be licensed back to BMS on an exclusive basis. Any termination or reversion of our rights to develop or commercialize VEC-162, including any reacquisition by BMS of our rights, may have a material adverse effect on our business.

VSF-173 is based in part on patents and other intellectual property that we have licensed on an exclusive basis from Novartis. Novartis has the option to reacquire rights to co-develop and exclusively commercialize VSF-173 following the completion of the Phase II trials, and an additional option to reacquire co-development rights and exclusive commercialization rights following the completion of the Phase III clinical trials, subject in each case to Novartis' payment of pre-determined royalties and other payments to us. In the event that Novartis chooses not to exercise either of these options and we decide to enter into a partnering arrangement to help us commercialize VSF-173, Novartis has a right of first refusal to negotiate such an agreement with us, as well as a right to submit a last matching counteroffer regarding such an agreement. In addition, our rights with respect to VSF-173 may terminate, in whole or in part, if we fail to meet certain development and commercialization milestones described in our license agreement relating to the time it takes us to complete our development work on VSF-173. These rights may also terminate in whole or in part if we fail to make royalty or milestone payments or if we do not comply with requirements in our license agreement regarding our financial condition. In the event of an early termination of our license agreement, all rights licensed and developed by us under this agreement may revert back to Novartis. Any termination or reversion of our rights to develop or commercialize VSF-173, including any reacquisition by Novartis of our rights, may have a material adverse effect on our business.

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

In addition to the rights we have licensed from Novartis and BMS relating to our product candidates, we rely upon intellectual property we own relating to our products, including patents, patent applications and trade secrets. As of September 30, 2007, we owned twenty nine provisional patent applications in the United States, two U.S. national stage applications under U.S. C. 371 and eight pending Patent Cooperation Treaty applications, which permit the pursuit of patents outside of the United States, relating to our product candidates in clinical development. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around these patents. In addition, we rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug development processes that involve proprietary know-how, information and technology that is not covered by patent applications. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United

States and abroad. If we are unable to protect or defend the intellectual property related to our technologies, we will not be able to establish or maintain a competitive advantage in our market.

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

The United States Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the “Hatch-Waxman Act,” provides for an extension of patent protection for drug compounds for a period of up to five years to compensate for time spent in development. Assuming we gain a five-year extension for each of our current product candidates in clinical development, and that we continue to have rights under our sublicense and license agreements with respect to these product candidates, we would have exclusive rights to iloperidone’s United States “new chemical entity” patent (the primary patent covering the compound as a new composition of matter) until 2016, to VEC-162’s United States new chemical entity patent until 2022 and to VSF-173’s United States new chemical entity patent until 2019. In Europe, similar legislative enactments allow patent protection in the European Union to be extended for up to five years through the grant of a Supplementary Protection Certificate. Assuming we gain such a five-year extension for each of our current product candidates in clinical development, and that we continue to have rights under our sublicense and license agreements with respect to these product candidates, we would have exclusive rights to iloperidone’s European new chemical entity patents until 2015, to VEC-162’s European new chemical entity patents until 2022 and to VSF-173’s European new chemical entity patents until 2017. Additionally, a recent directive in the European Union provides that companies who receive regulatory approval for a new compound will have a 10-year period of market exclusivity for that compound (with the possibility of a further one-year extension) in most EU countries, beginning on the date of such European regulatory approval, regardless of when the European new chemical entity patent covering such compound expires. A generic version of the approved drug may not be marketed or sold during such market exclusivity period. This directive may be of particular importance with respect to iloperidone, since the European new chemical entity patent for iloperidone will likely expire prior to the end of this 10-year period of market exclusivity. However, there is no assurance that we will receive the extensions of our patents or other exclusive rights available under the Hatch-Waxman Act or similar foreign legislation. If we fail to receive such extensions and exclusive rights, our ability to prevent competitors from manufacturing, marketing and selling generic versions of our products will be materially harmed.

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

Our commercial success depends in part on our not infringing the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would divert substantial financial and employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain additional licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to develop and commercialize further one or more of our product candidates.

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

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

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

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

**Risks related to our common stock**

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

The stock market has from time to time experienced significant price and volume fluctuations, and the market prices of the securities of life sciences companies without product revenues, such as ours, have historically been highly volatile. The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our common stock:

- publicity regarding actual or potential testing or trial results or the outcome of regulatory review relating to products under development by us or our competitors
- regulatory developments in the United States and foreign countries
- developments concerning any collaboration or other strategic transaction we may undertake
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors
- actual or anticipated variations in our quarterly operating results
- changes in estimates of our financial results or recommendations by securities analysts
- additions or departures of key personnel or members of our board of directors
- economic and other external factors beyond our control

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

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

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

In addition to our outstanding common stock, as of September 30, 2007 there were a total of 2,847,185 shares of common stock that we have registered and that we are obligated to issue upon the exercise

of currently outstanding options granted under our Second Amended and Restated Management Equity Plan and 2006 Equity Incentive Plan. Upon the exercise of these options in accordance with their respective terms, these shares may be resold freely, subject to restrictions imposed on our affiliates under Rule 144. If significant sales of these shares occur in short periods of time, these sales could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms. Additionally, the sale of additional equity securities at prices below the current market price of our common stock could result in dilution to our stockholders' interest.

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

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

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

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

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

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

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

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

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

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

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

- (i) \$772,000 in legal, accounting and printing fees
- (ii) \$7,155,000 in underwriters' discounts, fees and commissions and
- (iii) \$75,000 in miscellaneous expenses

We have used a portion of, and intend to continue to use, the proceeds of our initial public offering and our follow-on offering for general corporate and research and development expenses, including for our clinical trials for iloperidone, VEC-162 and VSF-173, the generation and submission of an NDA for iloperidone, the initiation and implementation of our commercialization strategy of iloperidone, and clinical manufacturing and other expenses relating to the development of our lead product candidates. The unused net proceeds from the initial public and follow-on offerings are invested in investment grade securities. This use of proceeds is not materially different from the use of proceeds described in the final prospectuses for our initial public offering and follow-on offering.

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

**Item 5. Other Information**

On November 7, 2007, based upon the determination of the Compensation Committee of the Company's Board of Directors, the Company entered into a tax indemnity agreement with Al Gianchetti, the Company's Chief Commercial Officer. Under the tax indemnity agreement, the Company or its successor will reimburse Mr. Gianchetti for any excise tax that he is required to pay under Section 4999 of the Internal Revenue Code of 1986, as amended, as well as the income and excise taxes imposed on the reimbursement. Section 4999 imposes a 20% excise tax on payments and distributions that are made or accelerated (or the vesting of which is accelerated) as a result of a change in control of the Company. The excise tax applies only if the aggregate value of the payments and distributions equals or exceeds 300% of Mr. Gianchetti's average annual compensation from the Company for the last five completed calendar years or, if less, all years of his employment with the Company. If the tax applies, it attaches to the excess of the aggregate value of the payments and distributions over 100% of Mr. Gianchetti's average annual compensation. In the Company's case, the payments and distributions consist of the continuation of salary, incentive bonus and health insurance coverage for varying periods of time and accelerated vesting of stock options to varying degrees.

The form of tax indemnity agreement is attached as Exhibit 10.21 to this report. An agreement in this form has also been entered into between the Company and each of Mihael H. Polymeropoulos, M.D., its President and Chief Executive Officer, Paolo Baroldi, M.D., Ph.D., its Senior Vice President and Chief Medical Officer, Chip Clark, its Senior Vice President, Chief Business Officer and Secretary, and Steven A. Shallcross, its Senior Vice President, Chief Financial Officer and Treasurer.

**Item 6. Exhibits**

| <u>Exhibit<br/>Number</u> | <u>Description</u>  |
|---------------------------|---|
| 10.20                     | Employment Agreement for Al Gianchetti dated October 25, 2007.  |
| 10.21                     | Form of Tax Indemnity Agreement.  |
| 31.1                      | Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.                         |
| 31.2                      | Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002.                         |
| 32.1                      | Certification of the Chief Executive Officer and Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002. |

The certification attached as Exhibit 32 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Vanda Pharmaceuticals Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.



**SIGNATURES**

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

Vanda Pharmaceuticals Inc.

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

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

November 8, 2007

*/s/ Steven A. Shallcross*

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

November 8, 2007

VANDA PHARMACEUTICALS INC.

EXHIBIT INDEX

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## VANDA PHARMACEUTICALS INC.

## EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement") is entered into as of October 25, 2007, by and between Al Gianchetti (the "Employee") and Vanda Pharmaceuticals Inc., a Delaware corporation (the "Company").

**1. Duties and Scope of Employment.**

(a) **Position.** For the term of his employment under this Agreement ("Employment"), the Company agrees to employ the Employee in the position of Chief Commercial Officer. The Employee shall be subject to the supervision of, and shall have such authority as is delegated to him by, the Chief Executive Officer of the Company, consistent with his position as Chief Commercial Officer. The Employee hereby accepts such employment and agrees to undertake the duties and responsibilities normally inherent in such position and such other duties and responsibilities as the Chief Executive Officer shall from time to time reasonably assign to him consistent with his position as Chief Commercial Officer.

(b) **Obligations to the Company.** During the term of his Employment, the Employee shall devote his full business efforts and time to the Company. During the term of his Employment, without the prior written approval of the Board of Directors of the Company (the "Board"), the Employee shall not render services in any capacity to any other person or entity and shall not act as a sole proprietor or partner of any other person or entity or as a shareholder owning more than five percent of the stock of any other corporation. The Employee shall comply with the Company's policies and rules, as they may be in effect from time to time during the term of his Employment.

(c) **No Conflicting Obligations.** The Employee represents and warrants to the Company that he is under no obligations or commitments, whether contractual or otherwise, that are inconsistent with his obligations under this Agreement. The Employee represents and warrants that he will not use or disclose, in connection with his employment by the Company, any trade secrets or other proprietary information or intellectual property in which the Employee or any other person has any right, title or interest and that his employment by the Company as contemplated by this Agreement will not infringe or violate the rights of any other person or entity. The Employee represents and warrants to the Company that he has returned all property and confidential information belonging to any prior employers.

**2. Cash and Incentive Compensation.**

(a) **Salary and Signing Bonus.** The Company shall pay the Employee as compensation for his services a base salary at a gross annual rate of not less than \$295,000. Such salary shall be payable in accordance with the Company's standard payroll procedures. (The annual compensation specified in this Subsection (a), together with any increases in such compensation that the Company may grant from time to time, is referred to in this Agreement as "Base Compensation.") The Employee will also receive a \$100,000 signing bonus that will become due and payable upon hire. The payment of such signing bonus will be subject to standard federal and state taxes and will be payable in accordance with the Company's standard payroll procedures. The Employee will also receive a \$35,000 bonus that will become due and payable once the Employee has completed one year of continuous service to the Company. This bonus will be subject to standard federal and state taxes and will be payable in accordance with the Company's standard payroll procedures.

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(b) **Incentive Bonuses.** The Employee shall be eligible to be considered for an annual incentive bonus with a target amount equal to 25% of his Base Compensation (the "Annual Target Bonus"). Such annual incentive bonus (if any) shall be awarded based on objective or subjective criteria established in advance by the Board or its Compensation Committee. The determinations of the Board or its Compensation Committee with respect to such bonus shall be final and binding. For the avoidance of doubt, (i) to be eligible for an annual incentive bonus for any given fiscal year of the Company, the Employee must have been employed continuously by the Company throughout such fiscal year, and (ii) provided the Employee has been employed continuously by the Company from the date of this Agreement through December 31, 2007, then, notwithstanding clause (i), the Employee's annual incentive bonus with respect to the Company's 2007 fiscal year will not be prorated, but will instead be based on the full amount of Base Compensation the Employee would have been entitled to receive had the Employee commenced his employment with the Company on January 1, 2007.

(c) **Stock Option.** Subject to the approval of the Board or its Compensation Committee, the Company shall grant the Employee a nonstatutory stock option under the Company's 2006 Equity Incentive Plan, covering 90,000 shares of the Company's Common Stock. Such option shall be granted as soon as reasonably practicable after the date of this Agreement. The per-share exercise price of such option shall be equal to the fair market value of one share of the Company's Common Stock on the date of grant. The term of such option shall be 10 years, subject to earlier expiration in the event of the termination of the Employee's Employment. The Employee shall vest in 25% of the option shares after the first 12 months of continuous service and shall vest in the remaining option shares in equal monthly installments over the next three years of continuous service. The vested and exercisable portion of the option shall be determined by adding 24 months to the Employee's actual period of service if, after a Change in Control, (i) the Employee's Employment is terminated by the Company for reasons other than Cause or (ii) the Employee's Employment is terminated by the Employee for Good Reason. The grant of such option shall be subject to the other terms and conditions set forth in the Company's 2006 Equity Incentive Plan, and the Company's standard form of stock option agreement under such Plan.

(d) **Restricted Stock Grant.** Subject to the approval of the Board or its Compensation Committee, the Company shall also award the Employee as compensation 3,000 shares of the Company's Common Stock under the Company's 2006 Equity Incentive Plan, which shall be "Restricted Shares" as defined in such Plan. The Employee shall vest in 25% of such Restricted Shares on each of the first, second, third and fourth anniversaries of this agreement. The vested portion of the Restricted Shares shall be determined by adding 24 months to the Employee's actual period of service if, after a Change in Control, (i) the Employee's Employment is terminated by the Company for reasons other than Cause or (ii) the Employee's Employment is terminated by the Employee for Good Reason. The Restricted Shares shall be subject to the terms of the Company's 2006 Equity Incentive Plan and such other terms as shall be determined by the Board or its Compensation Committee, and shall be evidenced by a restricted stock agreement to be executed by the Employee and the Company as soon as reasonably practicable following approval thereof.

For purposes of the foregoing paragraphs (c) and (d):

“Change in Control” shall mean (i) the consummation of a merger or consolidation of the Company with or into another entity, if persons who were not stockholders of the Company immediately prior to such merger or consolidation own immediately after such merger or consolidation 50% or more of the voting power of the outstanding securities of each of (A) the continuing or surviving entity and (B) any direct or indirect parent corporation of such continuing or surviving entity; or (ii) the sale, transfer or other disposition of all or substantially all of the Company’s assets. A transaction shall not constitute a Change in Control if its sole purpose is to change the state of the Company’s incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company’s securities immediately before such transaction.

“Cause” shall mean (i) an unauthorized use or disclosure of the Company’s confidential information or trade secrets, which use or disclosure causes material harm to the Company; (ii) a material breach of any agreement between Employee and the Company; (iii) a material failure to comply with the Company’s written policies or rules; (iv) conviction of, or plea of “guilty” or “no contest” to, a felony under the laws of the United States or any state thereof; (v) gross negligence or willful misconduct which causes material harm to the Company; or (vi) a continued failure to perform assigned duties after receiving written notification of such failure from the Board; or (vii) a failure by the Employee to cooperate in good faith with a governmental or internal investigation of the Company or its directors, officers or employees, if the Company has requested the Employee’s cooperation.

“Good Reason” shall mean any of the following events, if such event occurs without the Employee’s consent: (i) the Employee’s receipt of notice that his principal workplace will be relocated more than 30 miles; (ii) a reduction in the Employee’s base salary by more than 10%, unless pursuant to a Company-wide reduction affecting all employees proportionately; or (iii) a change in Employee’s position with the Company that materially reduces his level of authority or responsibility.

3. **Vacation and Employee Benefits.** During the term of his Employment, the Employee shall be eligible for 20 paid vacation days each year in accordance with the Company’s standard policy for similarly situated employees, as it may be amended from time to time. During the term of his Employment (and beginning on the first day of such Employment), the Employee shall be eligible to participate in any employee benefit plans maintained by the Company for similarly situated employees, subject in each case to the generally applicable terms and conditions of the plan in question, the completion of any required enrollment forms and the determinations of any person or committee administering such plan.

4. **Business Expenses.** During the term of his Employment, the Employee shall be authorized to incur necessary and reasonable travel, entertainment and other business expenses in connection with his duties hereunder. The Company shall reimburse the Employee for such expenses upon presentation of an itemized account and appropriate supporting documentation, all in accordance with the Company’s generally applicable policies.

## 5. Term of Employment.

(a) **Basic Rule.** The Company agrees to continue the Employee's Employment, and the Employee agrees to remain in Employment with the Company, from the date of this Agreement until the date when the Employee's Employment terminates pursuant to Subsection (b) or (c) below. The Employee's Employment with the Company shall be "at will," meaning that either the Employee or the Company may terminate the Employee's Employment at any time, with or without cause. Any contrary representations which may have been made to the Employee shall be superseded by this Agreement. This Agreement shall constitute the full and complete agreement between the Employee and the Company on the "at will" nature of the Employee's Employment, which may only be changed in an express written agreement signed by the Employee and a duly authorized officer of the Company.

(b) **Termination.** The Company may terminate the Employee's Employment at any time and for any reason (or no reason), and with or without cause, by giving the Employee notice in writing. The Employee may terminate his Employment by giving the Company 14 days' advance notice in writing. The Employee's Employment shall terminate automatically in the event of his death.

(c) **Permanent Disability.** The Company may terminate the Employee's Employment due to Permanent Disability by giving the Employee 30 days' advance notice in writing. For all purposes under this Agreement, "Permanent Disability" shall mean that the Employee, at the time notice is given, has failed to perform his duties under this Agreement for a period of not less than 90 consecutive days as the result of his incapacity due to physical or mental injury, disability or illness. In the event that the Employee satisfactorily resumes the performance of substantially all of his duties hereunder before the termination of his Employment under this Subsection (c) becomes effective, the notice of termination shall automatically be deemed to have been revoked.

(d) **Rights Upon Termination.** Except as expressly provided in Section 6, upon the termination of the Employee's Employment pursuant to this Section 5, the Employee shall only be entitled to the compensation, benefits and reimbursements described in Sections 2, 3 and 4 for the period preceding the effective date of the termination. The payments under this Agreement shall fully discharge all responsibilities of the Company to the Employee.

(e) **Termination of Agreement.** This Agreement shall terminate when all obligations of the parties hereunder have been satisfied. The termination of this Agreement shall not limit or otherwise affect any of the Employee's obligations under Section 7.

## 6. Termination Benefits.

(a) **General Release.** Any other provision of this Agreement notwithstanding, Subsections (b) and (d) below shall not apply unless the Employee (i) has executed a general release (in a form prescribed by the Company) of all known and unknown claims that he may then have against the Company or persons affiliated with the Company and (ii) has agreed not to prosecute any legal action or other proceeding based upon any of such claims. The release shall be in a form prescribed by the Company, without alterations. The Company shall deliver the form to the Employee within 30 days after his Employment termination date. The Employee shall execute the release within the period set forth in the form.

(b) **Severance Pay.** If, during the term of this Agreement, the Company terminates the Employee's Employment for any reason other than Cause or Permanent Disability, then the Company shall pay the Employee:

(i) **Base Compensation.** His Base Compensation for a period of 12 months following the termination of his Employment (the "Continuation Period"). Such Base Compensation shall be paid at the rate in effect at the time of the termination of Employment and in accordance with the Company's standard payroll procedures.

(ii) **Bonus Compensation.** A bonus (the "Severance Bonus") in an amount determined as follows:

(A) If the Employee's Employment is terminated prior to the first anniversary of the date of this Agreement, the Severance Bonus shall be equal to a pro-rata portion of the anticipated first-year Annual Target Bonus as determined by the Board in good faith.

(B) If the Employee's Employment is terminated on or following the first anniversary of the date of this Agreement and prior to the third anniversary of the date of this Agreement, the Severance Bonus shall be equal to the greater of (I) the most recent Annual Target Bonus and (II) the average of Annual Target Bonuses awarded for the prior years.

(C) If the Employee's Employment is terminated on or following the third anniversary of the date of this Agreement, the Severance Bonus shall be equal to the greater of (I) the most recent Annual Target Bonus and (II) the average of Annual Target Bonuses awarded for the prior three years.

Such Severance Bonus shall be payable in accordance with the Company's standard payroll procedures.

(c) **Section 409A.** If the Company determines that the Employee is a "specified employee" under Section 409A(a)(2)(B)(i) of the Internal Revenue Code of 1986, as amended (the "Code"), and the regulations thereunder when his Employment terminates, then (i) the salary continuation payments under Subsection (b)(i), to the extent not exempt from Section 409A of the Code, shall commence on the earliest practicable date that occurs more than six months after the Employment termination date, (ii) the installments that otherwise would have been paid under Subsection (b)(i) during the first six months following the Employment termination date shall be paid in a lump sum on the earliest practicable date in the seventh month after the Employment termination date and (iii) the Severance Bonus, to the extent not exempt from Section 409A of the Code, shall be paid on the earliest practicable date in the seventh month after the Employment termination date.

(d) **Health Insurance.** If Subsection (b) above applies, and if the Employee elects to continue his health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act ("COBRA") following the termination of his Employment, then the Company shall pay the Employee's monthly premium under COBRA until the earliest of (i) the close of the Continuation Period, (ii) the expiration of the Employee's continuation coverage under COBRA and (iii) the date when the Employee is offered substantially equivalent health insurance coverage in connection with new employment or self-employment.

7. **Non-Solicitation, Non-Disclosure and Non-Competition.** The Employee has entered into a Proprietary Information and Inventions Agreement with the Company, which agreement is incorporated herein by reference.

8. **Successors.**

(a) **Company's Successors.** This Agreement shall be binding upon any successor (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets which becomes bound by this Agreement.

(b) **Employee's Successors.** This Agreement and all rights of the Employee hereunder shall inure to the benefit of, and be enforceable by, the Employee's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

9. **Miscellaneous Provisions.**

(a) **Notice.** Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by overnight courier, U.S. registered or certified mail, return receipt requested and postage prepaid. In the case of the Employee, mailed notices shall be addressed to him at the home address which he most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Secretary.

(b) **Modifications and Waivers.** No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by the Employee and by an authorized officer of the Company (other than the Employee). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) **Whole Agreement.** No other agreements, representations or understandings (whether oral or written and whether express or implied) which are not expressly set forth in this Agreement have been made or entered into by either party with respect to the subject matter hereof. This Agreement and the Proprietary Information and Inventions Agreement contain the entire understanding of the parties with respect to the subject matter hereof.

(d) **Withholding Taxes.** All payments made under this Agreement shall be subject to reduction to reflect taxes or other charges required to be withheld by law.



(e) **Choice of Law.** The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of Maryland (except their provisions governing the choice of law).

(f) **Severability.** The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(g) **Arbitration.** Any controversy or claim arising out of or relating to this Agreement or the breach thereof, or the Employee's Employment or the termination thereof, shall be settled in the State of Maryland, by arbitration in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association. The decision of the arbitrator shall be final and binding on the parties, and judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The parties hereby agree that the arbitrator shall be empowered to enter an equitable decree mandating specific enforcement of the terms of this Agreement. The Company and the Employee shall share equally all fees and expenses of the arbitrator. The Employee hereby consents to personal jurisdiction of the state and federal courts located in the State of Maryland for any action or proceeding arising from or relating to this Agreement or relating to any arbitration in which the parties are participants.

(h) **No Assignment.** This Agreement and all rights and obligations of the Employee hereunder are personal to the Employee and may not be transferred or assigned by the Employee at any time. The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with any sale or transfer of all or a substantial portion of the Company's assets to such entity.

(i) **Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**[REMAINDER OF PAGE LEFT BLANK INTENTIONALLY]**

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the date first written above.

/s/ Al Gianchetti  
Al Gianchetti

VANDA PHARMACEUTICALS INC.

By: /s/ Mihael H. Polymeropoulos  
Title: CEO

TAX INDEMNITY AGREEMENT

This Tax Indemnity Agreement (this "Agreement") is made as of this 7 day of November, 2007 by and between Vanda Pharmaceuticals Inc. (the "Company") and Al Gianchetti (the "Executive").

**WHEREAS**, the Compensation Committee of the Company's Board of Directors has determined that the Company should enter into tax indemnity agreements with certain of its executives to reimburse certain excise taxes, interest and penalties they may be obligated to pay in connection with a change of control of the Company, so that the Company may preserve the financial incentives the Company created by granting stock options to those executives, and so that the Company may also continue to provide motivation for those executives to stay with the Company and act in its best interests.

**NOW, THEREFORE**, in consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged and agreed to, the parties hereto agree as follows:

**1. Gross-Up Payment.** If it is determined that any payment or distribution of any type to the Executive or for his benefit by the Company, any of its affiliates, any person who acquires ownership or effective control of the Company or ownership of a substantial portion of the Company's assets (within the meaning of section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and the regulations thereunder) or any affiliate of such person, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (the "Total Payments"), would be subject to the excise tax imposed by section 4999 of the Code or any interest or penalties with respect to such excise tax (such excise tax and any such interest or penalties are collectively referred to as the "Excise Tax"), then the Executive shall be entitled to receive an additional payment (a "Gross-Up Payment") in an amount calculated to ensure that after the Executive pays all taxes (and any interest or penalties imposed with respect to such taxes), including any Excise Tax, imposed upon the Gross-Up Payment, the Executive retains an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Total Payments.

**2. Determination by Accountant.** All determinations and calculations required to be made under this Agreement shall be made by an independent accounting firm selected by the Executive from among the largest five accounting firms in the United States (the "Accounting Firm"). The Accounting Firm shall provide its determination (the "Determination"), together with detailed supporting calculations regarding the amount of any Gross-Up Payment and any other relevant matter, to the Executive and the Company within five days after the Executive or the Company made a request (if the Executive reasonably believes that any of the Total Payments may be subject to the Excise Tax). If the Accounting Firm determines that no Excise Tax is payable by the Executive, it shall furnish the Executive with a written statement that it has concluded that no Excise Tax is payable (including the reasons therefor) and that the Executive has substantial authority not to report any Excise Tax on his federal income tax return. If a Gross-Up Payment is determined to be payable, it shall be paid to the Executive within five days after the Determination has been delivered to him or the Company. Any determination by the Accounting Firm shall be binding upon the Company and the Executive, absent manifest error.

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**3. Over- and Underpayments.** As a result of uncertainty in the application of section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments not made by the Company should have been made (“Underpayment”) or that Gross-Up Payments will have been made by the Company that should not have been made (“Overpayment”). In either event, the Accounting Firm shall determine the amount of the Underpayment or Overpayment that has occurred. In the case of an Underpayment, the Company shall promptly pay the amount of such Underpayment to the Executive or for his benefit. In the case of an Overpayment, the Executive shall, at the direction and expense of the Company, take such steps as are reasonably necessary (including the filing of returns and claims for refund), follow reasonable instructions from, and procedures established by, the Company, and otherwise reasonably cooperate with the Company to correct such Overpayment, provided, however, that (i) the Executive shall in no event be obligated to return to the Company an amount greater than the net after-tax portion of the Overpayment that the Executive has retained or has recovered as a refund from the applicable taxing authorities and (ii) this provision shall be interpreted in a manner consistent with the intent of paragraph 1 above, which is to make the Executive whole, on an after-tax basis, from the application of the Excise Tax, it being understood that the correction of an Overpayment may result in the Executive’s repaying to the Company an amount that is less than the Overpayment.

**4. Limitation on Parachute Payments.** Any other provision of this Agreement notwithstanding, if the Excise Tax could be avoided by reducing the Total Payments by \$25,000 or less, then the Total Payments shall be reduced to the extent necessary to avoid the Excise Tax and no Gross-Up Payment shall be made. If the Accounting Firm determines that the Total Payments are to be reduced under the preceding sentence, then the Company shall promptly give the Executive notice to that effect and a copy of the detailed calculation thereof. The Executive may then elect, in his sole discretion, which and how much of the Total Payments are to be eliminated or reduced (as long as after such election no Excise Tax shall be payable), and the Executive shall advise the Company in writing of his election within 10 days of receipt of notice. If the Executive make no such election within such 10-day period, then the Company may elect which and how much of the Total Payments are to be eliminated or reduced (as long as after such election no Excise Tax shall be payable), and it shall notify the Executive promptly of such election.

**[The rest of this page has been intentionally left blank.]**

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IN WITNESS WHEREOF, the Company and the Executive have duly executed this Agreement as of the date first written above.

VANDA PHARMACEUTICALS INC.

By: /s/ Mihael H. Polymeropoulos  
Title: CEO

By: /s/ Al Gianchetti  
Title: SVP, Chief Commercial Officer

**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 8, 2007

/s/ Mihael H. Polymeropoulos  
\_\_\_\_\_  
**Mihael H. Polymeropoulos**  
**Chairman and Chief Executive Officer**  
**(Principal Executive Officer)**

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

I, Steven A. Shallcross, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vanda Pharmaceuticals Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 8, 2007

/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, 2007 (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 8, 2007

/ S / Mihael H. Polymeropoulos

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

Date: November 8, 2007

/ S / Steven A. Shallcross

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

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