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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

**x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2008**

**OR**

**o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**FOR THE TRANSITION PERIOD FROM TO**

**Commission File Number 001-33389**

# VIVUS, INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

| **Delaware** | **94-3136179** |
|---|---|
| (STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION) | (IRS EMPLOYER IDENTIFICATION NUMBER) |
| **1172 Castro Street**<br>**Mountain View, California**<br>(Address of principal executive office) | **94040**<br>(Zip Code) |

**(650) 934-5200**
(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

**N/A**
(FORMER NAME, FORMER ADDRESS AND FORMER FISCAL YEAR, IF CHANGED SINCE LAST REPORT)

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 x No o

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

| | |
|---|---|
| Large accelerated filer o | Accelerated filer x |
| Non-accelerated filer o<br>(Do not check if a smaller reporting company) | Smaller reporting company o |

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

At October 24, 2008, 69,363,473 shares of common stock, par value $.001 per share, were outstanding.

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**VIVUS, INC.**

**Quarterly Report on Form 10-Q**

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CERTIFICATIONS

31.1-Certification of Chief Executive Officer
31.2-Certification of Chief Financial Officer
32.0-Certification of Chief Executive Officer and Chief Financial Officer




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## PART I: FINANCIAL INFORMATION

### ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

**VIVUS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(In thousands, except par value)**

| | SEPTEMBER 30 2008 (UNAUDITED) | DECEMBER 31 2007* |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 96,187 | $ 37,838 |
| Available-for-sale securities | 104,971 | 141,672 |
| Accounts receivable, (net of allowance for doubtful accounts of $81 and $29 at September 30, 2008 and December 31, 2007, respectively) | 2,516 | 4,202 |
| Inventories, net | 3,108 | 2,567 |
| Prepaid expenses and other assets | 3,541 | 5,313 |
| Total current assets | 210,323 | 191,592 |
| Property, plant and equipment, net | 6,845 | 7,417 |
| Available-for-sale securities, non-current | 2,964 | — |
| Restricted cash | 700 | 700 |
| Total assets | $ 220,832 | $ 199,709 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 9,488 | $ 7,768 |
| Accrued product returns | 2,610 | 2,498 |
| Accrued research and clinical expenses | 7,340 | 1,902 |
| Accrued chargeback reserve | 390 | 1,314 |
| Accrued employee compensation and benefits | 2,170 | 1,999 |
| Accrued and other liabilities | 1,558 | 1,698 |
| Deferred revenue-short term | 52,788 | 84,183 |
| Total current liabilities | 76,344 | 101,362 |
| Notes payable-net of current portion | 8,516 | 5,062 |
| Deferred revenue-long term | 1,376 | 33,118 |
| Total liabilities | 86,236 | 139,542 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding | — | — |
| Common stock; $.001 par value; 200,000 shares authorized; 69,361 shares issued and outstanding at | 69 | 59 |

| | | |
|---|---|---|
| September 30, 2008 and 58,873 at December 31, 2007 | | |
| Additional paid-in capital | 308,604 | 230,005 |
| Accumulated other comprehensive loss | (1,001) | (68) |
| Accumulated deficit | (173,076) | (169,829) |
| Total stockholders' equity | 134,596 | 60,167 |
| Total liabilities and stockholders' equity | $ 220,832 | $ 199,709 |

* Derived from audited consolidated financial statements filed in the Company's 2007 Annual Report on Form 10-K.

See accompanying notes to unaudited condensed consolidated financial statements.



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**VIVUS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE INCOME (LOSS)**
**(In thousands, except per share data)**
**(UNAUDITED)**

| | THREE MONTHS ENDED SEPTEMBER 30 | | NINE MONTHS ENDED SEPTEMBER 30 | |
|---|---|---|---|---|
| | 2008 | 2007 | 2008 | 2007 |
| Revenue: | | | | |
| United States product, net | $ 3,774 | $ 4,075 | $ 7,785 | $ 7,572 |
| International product | 657 | 944 | 2,511 | 3,003 |
| License and other revenue | 21,046 | 14,069 | 63,138 | 14,300 |
| Total revenue | 25,477 | 19,088 | 73,434 | 24,875 |
| Operating expenses: | | | | |
| Cost of goods sold and manufacturing expense | 2,547 | 2,736 | 8,263 | 8,498 |
| Research and development | 15,590 | 8,644 | 54,296 | 15,610 |
| Selling, general and administrative | 4,502 | 3,691 | 13,099 | 11,988 |
| Total operating expenses | 22,639 | 15,071 | 75,658 | 36,096 |
| | | | | |
| Income (loss) from operations | 2,838 | 4,017 | (2,224) | (11,221) |
| | | | | |
| Interest (expense) income: | | | | |
| Interest income | 1,248 | 1,811 | 4,681 | 3,276 |
| Interest expense | (282) | (125) | (589) | (409) |
| Other-than-temporary loss on impaired securities | (3,533) | — | (5,100) | — |
| Total interest (expense) income | (2,567) | 1,686 | (1,008) | 2,867 |
| Income (loss) before provision for income taxes | 271 | 5,703 | (3,232) | (8,354) |
| Provision for income taxes | (5) | (4,382) | (15) | (4,394) |
| Net income (loss) | $ 266 | $ 1,321 | $ (3,247) | $ (12,748) |
| Other comprehensive income (loss): | | | | |
| Unrealized (loss) gain on securities | (887) | 20 | (933) | 23 |
| Comprehensive (loss) income | $ (621) | $ 1,341 | $ (4,180) | $ (12,725) |
| | | | | |
| Net (loss) income per share: | | | | |
| Basic and diluted | $ 0.00 | $ 0.02 | $ (0.05) | $ (0.22) |
| Shares used in per share computation: | | | | |
| Basic | 66,122 | 58,627 | 61,801 | 58,449 |
| Diluted | 67,784 | 59,492 | 61,801 | 58,449 |

See accompanying notes to unaudited condensed consolidated financial statements.



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**VIVUS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(In thousands)**

| | NINE MONTHS ENDED SEPTEMBER 30 | |
|---|---|---|
| | 2008 (UNAUDITED) | 2007 (UNAUDITED) |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | $ (3,247) | $ (12,748) |
| Adjustments to reconcile net loss to net cash provided by (used for) operating activities: | | |

| | | |
|---|---|---|
| Provision for doubtful accounts | 52 | (50) |
| Provision for excess inventory | — | (3) |
| Depreciation | 856 | 807 |
| Net realized gain on investments | (175) | — |
| Other-than-temporary loss on impaired securities | 5,100 | — |
| Share-based compensation expense | 3,679 | 2,755 |
| Excess tax benefits related to share-based compensation expense | — | (904) |
| Gain on disposal of property and equipment | — | (17) |
| Sale of Evamist assets | — | 559 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 1,635 | 2,671 |
| Inventories | (541) | (142) |
| Prepaid expenses and other assets | 1,772 | (1,666) |
| Accounts payable | 1,720 | 3,329 |
| Accrued product returns | 112 | (502) |
| Accrued research and clinical expenses | 5,438 | 1,297 |
| Accrued chargeback reserve | (924) | (1,037) |
| Accrued employee compensation and benefits | 171 | (347) |
| Accrued and other liabilities | (171) | (112) |
| Deferred revenue | (63,137) | 135,700 |
| Income taxes payable | — | 4,373 |
| Net cash provided by (used for) operating activities | (47,660) | 133,963 |
| | | |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Property and equipment purchases | (284) | (228) |
| Proceeds from sale of property and equipment | — | 19 |
| Securities investment purchases | (39,667) | (39,024) |
| Proceeds from sale/maturity of securities investments | 67,546 | 25,468 |
| Net cash provided by (used for) investing activities | 27,595 | (13,765) |
| | | |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from notes payable | 4,222 | 379 |
| Payments of notes payable | (738) | (6,782) |
| Exercise of common stock options | 1,402 | 1,732 |
| Sale of common stock through employee stock purchase plan | 141 | 904 |
| Excess tax benefits related to share-based compensation expense | — | 149 |
| Proceeds from issuance of common stock | 73,387 | — |
| Net cash provided by (used for) financing activities | 78,414 | (3,618) |
| | | |
| NET INCREASE IN CASH AND CASH EQUIVALENTS | 58,349 | 116,580 |
| CASH AND CASH EQUIVALENTS: | | |
| Beginning of period | 37,838 | 44,628 |
| End of period | $ 96,187 | $ 161,208 |
| | | |
| SUPPLEMENTAL CASH FLOW DISCLOSURE: | | |
| Reclassification of income taxes payable to accumulated deficit | $ — | $ 1,206 |

See accompanying notes to unaudited condensed consolidated financial statements.



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**VIVUS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**SEPTEMBER 30, 2008**

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America. Accordingly, they do not include all of the information and footnotes required by United States generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the quarter and nine-month period ended September 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. The unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2007, as filed on March 7, 2008 with the Securities and Exchange Commission, or SEC. The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

*Use of Estimates*

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

2. REVENUE RECOGNITION

The Company recognizes product revenue when the following four criteria are met:

- persuasive evidence of an arrangement exists;
- shipment has occurred;
- the sales price is fixed or determinable; and
- collectibility is reasonably assured.

The Company recognizes revenue upon shipment when title passes to the customer and risk of loss is transferred to the customer. The Company does not have any post shipment obligations.

*United States*

The Company primarily sells its products through wholesalers in the United States. The Company provides for government chargebacks, rebates, returns and other adjustments in the same period the related product sales are recorded. Reserves for government chargebacks, rebates, returns and other adjustments are based upon analysis of historical data. Each period the Company reviews its reserves for government chargebacks, rebates, returns and other adjustments based on data available at that time. Any adjustment to these reserves results in charges to the amount of product sales revenue recognized in the period.

*International*

The Company has supply agreements with Meda AB, or Meda, to market and distribute MUSE internationally in some Member States of the European Union. In Canada, the Company entered into a license and supply agreement with Paladin Labs, Inc., or Paladin, for the marketing and distribution of MUSE. Sales to Meda, who supplies MUSE in the European marketplace, for 2007, 2006 and 2005 were 95.8%, 91.7% and 93.4% of international sales, respectively. The balance of international sales was made to Paladin.



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The Company invoices its international distributors based on an agreed transfer price per unit, which is subject to revision upon quarterly reconciliations based on contractual formulas. Final pricing for product shipments to international distributors is subject to contractual formulas based on the distributor's net realized price to its customers. The Company recognizes additional revenue, if any, upon finalization of pricing with its international distributors. International distributors generally do not have the right to return products unless the products are damaged or defective.

The Company initially recorded $1.5 million of unearned revenue related to an upfront payment in accordance with the international supply agreement signed with Meda in September 2002. In January 2006, the Company received a milestone payment from Meda of $2 million. The milestone payment provides Meda with the right to continue to sell and distribute MUSE in its European territories. These amounts are being recognized as income ratably over the term of the supply agreement. Through September 30, 2008, $1.7 million has been recognized as revenue.

*License and Other Revenue*

The Company recognizes license revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force, or EITF, Issue 00-21, *Revenue Arrangements with Multiple Deliverables*. Revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered item has standalone value to the customer, and whether there is objective, reliable evidence of the fair value of the undelivered items. Consideration received is allocated among the separate units of accounting based on their relative fair values, and the applicable revenue recognition criteria are identified and applied to each of the units.

Revenue from non-refundable, upfront license fees where the Company has continuing involvement is recognized ratably over the development or agreement period. Revenue associated with performance milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements.

*Sale of Evamist product*

On May 15, 2007, the Company closed its transaction with K-V Pharmaceutical Company, or K-V, for the sale of its product candidate, Evamist. At the time of the sale, Evamist was an investigational product and was not yet approved by the Food and Drug Administration, or FDA, for marketing. The sale transaction contained multiple deliverables, including: the delivery at closing of the Evamist assets, a grant of a sublicense of the Company's rights under a license agreement related to Evamist, and a license to the metered-dose transdermal spray, or MDTS, applicator; the delivery upon receipt of regulatory approval of the approved drug along with all regulatory submissions; and, lastly, the delivery after FDA approval of certain transition services and a license to improvements to the MDTS applicator. The Company received approval from the FDA to market Evamist on July 27, 2007, or FDA Approval, and on August 1, 2007, the Company transferred and assigned the Evamist FDA submissions, and all files related thereto, to K-V. The Company received an upfront payment of $10 million upon the closing and received an additional $140 million milestone payment in August 2007 upon FDA Approval. These payments are non-refundable. In August 2008, the Company assigned all of its rights and obligations under the Evamist license agreement to K-V.

Upon FDA Approval, the two remaining deliverables are the transition services to be performed under the Transition Services Agreement, or TSA, and a license to improvements to the MDTS applicator during the two-year period commencing with the closing, or May 15, 2007, and ending on May 15, 2009.

The Company has been able to establish fair value for the TSA. Given the unique nature of the license to improvements, the Company is unable to obtain objective, reliable evidence of its fair value.

Accordingly, the delivered items, together with the undelivered items, are treated as one unit of accounting. Since the deliverables are treated as a single unit of accounting, the total cash received, $150 million, will be recognized as revenue on a pro-rata basis over the term of the last deliverable, which in this case is the license to improvements that expires on May 15, 2009. As a result, the initial $10 million paid at closing and the $140 million paid upon FDA Approval have been recorded as deferred revenue and will be recognized as revenue together with the future billings, if any, under the TSA, ratably over the remaining 21.5-month term of the license to improvements, from August 1, 2007 to May 15, 2009. Through September 30, 2008, $97.7 million has been recognized as revenue.

The Company may also receive milestone payments of up to $30 million based upon sales of Evamist through the term of the agreements. Revenue associated with performance milestones will be recognized based upon the achievement of the milestones, as defined in the respective agreements.



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3. SHARE-BASED COMPENSATION

The Company accounts for share-based compensation in accordance with SFAS No. 123R, *Share-Based Payment*, which was adopted January 1, 2006, utilizing the modified prospective transition method.

Total estimated share-based compensation expense, related to all of the Company's share-based awards, recognized for the three and nine months ended September 30, 2008 and 2007 was comprised as follows (in thousands, except per share data):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2008 | 2007 | 2008 | 2007 |
| Cost of goods sold and manufacturing expense | $ 156 | $ 150 | $ 446 | $ 419 |
| Research and development | 321 | 231 | 1,138 | 685 |
| Selling, general and administrative | 553 | 529 | 2,095 | 1,651 |
| Share-based compensation expense before taxes | 1,030 | 910 | 3,679 | 2,755 |
| Related income tax benefits | — | — | — | — |
| Share-based compensation expense, net of taxes | $ 1,030 | $ 910 | $ 3,679 | $ 2,755 |
| Basic and diluted per common share | $ 0.02 | $ 0.02 | $ 0.06 | $ 0.05 |

At September 30, 2008, a total of 6,411,718 stock options were outstanding under the Company's stock option plans. Stock-based compensation expense recognized for the quarters and nine months ended September 30, 2008 and 2007 included compensation expense for stock options granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123. Included in stock-based compensation expense was $962,000 and $855,000 related to stock options, $23,000 and $41,000 related to the employee stock purchase plan, and $44,000 and $14,000 related to restricted stock units, net of the estimated forfeitures for the third quarters of 2008 and 2007, respectively. For the nine months ended September 30, 2008 and 2007, included in stock-based compensation expense was $3.6 million and $2.6 million related to stock options, $66,000 and $103,000 related to the employee stock purchase plan, and $60,000 and $43,000 related to restricted stock units, net of the estimated forfeitures for the first nine months of 2008 and 2007, respectively.

As of September 30, 2008, unrecognized estimated compensation expense totaled $4.0 million related to non-vested stock options and $11,000 related to the employee stock purchase plan. The weighted average remaining requisite service period of the non-vested options was 1.3 years and of the employee stock purchase plan was 1.5 months. In the third quarter of 2008, the 62,500 shares of previously outstanding restricted stock units vested and the remaining unamortized stock compensation related to those restricted stock units was recognized.

A summary of stock option award activity under these plans is as follows:

| | Nine Months Ended September 30, 2008 | |
|---|---|---|
| | Shares | Weighted Average Exercise Price |
| Outstanding at January 1, 2008 | 5,348,501 | $ 4.25 |
| Granted | 1,531,944 | $ 6.05 |
| Exercised | (422,239) | $ 3.78 |
| Cancelled | (46,488) | $ 5.54 |
| Outstanding at September 30, 2008 | 6,411,718 | $ 4.70 |
| Options exercisable at September 30, 2008 | 3,692,264 | |
| Weighted average fair value of options granted | | $ 4.43 |



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A summary of restricted stock units award activity under the 2001 Plan as of September 30, 2008 and changes during the nine-month period then ended are presented below:

| | Nine Months Ended September 30, 2008 | | | |
|---|---|---|---|---|
| | Number of Restricted Stock Units | Weighted Average Grant Date Fair Value | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value |

| | | | | |
|---|---|---|---|---|
| Restricted stock units outstanding January 1, 2008 | 62,500 | $ 2.04 | 3.7 | $ 255,000 |
| Granted | — | — | — | — |
| Vested | (62,500) | 2.04 | — | — |
| Forfeited | — | — | — | — |
| Restricted stock units outstanding, September 30, 2008 | — | $ — | — | $ — |

At September 30, 2008, stock options were outstanding and exercisable as follows:

| | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Prices | Number Outstanding at September 30, 2008 | Weighted-Average Remaining Contractual Life | Weighted-Average Exercise Price | Number Exercisable September 30, 2008 | Weighted-Average Exercise Price |
| $2.19 - $4.15 | 2,320,229 | 5.32 years | $ 3.54 | 1,939,147 | $ 3.55 |
| $4.25 - $5.67 | 2,271,627 | 6.98 years | $ 4.54 | 1,259,974 | $ 4.68 |
| $5.69 - $8.08 | 1,819,862 | 8.03 years | $ 6.38 | 493,143 | $ 7.23 |
| $2.19 - $8.08 | 6,411,718 | 6.67 years | $ 4.70 | 3,692,264 | $ 4.43 |

The aggregate intrinsic value of outstanding options as of September 30, 2008 was $20.8 million, of which $13.0 million related to exercisable options.

At September 30, 2008, 984,670 options remain available for grant. On May 5, 2008, 1,000,000 shares were registered on a Form S-8 filed with the SEC. In the nine months ended September 30, 2008, in accordance with the terms of the 2001 Plan, the Company transferred a net total of 5,000 expired plan shares to the 2001 Plan. Options under these plans generally vest over four years, and all options expire after 10 years.

As of September 30, 2008, 1,150,130 shares have been issued to employees and there are 249,870 shares available for issuance under the Employee Stock Purchase Plan.

*Valuation Assumptions*

The fair value of each option award is estimated on the grant date using a Black-Scholes option-pricing model that uses the weighted average assumptions noted in the following table. Prior to January 1, 2008, the Company calculated the estimated life of stock options granted using a “simplified” method, which is based on the average of the vesting term and the term of the option, as a result of guidance from the SEC, as contained in Staff Accounting Bulletin No. 107 permitting the initial use of this method. Effective January 1, 2008, the expected term, which represents the period of time that options granted are expected to be outstanding, is derived by analyzing the historical experience of similar awards, giving consideration to the contractual terms of the stock-based awards, vesting schedules and expectations of future employee behavior. Expected volatilities are estimated using the historical share price performance over the expected term of the option. The Company also considers other factors such as its planned clinical trials and other company activities that may affect the volatility of VIVUS’ stock in the future but determined that at this time, the historical volatility was more indicative of expected future stock price volatility. The risk-free interest rate for the period matching the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of the grant. The Black-Scholes Model also requires a single expected dividend yield as an input. The Company does not anticipate paying any dividends in the near future.



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The following table sets forth information about the weighted-average assumptions used for options granted in the nine months ended September 30, 2008 and 2007:

| | Nine Months Ended September 30 | |
|---|---|---|
| | 2008 | 2007 |
| Expected life (in years) | 5.61 | 6.16 |
| Volatility | 59.91% | 67.59% |
| Risk-free interest rate | 2.74% | 4.59% |
| Dividend yield | — | — |

4. CASH, CASH EQUIVALENTS AND AVAILABLE-FOR-SALE SECURITIES

The fair value and the amortized cost of cash, cash equivalents, and available-for-sale securities by major security type at September 30, 2008 and December 31, 2007 are presented in the tables that follow. Fair values are based on market prices obtained from a number of pricing methods used to derive the fair value of the securities on a recurring basis, which include the use of independent pricing services and input from brokers and portfolio managers. For each category of investment securities, the table presents gross unrealized holding gains and losses.

As of September 30, 2008 (in thousands) (unaudited):

| Cash and Cash Equivalents | Amortized Cost | Estimated Fair Value | Unrealized Holding Gains | Unrealized Holding Losses |
|---|---|---|---|---|
| Cash and money market | $ 81,106 | $ 81,106 | $ — | $ — |
| U.S. Treasury securities and debt securities of U.S. government agencies | 9,199 | 9,203 | 4 | — |
| Commercial paper | 3,128 | 3,128 | — | — |
| Corporate bonds | 2,750 | 2,750 | — | — |
| Total cash and cash equivalents | $ 96,183 | $ 96,187 | $ 4 | $ — |

| Available-for-sale Securities | Amortized Cost | Estimated Fair Value | Unrealized Holding | Unrealized Holding |
|---|---|---|---|---|

| | | | Gains | Losses |
|---|---|---|---|---|
| U.S. Treasury securities and debt securities of U.S. government agencies | $ 33,138 | $ 33,145 | $ 7 | $ — |
| Commercial paper | 6,630 | 6,630 | — | — |
| Corporate bonds | 38,009 | 37,012 | — | (997) |
| Asset backed and other securities | 31,163 | 31,148 | — | (15) |
| Total available-for-sale securities | $ 108,940 | $ 107,935 | $ 7 | $ (1,012) |

As of December 31, 2007 (in thousands):

| Cash and Cash Equivalents | Amortized Cost | Estimated Fair Value | Unrealized Holding Gains | Unrealized Holding Losses |
|---|---|---|---|---|
| Cash and money market | $ 19,358 | $ 19,358 | $ — | $ — |
| Commercial paper | 16,953 | 16,954 | 1 | — |
| Corporate bonds | 1,526 | 1,526 | — | — |
| Total cash and cash equivalents | $ 37,837 | $ 37,838 | $ 1 | $ — |



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| Available-for-sale Securities | Amortized Cost | Estimated Fair Value | Unrealized Holding Gains | Unrealized Holding Losses |
|---|---|---|---|---|
| Commercial paper | $ 246 | $ 246 | $ — | $ — |
| Corporate bonds | 59,464 | 59,367 | — | (97) |
| Asset backed and other securities | 82,031 | 82,059 | 28 | — |
| Total available-for-sale securities | $ 141,741 | $ 141,672 | $ 28 | $ (97) |

The following table summarizes the Company's available-for-sale securities by the contractual maturity date as of September 30, 2008 (in thousands) (unaudited):

| | Amortized Cost | Estimated Fair Value |
|---|---|---|
| Due within one year | $ 74,905 | $ 74,014 |
| Due within one year to two years | 2,872 | 2,773 |
| *No single maturity date | 31,163 | 31,148 |
| | $ 108,940 | $ 107,935 |

* Securities with no single maturity date include mortgage and asset backed securities that consist of several payment streams. For certain of these securities, principal and interest payments are received monthly or quarterly. In addition, a certain portion of these investments may be repaid prior to their legal maturity.

Actual maturities may differ from the contractual maturities because borrowers may have the right to call or prepay certain obligations.

The following table summarizes the net realized gains (losses) on available-for-sale securities for the periods presented (in thousands):

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| | September 30, 2008 (unaudited) | September 30, 2007 (unaudited) | September 30, 2008 (unaudited) | September 30, 2007 (unaudited) |
| Realized gains | $ 91 | $ 2 | $ 245 | $ 2 |
| Realized losses | (5) | — | (70) | — |
| Net realized gains | $ 86 | $ 2 | $ 175 | $ 2 |

At September 30, 2008 and December 31, 2007, we had the following available-for-sale securities that were in an unrealized loss position but were not deemed to be other-than-temporarily impaired (in thousands):

| | Less Than 12 Months | | 12 Months or Greater | |
|---|---|---|---|---|
| September 30, 2008 | Gross Unrealized Losses | Estimated Fair Value | Gross Unrealized Losses | Estimated Fair Value |
| U.S. Treasury securities and debt securities of U.S. | $ (30) | $ 15,141 | $ — | $ — |
| Commercial paper | (1) | 1,683 | — | — |
| Corporate bonds | (1,017) | 27,110 | — | — |
| Asset backed and other securities | (86) | 8,019 | — | — |
| Total | $ (1,134) | $ 51,953 | $ — | $ — |



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| | Less Than 12 Months | | 12 Months or Greater | |
|---|---|---|---|---|
| | Gross | Estimated | Gross | Estimated |

| December 31, 2007 | Unrealized Losses | Fair Value | Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Commercial paper | $ (1) | $ 11,221 | $ — | $ — |
| Corporate bonds | (115) | 43,632 | — | — |
| Asset backed and other securities | (93) | 22,233 | — | — |
| Total | $ (209) | $ 77,086 | $ — | $ — |

The gross unrealized losses reported above for September 30, 2008 and December 31, 2007 were caused by general fluctuations in market interest rates from the respective purchase date of these securities through the end of those periods. No significant facts or circumstances have occurred to indicate that these unrealized losses are related to any deterioration in the creditworthiness of the issuers of the marketable securities we own. Based on our review of these securities, including our assessment of the duration and severity of the related unrealized losses, we have not recorded any other-than-temporary impairments on these investments.

As of September 30, 2008 and December 31, 2007, the temporary unrealized loss on available-for-sale securities, net of tax, of $1 million and $68,000, respectively, were included in accumulated other comprehensive income in the accompanying unaudited condensed consolidated balance sheets. As of September 30, 2008, a significant portion of the available-for-sale securities that the Company held were investment grade.

SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and SAB Topic 5M, *Accounting for Non-current Marketable Equity Securities*, provide guidance on determining when an investment is other-than-temporarily impaired. Investments are reviewed quarterly for indicators of other-than-temporary impairment. This determination requires significant judgment. In making this judgment, the Company employs a systematic methodology quarterly that considers available quantitative and qualitative evidence in evaluating potential impairment of its investments. If the cost of an investment exceeds its fair value, the Company evaluates, among other factors, general market conditions, the duration and extent to which the fair value is less than cost, and its intent and ability to hold the investment. The Company also considers specific adverse conditions related to the financial health of and business outlook for the investee, including industry and sector performance, and rating agency actions. Once a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis in the investment is established. During the Company's quarter end assessments, the Company determined that a decline in value of certain securities was other-than-temporary. Accordingly, the Company recorded impairment adjustments of $3.5 million and $ 5.1 million in the three and nine months ended September 30, 2008, respectively. The Company included this non-cash impairment charge in other-than-temporary loss on impaired securities in the condensed consolidated statements of operations and other comprehensive income (loss). Included in the $3.5 million charge taken in the third quarter was $2.2 million related to corporate bonds issued by Lehman Brothers Holdings Inc., or Lehman (or their respective subsidiaries, as appropriate). On September 15, 2008, Lehman filed for bankruptcy protection under Chapter 11 of the United States Bankruptcy Code. Accordingly, recovery of the full value of our Lehman bonds, if any, is deemed remote and we recognized an other-than-temporary impairment in the three months ended September 30, 2008. In addition, other-than-temporary impairments recognized in the third quarter of 2008 included impairments on investments for which the Company determined that the impairment was other-than-temporary due to credit downgrades and/or the Company's intent and ability to hold the investment to maturity. These securities covered a number of industries. If market, industry, and/or investee conditions deteriorate, the Company may incur further impairments. In addition, due to the current lack of a readily available market for certain of the Company's available-for-sale securities totaling $3 million and the continued uncertainty in the capital markets, the Company expects those securities to recover their carrying values beyond the next 12 months. Consequently, the Company has classified those available-for-sale securities as non-current in the condensed consolidated balance sheets.

From 2005 and until December 2007, the Company had an investment in Columbia Strategic Cash Portfolio, or Strategic Cash, offered by the Company's investment advisor, Columbia Management LLC, or Columbia, an affiliate of Bank of America. Strategic Cash is an enhanced money market fund in which the fund sought to maintain a $1 per share net asset value. The Company used Strategic Cash for the investment of excess cash, and periodic transfers were made from Strategic Cash to the operating cash account to fund current operations.



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In early December 2007, VIVUS was notified by Columbia that the Strategic Cash fund was closed and that the fund was to be liquidated. The fund no longer supported the $1 per share net asset value and switched to a market value fund in which all investments were marked to market. VIVUS was given the option of staying in the fund and receiving cash proceeds from the fund as its holdings were liquidated or receiving a pro-rata share of the investments held by the fund. Upon advice from the investment advisor, the Company took a redemption-in-kind consisting of cash, interest receivable and a pro-rata distribution of the underlying securities, consisting principally of high quality corporate debt and asset-backed securities. Prior to the redemption the Company's investment in Strategic Cash was $84.4 million. On December 20, 2007 and December 21, 2007, the Company received its redemption-in-kind consisting of securities with a market value of $68.7 million, interest receivable of $300,000 and cash of $14.4 million. The difference between the Company's investment in Strategic Cash of $84.4 million and the fair value of the securities, cash and interest receivable totaling $83.4 million received in-kind resulted in a loss of $1 million. This loss of $1 million was reflected in interest income in the consolidated statements of operations and other comprehensive income (loss) for the year ended December 31, 2007.

*Fair Value Measurements*

Effective January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. Broadly, the SFAS 157 framework clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, SFAS No. 157 establishes a three-tier value hierarchy, which prioritizes the inputs used in measuring fair value as follows: (Level 1) observable inputs such as quoted prices in active markets; (Level 2) inputs other than the quoted prices in active markets that are observable either directly or indirectly; and (Level 3) unobservable inputs in which there is little or no market data, which require the Company to develop its own assumptions. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. On a recurring basis, VIVUS measures its marketable securities at fair value.

The following fair value hierarchy tables present information about the Company's assets (available-for-sale securities current and non-current) measured at fair value on a recurring basis as of September 30, 2008 (in thousands):

| | Basis of Fair Value Measurements | | |
|---|---|---|---|
| | Balance at September 30, 2008 (unaudited) | Level 2 | Level 3 |
| Assets: | | | |
| U.S. Treasury securities and debt securities of U.S. government agencies | $33,145 | $33,145 | $— |
| Commercial Paper | 6,630 | 6,630 | — |
| Corporate Bonds | 37,012 | 33,739 | 3,273 |
| Asset Backed and Other Securities | 31,148 | 28,692 | 2,456 |
| Total | $107,935 | $102,206 | $5,729 |
| | | | |
| Balance Sheet Presentation | | | |
| Available-for-sale securities | $104,971 | | |
| Available-for-sale securities, non-current | 2,964 | | |
| Total | $107,935 | | |

The following table presents additional information about Level 3 assets measured at fair value on a recurring basis. Unobservable inputs are used to determine the fair value of positions that the Company has classified within the Level 3 category. The types of instruments valued based on Level 3 inputs include some corporate bonds, residential mortgage asset backed securities in the United States, United Kingdom and Australian markets and approximately seven structured investment vehicles (SIVs). The changes in Level 3 assets measured at fair value on a recurring basis for the three and nine months ended September 30, 2008 were (in thousands):

| Activity for the Three Months Ended September 30, 2008 (unaudited) | Fair Value Measurements Using Significant Unobservable Inputs (Level 3) |
|---|---|
| Balance at June 30, 2008 | $ 9,789 |
| Total unrealized gains included in other comprehensive income | 27 |
| Total other-than-temporary impairment | (650) |
| Purchases, sales, issuances and settlements, net | (1,800) |
| Net transfers of Level 3 securities (a) | (1,637) |
| Balance at September 30, 2008 | $ 5,729 |
| | |
| The amount of total losses for the period included in net income attributable to the change in unrealized losses relating to securities still held at the reporting date | $ (650) |

(a) Transfers out of Level 3 are considered to occur at the beginning of the period. Transfers into Level 3 are considered to occur at the end of the period.





| Activity for the Nine Months Ended September 30, 2008 (unaudited) | Fair Value Measurements Using Significant Unobservable Inputs (Level 3) |
|---|---|
| Balance at December 31, 2007 | $ 1,332 |
| Total unrealized losses included in other comprehensive loss | (4) |
| Total other-than-temporary impairment | (1,261) |
| Purchases, sales, issuances and settlements, net | (1,984) |
| Net transfers of Level 3 securities (a) | 7,646 |
| Balance at September 30, 2008 | $ 5,729 |
| | |
| The amount of total losses for the period included in net loss attributable to the change in unrealized losses relating to securities still held at the reporting date | $ (1,261) |

(a) Transfers out of Level 3 are considered to occur at the beginning of the period. Transfers into Level 3 are considered to occur at the end of the period.

The following table presents the amounts of unrealized losses for the three and nine months ended September 30, 2008 relating to those assets for which the Company utilized significant Level 3 inputs to determine fair value and that were still held by the Company at September 30, 2008 (in thousands):

| Activity for the Three Months Ended September 30, 2008 (unaudited) | Available-for-sale securities |
|---|---|
| Total other-than-temporary impairment for the period | $ (650) |

| | |
|---|---|
| Change in unrealized losses to securities still held at reporting date | $ 27 |

| Activity for the Nine Months Ended September 30, 2008 (unaudited) | Available-for-sale securities |
|---|---|
| Total other-than-temporary impairment for the period | $ (1,261) |
| Change in unrealized losses to securities still held at reporting date | $ (4) |

5. INVENTORIES

Inventories are recorded net of reserves of $1.6 million and $1.7 million as of September 30, 2008 and December 31, 2007, respectively. Inventory balances, net of reserves, consist of (in thousands):

| | SEPTEMBER 30, 2008 (unaudited) | DECEMBER 31, 2007 |
|---|---|---|
| Raw materials and component parts | $ 2,207 | $ 2,224 |
| Work in process | 62 | 38 |
| Finished goods | 839 | 305 |
| Inventory, net | $ 3,108 | $ 2,567 |

As noted above, the Company has recorded significant reserves against the carrying value of its inventory of raw material and certain component parts. The reserves relate primarily to inventories that the Company estimated would have no future use. In 2007, the Company disposed of $2.8 million of fully reserved alprostadil. The disposal had no impact on cost of goods sold. The Company determined that it likely would continue to use some portion of the fully reserved component parts in production. The Company used $62,000 and $75,000 of its fully reserved component parts inventory during the first nine months of 2008 and 2007, respectively. When the Company records inventory reserves, it establishes a new, lower cost basis for the inventory for accounting purposes. Accordingly, to the extent that this fully reserved inventory was used in production in the first nine months of 2008 and 2007, it was charged to cost of goods sold at a zero basis, which had a favorable impact on cost of goods sold. The original cost of the fully reserved inventory related to component parts is $655,000 as of September 30, 2008, and the Company intends to continue to use this reserved component parts inventory in production when appropriate.



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6. PREPAID EXPENSES AND OTHER ASSETS

Prepaid expenses and other assets as of September 30, 2008 and December 31, 2007, respectively, consist of (in thousands):

| | SEPTEMBER 30, 2008 (unaudited) | DECEMBER 31, 2007 |
|---|---|---|
| Receivable from Food and Drug Administration | $ 1,877 | $ 1,932 |
| Refundable federal income taxes | 175 | 919 |
| Prepaid clinical studies | 225 | 1,277 |
| Interest receivable | 399 | 825 |
| Prepaid insurance | 292 | 134 |
| Other prepaid expenses and assets | 573 | 226 |
| Total | $ 3,541 | $ 5,313 |

The Company has paid product and establishment fees for its marketed product, MUSE, for the fiscal year 2007 of $512,000 (which was paid to the FDA in October 2006), for the fiscal year 2008 of $653,000 (which was paid to the FDA in October 2007) and for the fiscal year 2009 of $712,000 (which was paid to the FDA in September 2008). The Company believes it is due a refund pursuant to Section 736(d)(1)(C) of the Federal Food, Drug and Cosmetic Act, or FDC Act, on the basis that the fees paid by the Company exceed the anticipated present and future costs incurred by the FDA in conducting the process for the review of human drug applications for VIVUS, Inc. The Company also paid an application fee to the FDA in September 2006 for the NDA for Evamist of $767,000 for which it received a refund in April 2008, on this same basis.

7. DEERFIELD FINANCING

On April 3, 2008, the Company entered into several agreements with Deerfield Management Company, L.P., or Deerfield, a healthcare investment fund, and its affiliates, Deerfield Private Design Fund L.P. and Deerfield Private Design International, L.P. (collectively, the Deerfield Affiliates). Under the agreements, Deerfield and its affiliates agreed to provide $30 million in funding to the Company. The $30 million in funding consists of $20 million from a Funding and Royalty Agreement, or FARA, entered into with a newly incorporated subsidiary of Deerfield, or Deerfield Sub, and $10 million from the sale of the Company's common stock under a securities purchase agreement. Under the FARA, the Deerfield Affiliates made $3.3 million payments to the Company in April and August 2008 and will make four quarterly payments of approximately $3.3 million thereafter. The Company will pay royalties on the current net sales of MUSE and if approved, future sales of avanafil, an investigational product candidate, to the Deerfield Sub. The term of the FARA is 10 years. The FARA includes covenants requiring the Company to use commercially reasonable efforts to preserve its intellectual property, manufacture, promote and sell MUSE, and develop avanafil. At the closing on April 15, 2008, under the securities purchase agreement, the Deerfield Affiliates purchased 1,626,017 shares of the Company's common stock for an aggregate purchase price of $10 million and the Company paid to the Deerfield Affiliates a $500,000 fee and reimbursed approximately $200,000 in certain expenses incurred in this transaction, registered under the shelf Registration Statement (File Number 333-135793) filed with the SEC, on July 14, 2006. The number of shares was determined based on the volume weighted average price on the Nasdaq Global Market of the Company's common stock on the three days prior to the execution of the securities purchase agreement dated as of April 3, 2008. The agreements also provided the Company with an option to purchase, and the Deerfield Affiliates with an option to compel the Company to purchase, or put right, the Deerfield Sub holding the royalty rights. If the Company exercises its right to purchase the Deerfield Sub, the net price will be $23 million if exercised within three years, or $26 million if exercised after three years but before four years (the purchase prices are subject to other adjustments as defined in the agreement). After three years from the closing, the Deerfield Affiliates may exercise the right to compel the Company to purchase the Deerfield Sub at a price of $17 million. This price could increase up to $26 million, and the timing of the sale of the shares could be accelerated under certain conditions

including a change-in-control, sale of MUSE or avanafil, sale of major assets and the sale of securities in a transaction or a series of related transactions by the Company that exceed 20% of VIVUS' outstanding common stock at the date the Option and Put Agreement was signed if at the time of the sale the Company's market capitalization is below $300 million each, a Major Transaction. Under these conditions, the cost of the shares of Deerfield Sub would be $23 million on or before the third anniversary and $26 million from the third through tenth anniversary. The sale of the shares of Deerfield Sub could also accelerate if the Company's cash, cash equivalents and available for sale securities falls below $15 million or the Company's market capitalization falls below $50 million. The purchase prices under the put right are subject to other adjustments as defined in the agreements. If either party exercises its option, any further royalty payments would be effectively terminated. In exchange for the option right, the Company paid $2 million to the Deerfield Affiliates. The Company's intellectual property and all of the accounts receivable, inventory and equipment arising out of or relating to MUSE and avanafil are collateral for this transaction.



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The Company has evaluated the Deerfield financing in accordance with FASB Financial Interpretation No., or FIN, 46(R), *Consolidation of Variable Interest Entities*, or FIN 46R, and determined that the Deerfield Sub may constitute a Variable Interest Entity, or VIE; however, the Company has also determined that VIVUS is not the primary beneficiary of this VIE at this time and has therefore concluded that the Company is not required to consolidate the Deerfield Sub (see Note 8: "Notes Payable").

8. NOTES PAYABLE

*Deerfield Financing*

In accordance with Emerging Issues Task Force (EITF) Issue 88-18, *Sale of Future Revenues*, the FARA transaction is in substance a financing arrangement, or loan, that will be repaid by VIVUS. The minimum repayment amount would be $17 million, the amount of the unconditional put option held by the Deerfield Affiliates, plus royalties paid during the term of the agreement on sales of MUSE and, if approved, avanafil. Accordingly, the Company will record the advances from the Deerfield Affiliates, net of the $2 million option right payment and related fees and expenses, as a loan. The loan balance will increase as the advances are received. The loan balance will increase quarterly up to the minimum amount owed of $17 million. The minimum amount to be recorded is lower than the contractual amounts owed if the Company exercises its call option of $23 million to $26 million, or if the Deerfield Affiliates require the Company to purchase the shares as a result of a "Major Transaction" (see Note 7: "Deerfield Financing"). Using the interest method under APB Opinion No. 21, *Interest on Receivables and Payables*, interest expense on the loan will be calculated and recognized over three years, which is the estimated term of the loan based on the earliest date that the Deerfield Affiliates could require the Company to repay the amounts advanced. The Deerfield Affiliates will receive a quarterly payment based on net sales of MUSE. The initial imputed effective annual interest rate on the financing was approximately 32% as calculated based upon quarterly advances under the FARA, up to a loan balance of $17 million, offset by the estimated quarterly royalty payments to the Deerfield Affiliates. The imputed effective interest rate is utilized for purposes of calculating the interest expense only and does not reflect the amount of royalty paid to the Deerfield Affiliates on a quarterly basis. Quarterly royalty payments are based on a percentage of net MUSE sales at a rate substantially lower than the imputed effective interest rate used to calculate interest expense.

*Crown Bank N.A. Loan*

On January 4, 2006, VIVUS, Inc. and Vivus Real Estate LLC, a wholly owned subsidiary of VIVUS, Inc., jointly, the Company, entered into a Term Loan Agreement and a Commercial Mortgage Note, or the Agreements, with Crown Bank N. A., or Crown, secured by the land and buildings, among other assets, located at 735 Airport Road and 745 Airport Road in Lakewood, New Jersey, or the Facility. The Facility is the Company's principal manufacturing facility, which the Company purchased on December 22, 2005. Under the Agreements, the Company borrowed $5,375,000 on January 4, 2006 from Crown payable over a 10-year term. The interest rate is adjusted annually to a fixed rate for the year equal to the prime rate plus 1%, with a floor of 7.5%. Principal and interest are payable monthly based upon a 20-year amortization schedule and are adjusted annually at the time of the interest rate reset. All remaining principal is due on February 1, 2016. The interest rate was 7.5% and 9.25% for the first nine months of 2008 and 2007, respectively. Because the interest rate is variable, and based on a market rate, the carrying value of the debt approximates fair value. The Agreements contain prepayment penalties, and a requirement to maintain a depository account at Crown with a minimum collected balance of $100,000 which, if not maintained, will result in an automatic increase in the interest rate on the note of one-half (0.5%) percent. The Facility, assignment of rents and leases on the Facility, and a $700,000 Certificate of Deposit held by Crown, classified as restricted cash, serve as collateral for these Agreements.

Total long-term notes payable consist of the following (in thousands):

| | September 30, 2008 (unaudited) | December 31, 2007 |
|---|---|---|
| Deerfield loan | $ 3,579 | $ — |
| Crown Bank N.A. loan | 5,080 | 5,175 |
| Total notes payable | 8,659 | 5,175 |
| Less current portion | (143) | (113) |
| Total long-term notes payable | $ 8,516 | $ 5,062 |

Current portion of notes payable is included under the heading "Accrued and other liabilities".



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Future minimum principal payments of the long-term notes payable as of September 30, 2008 are as follows (in thousands):

| As of September 30, 2008 | Deerfield loan | Crown Bank N.A. Loan | Total |
|---|---|---|---|
| 2008 (remainder of) | $ — | $ 35 | $ 35 |
| 2009 | — | 145 | 145 |

| | | | |
|---|---|---|---|
| 2010 | — | 157 | 157 |
| 2011 | 3,579 | 169 | 3,748 |
| 2012 | — | 181 | 181 |
| Thereafter | — | 4,393 | 4,393 |
| Total | $ 3,579 | $ 5,080 | $ 8,659 |

9. AGREEMENTS

In 2001, VIVUS entered into a Development, Licensing and Supply Agreement with Tanabe for the development of avanafil, an oral PDE5 inhibitor product candidate for the treatment of erectile dysfunction. Under the terms of the 2001 Development, Licensing and Supply Agreement with Tanabe, the Company paid a $2 million license fee obligation to Tanabe in the year ended December 31, 2006. The Company expects to make other substantial payments to Tanabe in accordance with its agreements with them as the Company continues to develop and, if approved for sale, commercialize avanafil for the oral treatment of male sexual dysfunction. Such potential future milestone payments total $19 million and include payments upon: the enrollment of the first patient in the first Phase 3 clinical studies; the first submission of an NDA; obtainment of the first regulatory approval in the United States and any major European country; and achievement of $250 million or more in calendar year sales.

The term of the Tanabe agreement is based on a country-by-country and on a product-by-product basis. The term shall continue until the later of (i) ten years after the date of the first sale for a particular product, or (ii) the expiration of the last to expire patents within the Tanabe patents covering such product in such country. In the event that the Company's product is deemed to be (i) insufficiently effective or insufficiently safe relative to other PDE5 inhibitor compounds based on published information, or (ii) not economically feasible to develop due to unforeseen regulatory hurdles or costs as measured by standards common in the pharmaceutical industry for this type of product, the Company has the right to terminate the agreement with Tanabe with respect to such product.

In February 2004, the Company entered into exclusive licensing agreements with Acrux Limited, or Acrux, and a subsidiary of Acrux under which it agreed to develop and, if approved, commercialize Testosterone MDTS, or Luramist, and Evamist in the United States for various female health applications. Under the terms of the agreements, the Company agreed to pay to Acrux for Luramist licensing fees of $2 million, up to $3.3 million for the achievement of certain clinical development milestones, up to $3 million for achieving product approval milestones, and royalties on net sales in the United States following approval and commercialization. For Evamist, the Company agreed to pay to Acrux licensing fees of $1 million, up to $1 million for the achievement of certain clinical development milestones, up to $3 million for achieving product approval milestones, and royalties on net sales in the United States following approval and commercialization. The Company made a $1 million milestone payment to Acrux in October 2006 related to the submission of an NDA to the FDA for Evamist. Upon approval of the NDA for Evamist, a $3 million product approval milestone became due and was paid to Acrux in August 2007. Under the terms of the Asset Purchase Agreement with K-V for the sale of Evamist, K-V paid $1.5 million of this $3 million obligation. In August 2008, the Company assigned all of its rights and obligations under the Evamist license agreement to K-V. See Note 11: "Sale of Evamist Product" below for additional information concerning the terms of this agreement.

The Company has entered into several agreements to license patented technologies that are essential to the development and production of the Company's transurethral product for the treatment of erectile dysfunction. In connection with these agreements, the Company is obligated to pay royalties on product sales of MUSE (4% of United States and Canadian product sales and 3% of sales elsewhere in the world). In the first nine months of 2008 and 2007, the Company recorded royalty expenses of $461,000 and $482,000, respectively, as cost of goods sold and manufacturing expense.

International sales are transacted through distributors. The distribution agreements include certain milestone payments from the distributors to the Company including upon achieving established sales thresholds. To date, the Company has collected $3.6 million in milestone payments from its current international distributors.



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10. INCOME TAXES

The Company makes certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes.

As part of the process of preparing its condensed consolidated financial statements, the Company is required to estimate its income taxes in each of the jurisdictions in which it operates. This process involves the Company estimating its current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included in the Company's condensed consolidated balance sheets.

The Company assesses the likelihood that it will be able to recover its deferred tax assets. The Company considers all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that the Company will recover its deferred tax assets, the Company will increase its provision for taxes by recording a valuation allowance against the deferred tax assets that the Company estimates will not ultimately be recoverable. As a result of the Company's analysis of all available evidence, both positive and negative, as of September 30, 2008, it was not considered more likely than not that the Company's deferred tax assets would be realized.

However, should there be a change in the Company's ability to recover its deferred tax assets, the Company would recognize a benefit to its tax provision in the period in which the Company determines that it is more likely than not that it can recover its deferred tax assets.

11. SALE OF EVAMIST PRODUCT

On March 30, 2007, the Company entered into a definitive agreement with K-V to transfer the assets and grant a sublicense of its rights under the Company's licensing agreement with Acrux related to Evamist, a metered dose transdermal spray for the treatment of menopause symptoms, to K-V, or the Transaction. In August 2008, the Company assigned all of its rights and obligations under the Evamist license agreement to K-V. At the time of the sale, Evamist was an investigational product not yet approved by the FDA for marketing. Under the Transaction, the Company received an upfront payment of $10

million at the closing and, upon approval of the NDA for Evamist on July 27, 2007 and the transfer and assignment of the NDA submissions to K-V on August 1, 2007 received an additional $140 million.

The Company may also receive certain one-time payments of up to $30 million based on K-V achieving certain annual net sales thresholds for Evamist. In addition, under the terms of the Transaction, K-V reimbursed VIVUS for $1.5 million of the $3 million milestone payment paid by VIVUS to Acrux upon FDA Approval of the NDA. In connection with the Transaction, in order to obtain Tanabe's release of liens against all assets including the Evamist assets and intellectual property, the Company repaid the Tanabe line of credit (see Note 8: "Notes Payable").



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12. NET INCOME (LOSS) PER SHARE

Net income (loss) per share is calculated in accordance with SFAS No. 128, *Earnings per Share*, which requires a dual presentation of basic and diluted earnings per share, or EPS. Basic net income (loss) per share is based on the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options. Common share equivalents are excluded from the computation in periods in which they have an anti-dilutive effect. Stock options for which the price exceeds the average market price over the period have an anti-dilutive effect on net income per share and, accordingly, are excluded from the calculation. When there is a net loss, other potentially dilutive common equivalent shares are not included in the calculation of net loss per share since their inclusion would be anti-dilutive. A reconciliation of the numerator and denominator used in the calculation of basic and diluted net income (loss) per share follows (in thousands, except per share amounts):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2008 (unaudited) | 2007 (unaudited) | 2008 (unaudited) | 2007 (unaudited) |
| Net income (loss) | $ 266 | $ 1,321 | $ (3,247) | $ (12,748) |
| Basic weighted-average shares outstanding | 66,122 | 58,627 | 61,801 | 58,449 |
| Dilutive effect of: | | | | |
| Options to purchase common stock | 1,662 | 865 | — | — |
| Diluted weighted-average shares outstanding | 67,784 | 59,492 | 61,801 | 58,449 |
| Net income (loss) per share: | | | | |
| Basic | $ 0.00 | $ 0.02 | $ (0.05) | $ (0.22) |
| Diluted | $ 0.00 | $ 0.02 | $ (0.05) | $ (0.22) |

For the three months ended September 30, 2008 and 2007, respectively, 1,040,257 and 2,064,999 options outstanding were not included in the computation of diluted net loss per share for the Company because the effect would be anti-dilutive.

As the Company recognized a net loss for the nine months ended September 30, 2008 and 2007, all potential common equivalent shares were excluded for these periods as they were anti-dilutive. For the nine months ended September 30, 2008, and 2007, respectively, 3,278,426 and 2,953,372 options outstanding were not included in the computation of diluted net loss per share for the Company because the effect would be anti-dilutive.

13. COMMITMENTS AND CONTINGENCIES

*Lease Commitments*

In November 2006, the Company entered into a 30-month lease for the existing Mountain View corporate headquarters location with its existing landlord. The lease commenced on February 1, 2007. The base monthly rent is set at $1.85 per square foot or $26,000 per month. The lease expires on July 31, 2009 and allows the Company one option to extend the term of the lease for a period of one year from the expiration of the lease.

Future minimum lease payments under operating leases are as follows (in thousands):

| | |
|---|---|
| 2008 (remainder) | $ 137 |
| 2009 | 320 |
| | $ 457 |



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*Manufacturing Agreements*

In November 2002, the Company entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. In May 2007, the terms of the agreement were amended to require the purchase of a minimum total of $2.3 million of product from 2007 through 2011. The Company's remaining commitment under this agreement is $1.5 million.

In January 2004, the Company entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. In February 2006, the terms of this agreement were amended to require the purchase of a minimum total of $1.5 million of product from 2006

through 2008. The Company's remaining commitment under this agreement is $765,000.

*Other Agreements*

The Company has entered into various agreements with clinical consultants and clinical research organizations to perform clinical studies on its behalf and, at September 30, 2008, its remaining commitment under these agreements totaled $42.8 million. The Company has remaining commitments under various general and administrative services agreements totaling $1.9 million at September 30, 2008, including $1.2 million related to Mr. Wilson's Employment Agreement (see paragraph below). The Company has also entered into various agreements with research consultants and other contractors to perform regulatory services, drug research, testing and manufacturing including animal studies and, at September 30, 2008, its remaining commitment under these agreements totaled $4.4 million. In addition, the Company has entered into marketing promotion and related agreements for its erectile dysfunction product, MUSE. At September 30, 2008, its remaining commitment under these marketing agreements totaled $779,000.

On December 19, 2007, the Compensation Committee of the Board of Directors of the Company approved an employment agreement, or the Employment Agreement, with Leland F. Wilson, the Company's President and Chief Executive Officer. The Employment Agreement includes salary, incentive compensation, retirement benefits and length of employment, among other items, as agreed to with Mr. Wilson. The Employment Agreement has an initial term of two years commencing on the effective date, June 1, 2007, or the Effective Date. On the second anniversary of the Effective Date, the Employment Agreement will automatically renew for an additional one-year term unless either party provides the other party with a notice of non-renewal.

*Indemnifications*

In the normal course of business, the Company provides indemnifications of varying scope to certain customers against claims of intellectual property infringement made by third parties arising from the use of its products and to its clinical research organizations and investigator sites against liabilities incurred in connection with any third-party claim arising from the work performed on behalf of the Company. Historically, costs related to these indemnification provisions have not been significant and the Company is unable to estimate the maximum potential impact of these indemnification provisions on its future results of operations.

Pursuant to the terms of the Asset Purchase Agreement for the sale of the Evamist product to K-V, the Company made certain representations and warranties concerning its rights and assets related to Evamist and the Company's authority to enter into and consummate the transaction. The Company also made certain covenants which survive the closing date of the transaction, including a covenant not to operate a business that competes, in the United States, and its territories and protectorates, with the Evamist product. See Note 18: "Legal Matters" for further information regarding Acrux.

Pursuant to the terms of the Funding and Royalty Agreement with Deerfield, the Company made certain representations, warranties and covenants related to MUSE and avanafil. Covenants include that it will maintain all registrations and regulatory rights to sell and promote MUSE in the United States, it will continue to manufacture and promote MUSE and will continue the development of avanafil. The Company also entered into a covenant that it will not manufacture, promote or sell any product that competes with avanafil in the United States other than MUSE.

To the extent permitted under Delaware law, the Company has agreements whereby it indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The indemnification period covers all pertinent events and occurrences during the officer's or director's lifetime. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited; however, the Company maintains director and officer insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.



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14. CONCENTRATION OF CUSTOMERS AND SUPPLIERS

During the first nine months of 2008 and 2007, sales to significant customers as a percentage of total revenues were as follows:

| | 2008 | 2007 |
|---|---|---|
| Customer A | 36% | 47% |
| Customer B | 27% | 14% |
| Customer C | 12% | 12% |
| Customer D | 18% | 22% |

The Company relies on third party sole-source manufacturers to produce its clinical trial materials, components and raw materials. Third party manufacturers may not be able to meet the Company's needs with respect to timing, quantity or quality. Several of the Company's manufacturers are sole-source manufacturers where no alternative suppliers exist. In the three and nine months ended September 30, 2008, the Company spent $10.3 million and $37.1 million, respectively, for services provided by one clinical research organization on the Qnexa Phase 3 studies, which represented 66% and 68%, respectively, of the Company's total research and development expenses. In the three months ended September 30, 2007, the Company spent $2.4 million on clinical supplies and formulation work performed by the Company's sole-source manufacturer which represented 28% of the Company's total research and development expenses.

15. RESEARCH AND DEVELOPMENT

Research and development expenses including advertising for clinical trials and patient recruitment costs are expensed as incurred.

16. EQUITY TRANSACTIONS

On April 3, 2008, the Company entered into several agreements with the Deerfield Affiliates (see Note 7: "Deerfield Financing"). Under the agreements, Deerfield and its affiliates agreed to provide $30 million in funding to the Company. The $30 million in funding consists of $20 million from a FARA and $10 million from the sale of the Company's common stock under a securities purchase agreement. At the closing on April 15, 2008, under the securities purchase agreement, the Deerfield Affiliates purchased 1,626,017 shares of the Company's common stock for an aggregate purchase price of $10 million and the

Company paid to the Deerfield Affiliates a $500,000 fee and reimbursed approximately $200,000 in certain expenses incurred in this transaction, registered under the shelf Registration Statement (File Number 333-135793) filed with the SEC on July 14, 2006. The number of shares was determined based on the volume weighted average price on the Nasdaq Global Market of the Company's common stock on the three days prior to the execution of the securities purchase agreement dated as of April 3, 2008.

On May 5, 2008, the Company filed with the SEC a shelf Registration Statement on Form S-3 (File Number 333-150649) and was declared effective by the SEC on May 29, 2008, providing the Company with the ability to offer and sell up to an aggregate of $150 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering.

On May 5, 2008, the Company filed a Form S-8 with the SEC registering 1,000,000 shares of common stock, par value $0.001 per share, under the 2001 Stock Option Plan, as amended.

On May 6, 2008, the Company filed with the SEC a Post-Effective Amendment No. 1 to Form S-3 (File No. 333-135793), or the Registration Statement, which was filed with the SEC on July 14, 2006, to amend the Registration Statement to deregister any securities registered pursuant to the Registration Statement and not otherwise sold thereunder.

On August 6, 2008, the Company sold $65 million of its common stock in a registered direct offering. Under the terms of the financing, the Company sold 8,365,508 shares of its common stock at a price of $7.77 per share. On August 5, 2008, the Company filed a prospectus supplement with the SEC relating to this registered direct offering under the existing shelf Registration Statement (File Number 333-150649).

17. RELATED PARTY TRANSACTIONS

Mario M. Rosati, one of the Company's directors until June 13, 2008, is also a member of Wilson Sonsini Goodrich & Rosati, Professional Corporation, which has served as the Company's outside corporate counsel since its formation and has received compensation at normal commercial rates for these services. In the first nine months of 2008 and 2007, the Company paid



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$606,000 and $699,000, respectively, to Wilson Sonsini Goodrich & Rosati. On April 17, 2008, Mr. Rosati notified the Company of his decision not to stand for re-election at the Company's 2008 annual meeting held on June 13, 2008 and is no longer a member of the Company's Board of Directors as of that date.

18. LEGAL MATTERS

In the normal course of business, the Company receives claims and makes inquiries regarding patent infringement and other legal matters. The Company believes that it has meritorious claims and defenses and intends to pursue any such matters vigorously.

The Company and Acrux Limited, or Acrux, are parties to the Testosterone Development and Commercialization Agreement, or the Testosterone Agreement, and the Estradiol Development and Commercialization Agreement, or the Evamist Agreement, each dated February 12, 2004, or collectively, the Acrux Agreements. The Acrux Agreements cover the Company's investigational product candidate, Luramist, and the Company's former investigational product candidate, Evamist, both of which are licensed from Acrux under the Acrux Agreements. The Company received a letter dated November 13, 2006 from legal counsel for Acrux containing various claims of breach under the Acrux Agreements. The Company responded that there is no merit to Acrux's claims and that it has meritorious defenses to such claims. Acrux has since approved the Company's assignment of the Company's rights and obligations under the Evamist Agreement to K-V as part of K-V's purchase of Evamist and released the Company from any claims or liabilities arising from the Evamist Agreement. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding its claims related to Luramist. Acrux's demand seeks a reversion of all rights assigned to the Company related to Luramist, monetary damages, a portion of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. The Company continues to believe that it is in compliance with all material aspects of the Testosterone Agreement and that it does not owe monetary damages or any milestone payment under the Testosterone Agreement. The Company also believes that it has valid counterclaims against Acrux and has requested that it be allowed to include such counterclaims in the arbitration. Otherwise, the arbitration process is proceeding, with the parties having selected and qualified a panel of three arbitrators and having agreed to a schedule of pre-hearing discovery. Absent a resolution to the dispute, the arbitration hearing is currently scheduled to commence in January 2009. In the event that Acrux should prevail in this matter, it could have a material adverse effect on the Company's business, financial condition and results of operations and cash flow.

The Company is not aware of any other asserted or unasserted claims against it where an unfavorable resolution would have an adverse material impact on the operations or financial position of the Company.

19. STOCKHOLDER RIGHTS PLAN

On March 26, 2007, the Board of Directors of the Company adopted a Stockholder Rights Plan, or the Rights Plan, and amended its bylaws. Under the Rights Plan, the Company will issue a dividend of one right for each share of its common stock held by stockholders of record as of the close of business on April 13, 2007.

The Rights Plan is designed to guard against partial tender offers and other coercive tactics to gain control of the Company without offering a fair and adequate price and terms to all of the Company's stockholders. The Rights Plan is intended to provide the Board of Directors with sufficient time to consider any and all alternatives to such an action and is similar to plans adopted by many other publicly traded companies. The Rights Plan was not adopted in response to any efforts to acquire the Company and the Company is not aware of any such efforts.

Each right will initially entitle stockholders to purchase a fractional share of the Company's preferred stock for $26.00. However, the rights are not immediately exercisable and will become exercisable only upon the occurrence of certain events. If a person or group acquires, or announces a tender or exchange offer that would result in the acquisition of 15% or more of the Company's common stock while the Stockholder Rights Plan remains in place, then, unless the rights are redeemed by the Company for $.001 per right, the rights will become exercisable by all rights holders except the acquiring person or group for the Company's shares or shares of the third party acquirer having a value of twice the right's then-current exercise price.

The Board of Directors also amended provisions of the Company's bylaws concerning procedures for the calling of special stockholder meetings and establishing the agenda and Board of Director nominees at annual stockholders meetings. The Company filed these bylaw amendments with the SEC on Form 8-K on March 28, 2007.



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

This Management's Discussion and Analysis of Financial Conditions and Results of Operations and other parts of this Form 10-Q contain "forward-looking" statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as "believe," "expect," "intend," "anticipate," "should," "planned," "estimated," and "potential," among others. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our history of losses and variable quarterly results; (2) substantial competition; (3) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (4) our reliance on sole source suppliers; (5) our limited sales and marketing efforts and our reliance on third parties; (6) failure to continue to develop innovative products; (7) risks related to noncompliance with United States Food and Drug Administration, or the FDA, regulations; (8) our ability to demonstrate through clinical testing the safety and effectiveness of our clinical candidates; (9) the timing of initiation and completion of clinical trials and submissions to the FDA; (10) the volatility and liquidity of the financial markets; and (11) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, or the SEC, including those set forth in this filing as "Risk Factors Affecting Operations and Future Results."

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the quarter and nine-month period ended September 30, 2008 are not necessarily indicative of the results that may be expected for the full fiscal year or any future period.

**BUSINESS OVERVIEW**

VIVUS, Inc. is a pharmaceutical company, incorporated in 1991, dedicated to the development and commercialization of therapeutic products for large underserved markets. The investigational products currently under development could serve the obesity, diabetes and sexual health markets. Our current and investigational product candidates in development will encompass patented proprietary formulations and novel delivery systems. Investigational products may be developed by seeking new indications for previously approved pharmaceutical products. To date, through employment of this strategy, we have one commercial product and several investigational product candidates in late stages of clinical development to treat obesity, diabetes and sexual health disorders. With respect to obesity, analysts estimate that this potential worldwide market could exceed $5 billion annually. Sales of approved drugs for diabetes exceed $10 billion. The indications targeted by VIVUS' investigational sexual health products each represent a projected market greater than $1 billion annually.

The current investigational product pipeline includes three late-stage clinical product candidates, each addressing specific components of the obesity, diabetes and sexual health markets. One of these investigational products, Qnexa™, is in Phase 3 clinical trials for obesity and has completed a Phase 2 clinical trial for diabetes.

All of the pivotal Phase 3 studies for Qnexa for obesity were initiated in the fourth quarter of 2007 and are fully enrolled. The co-primary endpoints for these studies will evaluate the differences between treatments from baseline to the end of the treatment period, in mean percent weight loss and in the percentage of subjects achieving weight loss of 5% or more. All Phase 3 studies will utilize our novel once-a-day formulation of Qnexa, which at full strength contains 15 mg phentermine immediate release and 92 mg topiramate controlled release. Pharmacokinetic-Pharmacodynamic (PK/PD) studies indicated that the once-a-day formulation is comparable to the twice-a-day formulation used in the Phase 2 obesity study.

Our late-stage investigational product pipeline includes:

- **Qnexa,** being developed to treat obesity, for which the pivotal Phase 3 studies are ongoing;
- **Qnexa,** being developed to treat diabetes, for which a Phase 2 study has been completed;
- **Avanafil,** being developed to treat erectile dysfunction, for which Phase 2 studies have been completed; and
- **Luramist™** (Testosterone MDTS®), being developed to treat hypoactive sexual desire disorder in women, for which a Phase 2 study has been completed.



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On April 3, 2008, we entered into several agreements with Deerfield Management Company, L.P., or Deerfield, a healthcare investment fund, and its affiliates, Deerfield Private Design Fund L.P. and Deerfield Private Design International, L.P. (collectively, the Deerfield Affiliates). Under the agreements, Deerfield and its affiliates agreed to provide $30 million in funding to the Company. The $30 million in funding consists of $20 million from a Funding and Royalty Agreement, or the FARA, entered into with a newly incorporated subsidiary of Deerfield, or the Deerfield Sub, and $10 million from the sale of our common stock under a securities purchase agreement. Under the FARA, the Deerfield Affiliates made $3.3 million payments to us in April and August 2008 and will make four quarterly payments of approximately $3.3 million thereafter. We will pay royalties on the current net sales of MUSE and if approved, future sales of avanafil, an investigational product candidate, to the Deerfield Sub. The term of the FARA is 10 years. The FARA includes covenants requiring us to use commercially reasonable efforts to preserve our intellectual property, manufacture, promote and sell MUSE, and develop avanafil. At the closing on April 15, 2008, under the securities purchase agreement, the Deerfield Affiliates purchased 1,626,017 shares of our common stock for an aggregate purchase price of $10 million and we paid to the Deerfield Affiliates a $500,000 fee and reimbursed approximately $200,000 in certain expenses incurred in this

transaction. The number of shares was determined based on the volume weighted average price on the Nasdaq Global Market of the Company's common stock on the three days prior to the execution of the securities purchase agreement dated as of April 3, 2008. The agreements also provided us with an option to purchase, and the Deerfield Affiliates with an option to compel us to purchase, the Deerfield Sub holding the royalty rights. If we exercise our right to purchase the Deerfield Sub, the net price will be $23 million if exercised within three years, or $26 million if exercised after three years but before four years (the purchase prices are subject to other adjustments as defined in the agreement). After three years from the closing, the Deerfield Affiliates may exercise the right to compel us to purchase the Deerfield Sub at a price ranging from $17 million to $26 million based upon various circumstances. If either party exercises its option, any further royalty payments would be effectively terminated. In exchange for the option right, we paid $2 million to the Deerfield Affiliates. Our intellectual property and all of the accounts receivable, inventory and equipment arising out of or relating to MUSE and avanafil are collateral for this transaction.

Our former investigational product candidate, Evamist™, a metered dose transdermal estradiol spray approved for the treatment of vasomotor symptoms associated with menopause, was sold to K-V Pharmaceutical Company, or K-V, on May 15, 2007. We had completed Phase 3 studies for Evamist in May 2006 and a New Drug Application, or NDA, was approved by the FDA on July 27, 2007.

On March 30, 2007, we announced that we had entered into a definitive agreement with K-V to transfer certain of our assets and grant a sublicense under our exclusive rights to certain patents and know-how related to Evamist pursuant to our Estradiol Development and Commercialization Agreement with FemPharm Pty Ltd. and Acrux DDS Pty Ltd. (together referred to as Acrux), dated February 12, 2004, as amended, or the Evamist Agreement, to K-V. On May 15, 2007, the transaction with K-V closed. Under the terms of the transaction, we received an upfront payment of $10 million upon the closing. On August 1, 2007, we transferred and assigned the Evamist FDA submissions, and all files related thereto to K-V, and on August 8, 2007, we received a $140 million milestone payment from K-V. K-V also paid $1.5 million of the $3 million product approval milestone payment due to Acrux upon approval of Evamist. We are also eligible to receive certain one-time milestone payments from K-V totaling up to $30 million based on the achievement of certain annual net sales thresholds for Evamist. In August 2008, the Company assigned all of its rights and obligations under the Evamist license agreement to K-V.

In 1997, we launched MUSE (alprostadil) in the United States and, together with our partners, internationally. We market MUSE as a prescription product for the treatment of erectile dysfunction.

*Our Future*

Our goal is to build a successful pharmaceutical company through the development and commercialization of innovative proprietary products. We intend to achieve this by:

- capitalizing on our clinical and regulatory expertise and experience to advance the development of investigational product candidates in our pipeline;
- establishing strategic relationships with marketing partners to maximize sales potential for our products that require significant commercial support; and
- licensing complementary clinical stage investigational product candidates or technologies with competitive advantages from third parties for new and established markets.



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It is our objective to become a leader in the development and commercialization of products for large underserved markets. We believe that we have strong intellectual property supporting several opportunities in obesity, diabetes and sexual health. Our future growth will depend on our ability to further develop and obtain regulatory approval of our investigational product candidates as well as in-licensing and product line extensions.

We have funded operations primarily through private and public offerings of our common stock, the sale of the rights to Evamist and through product sales of MUSE. We expect to generate future net losses due to increases in operating expenses as our various investigational product candidates are advanced through the various stages of clinical development. In connection with the sale of Evamist, we received to date an aggregate of $150 million. The sale of Evamist was a unique transaction. As discussed in Note 11: Sale of Evamist Product, an initial $10 million was paid at closing and $140 million was paid upon the FDA's approval of the Evamist NDA. These payments are non-refundable and have been recorded as deferred revenue and will be recognized as license and other revenue ratably over a 21.5-month period, from August 1, 2007 to May 15, 2009, which is the remaining term of a license to improvements to the MDTS applicator. As compared to revenues from sales of MUSE, license and other revenue will be significant on a quarterly basis until all of the revenue from the sale of Evamist is recognized which is currently expected to be May 2009. Since the $150 million has been received and we have no related contingencies, the future recognition of revenue and the corresponding reduction of deferred revenue related to the Evamist sale will have no impact on our cash flows from operations in future periods through May 2009. As of September 30, 2008, we have incurred a cumulative deficit of $173.1 million and expect to incur operating losses in future years.

***Year-to-Date 2008***

Year-to-date highlights include:

- **Completion of Phase 2 Study of Qnexa for Diabetes —** In June 2008, we announced the results of our OB-202 diabetes study, a 28-week, Phase 2 clinical trial in type 2 diabetes. Subjects treated with Qnexa had a reduction in hemoglobin A1c, a common measure of glycemic control, of 1.2% and experienced an 8.0% weight loss on an intent-to-treat, or ITT, basis.
- **Completion of Enrollment of the Phase 3 Qnexa for Obesity Studies —** Through April 2008, we completed enrollment of all of the pivotal studies. The co-primary endpoints for these studies will evaluate the differences between treatments from baseline to the end of the treatment period, in mean percent weight loss and in the percentage of subjects achieving weight loss of 5% or more. Specifically, the Phase 3 studies include:
  - EQUATE (OB-301), a 28-week study in which approximately 700 patients with Body Mass Index, or BMI, ranging from 30 to 45 have been enrolled.

- EQUIP (OB-302), a 56-week study in which approximately 1,250 morbidly obese patients with BMI that equals or exceeds 35 have been enrolled.

- CONQUER (OB-303), a 56-week study in which approximately 2,500 patients with a BMI ranging from 27 to 45 and two related co-morbidities including hypertension, dyslipidemia and type 2 diabetes have been enrolled.

- **Initiation of Extension Study with Qnexa for Diabetes —** In January 2008, we announced the initiation of a six-month extension study for patients currently enrolled in the OB-202 diabetes study.

- **Special Protocol Assessment Completed and Agreement Reached with the FDA on Safety Study for Luramist —** In the first quarter of 2008, we completed the Special Protocol Assessment, or SPA, process and reached agreement with the FDA on the safety requirements for Luramist (testosterone MDTS). The pivotal Phase 3 studies will include two six-month studies in menopausal women with hypoactive sexual desire disorder. The safety outcomes study will enroll 5,200 postmenopausal women aged 50 or over with at least one cardiovascular risk factor.

- **Entered into Funding Collaboration for the Phase 3 Studies of Avanafil for Erectile Dysfunction —** In April 2008, we entered into agreements with Deerfield Management. Under the terms of the agreements, Deerfield will provide funds for the Phase 3 program for avanafil. The $30 million in funding will be provided by Deerfield from two sources: $20 million under a Funding and Royalty Agreement and $10 million from the sale of our common stock. We have granted Deerfield a royalty interest on sales of MUSE, our product currently marketed for the treatment of erectile dysfunction as part of the funding collaboration.



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***Our Product Pipeline***

We currently have the following research and development programs for investigational product candidates targeting obesity, diabetes and sexual health:

| Product | Indication | Status | Patent Expiry and Number |
|---|---|---|---|
| Qnexa (phentermine and topiramate CR) | Obesity | Phase 3 initiated for Obesity | 2019 (US 7,056,890 B2) |
| Qnexa (phentermine and topiramate CR) | Diabetes | Phase 2 completed | 2019 (US 7,056,890 B2) |
| Luramist (Testosterone MDTS) | Hypoactive sexual desire disorder (HSDD) | Phase 2 completed | 2017 (US 6,818,226) |
| Avanafil (PDE5 inhibitor) | Erectile dysfunction (ED) | Phase 2 completed | 2020 (US 6,656,935) |

**Obesity**

In 2004, the U.S. Centers for Disease Control and Prevention, or the CDC, ranked obesity as one of the top health threats in America. Obesity is a chronic condition that affects millions of people and often requires long-term or invasive treatment to promote and sustain weight loss. Obesity is the second leading cause of preventable death in the United States. The American Obesity Association estimates that approximately 127 million or 64.5% of adults in the United States are overweight, and an estimated 60 million or 30.5% are obese. According to a study performed by the CDC, as reported in the Journal of the American Medical Association, an estimated 112,000 excess deaths a year in the United States are attributable to obesity. The total direct and indirect costs attributed to overweight and obesity amounted to approximately $117 billion in 2000. Additionally, Americans spend more than $30 billion annually on weight-loss products and services.

**Diabetes**

Diabetes is a significant worldwide disease. Based on the third edition of the *Diabetes Atlas* published in 2006, the International Diabetes Federation estimated that in 2007 there were 246 million people with diabetes worldwide, with 46% of those affected in the 40 to 59 age group. Diabetes, mostly type 2 diabetes, now affects 5.9% of the world's adult population with almost 80% of the total in developing countries. The United States Centers for Disease Control and Prevention estimates, based on 2007 data, that nearly 24 million people in the United States have diabetes, mostly type 2 diabetes, and that 57 million people have pre-diabetes, a condition that puts people at increased risk of diabetes. Type 2 diabetes is characterized by inadequate response to insulin and/or inadequate secretion of insulin as blood glucose levels rise. Therapies for type 2 diabetes are directed toward correcting the body's inadequate response with oral or injectable medications, or directly modifying insulin levels through injection of insulin or insulin analogs.

The currently approved oral medications for type 2 diabetes include insulin releasers such as glyburide, insulin sensitizers such as Actos and Avandia, inhibitors of glucose production by the liver such as metformin, DPP-IV inhibitors like Januvia, as well as Precose and Glyset, which slow the uptake of glucose from the intestine. The worldwide market for diabetes medications exceeded $10 billion in 2004, of which oral drugs exceeded $6 billion. However, it is estimated that a significant portion of type 2 diabetics fail oral medications and require injected insulin therapy. Current oral medications for type 2 diabetes have a number of side effects, including hypoglycemia, weight gain and edema. Numerous pharmaceutical and biotechnology companies are seeking to develop insulin sensitizers, novel insulin formulations and other therapeutics to improve the treatment of diabetes. Previous clinical studies of topiramate in type 2 diabetics resulted in a reduction of hemoglobin A1c, a measure used to determine treatment efficacy of anti-diabetic agents. In June 2008, we announced the results of our OB-202 diabetes study, a 28-week, Phase 2 clinical trial in type 2 diabetes. Subjects treated with Qnexa had a reduction in hemoglobin A1c, a common measure of glycemic control, of 1.2%, from 8.7% to 7.5%. We are currently conducting a six-month extension study for patients previously enrolled in the OB-202 diabetes study. The extension study, DM-230, will allow subjects to continue, in a blinded fashion as randomized, in the study for an additional 28 weeks.

***Qnexa for Obesity***

Qnexa is our proprietary oral investigational product candidate for the treatment of obesity, incorporating low doses of active ingredients from two previously approved products, topiramate and phentermine. By combining each of these compounds, we believe Qnexa can simultaneously address excessive appetite and high threshold for satiety, or the feeling of being full, the two main mechanisms that impact eating behavior. Qnexa is a once-a-day capsule containing a proprietary formulation of topiramate and phentermine.

Previously, we reported results from a Phase 2 double-blind, randomized, and placebo-controlled clinical trial in which patients on Qnexa lost on average 25.1 pounds as compared to patients in the placebo group who lost 4.8 pounds. This trial involved 200 subjects, 159 women and 41 men with an average approximate age of 40 and a mean BMI of 38.6. (A BMI of > 30 is classified as obese per guidelines from the U.S. Department of Health and Human Services.) Patients completing the 24-week treatment period lost on average approximately 11% of baseline body weight, as compared to an average 2.8% in the placebo group. The difference between the Qnexa arm and the placebo arm was statistically significant. Qnexa was well-tolerated in this trial. The study completion rate for patients on Qnexa over the 24-week treatment period was 92%, as compared to 62% for patients in the placebo group. Adverse events occurring in greater than 10% in the Qnexa arm as compared to placebo included paresthesia (mild tingling of the extremities), altered taste, increased urinary frequency and headache. There were no dropouts in the Qnexa arm due to serious or severe adverse events.

The Phase 2 study also demonstrated significant improvements in patients' quality of life, such as self-esteem, public distress and physical function when treated with Qnexa. Treatment with topiramate alone showed no improvement in any aspects of quality of life despite primary significant weight loss. These results suggest that the component of phentermine increases the tolerability of topiramate, which was the scientific rationale for combining these two agents at low doses for the treatment of obesity and related co-morbidities.

In addition, Qnexa-treated subjects had a significant reduction of waist circumference, triglycerides, systolic blood pressure, C-reactive protein and total cholesterol compared to patients in the placebo group. These secondary findings suggest that Qnexa may improve several important metabolic disease risk factors in obese patients. According to the American Heart Association, "The metabolic syndrome is characterized by a group of metabolic risk factors in one person." Such factors include but are not limited to abdominal obesity and blood fat disorders that foster plaque buildup in artery walls including: high triglycerides, low HDL cholesterol, high LDL cholesterol, and elevated blood pressure. People with metabolic syndrome have an increased risk of coronary heart disease and other conditions that result from the buildup of plaque in artery walls (e.g., stroke and peripheral vascular disease) and type 2 diabetes. The current FDA guidelines state that on its own, metabolic syndrome represents a cluster of laboratory and clinical findings that serve as markers for increased risk for cardiovascular disease and type 2 diabetes, and is prevalent in as much as 25% of the adult American population. The FDA does not consider the metabolic syndrome to represent a distinct disease entity or treatment indication. Nonetheless, in addition to lifestyle modification, a host of approved drug therapies now exist to address individual or multiple components of the syndrome (e.g., lipid altering agents, antihypertensives, insulin sensitizers). We completed an initial Phase 2 clinical trial (OB-202) in patients with type 2 diabetes and a six-month extension study for patients currently enrolled in the OB-202 diabetes study (DM-230) is currently underway. We may, in the future, conduct additional studies of Qnexa on these components of metabolic syndrome.

The primary efficacy endpoint for Phase 3 weight loss trials as recommended by the FDA is an assessment of the mean percent reduction in baseline body weight compared to placebo and the proportion of subjects who lose 5% or more of their baseline body weight over a one-year period. New FDA draft guidelines for obesity products set forth a primary efficacy benchmark in Phase 3 trials of at least 35% of patients achieving 5% weight loss. The weight loss in patients taking the obesity product should also be twice the weight loss of the placebo group. In our Phase 2 trial after 24 weeks, 82% of patients lost 5% of their baseline weight as compared to 14% in the placebo group. In Europe, the Committee for Medicinal Products for Human Use of the European Medicines Agency has recommended that demonstration of significant weight loss of at least 10% of baseline weight is considered to be a valid primary endpoint for anti-obesity drugs. In the Phase 2 study after 24 weeks, 50% of the patients on Qnexa lost 10% of their baseline weight as compared to 8% of the patients in the placebo group. The FDA and the Medicines and Healthcare products Regulatory Agency, the regulatory authority in the United Kingdom, require obesity studies to be conducted for at least one year. While the results from our single center Phase 2 trial for six months of treatment meet these guidelines, there can be no assurance that these results can be replicated in a multi-center, one-year, Phase 3 trial, or with a once-a-day formulation of the product. We completed the development of our once-a-day formulation of Qnexa prior to the initiation of our Phase 3 clinical trials.





In June 2007, we announced the formation of our Qnexa Scientific Advisory Board, or the Qnexa SAB, consisting of well-known experts in the areas of obesity, clinical trial design, psychology and diabetes. We appointed Dr. David Allison, Dr. Nancy Bohannon, Dr. Arthur Frank, Dr. Donna Ryan, Dr. Xavier Pi-Sunyer and Dr. Tom Wadden to the Qnexa SAB. These experts have provided guidance concerning Qnexa Phase 3 clinical trials and are available for continuing consultations.

We have successfully completed the Special Protocol Assessment, or SPA, process and have reached agreement with the FDA regarding key elements of the pivotal Phase 3 clinical trials of Qnexa for the treatment of obesity and weight-related co-morbidities. We have reached agreement with the FDA on study design features that will be employed throughout the entire Phase 3 program including the co-primary endpoints of the study, scope and size of the patient population, specific safety assessments, inclusion/exclusion criteria, duration of the trials and the statistical method for analyzing the co-primary study endpoints.

Under the SPA process, a sponsor may seek the FDA's agreement on the design and analysis of a clinical trial intended to form the primary basis of an efficacy claim. If the FDA agrees in writing, its agreement may not be changed by the sponsor or the FDA after the trial begins except in limited circumstances, such as the FDA determining that a substantial scientific issue essential to determining the safety or effectiveness of the product was identified after the trial had begun. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on it as the basis for approval with respect to effectiveness.

The Phase 3 Qnexa program includes two pivotal, double-blind, placebo-controlled, multi-center studies comparing Qnexa to placebo over a 56-week treatment period. In November 2007, we initiated both of these two pivotal Phase 3 studies of Qnexa. All Phase 3 studies are utilizing our once-a-day formulation of Qnexa, which at full strength contains 15 mg phentermine immediate release and 92 mg topiramate controlled release. The studies are designed to prospectively demonstrate the safety and efficacy of Qnexa in obese and overweight patients with different baseline characteristics. The first study, known as EQUIP (OB-302), enrolled over 1,250 morbidly obese patients with a BMI that equals or exceeds 35 with or without controlled co-morbidities. The EQUIP study completed enrollment in March 2008. The second trial, known as CONQUER (OB-303), enrolled overweight and obese adult

subjects with BMI's from 27 to 45 and at least two co-morbid conditions, such as hypertension, dyslipidemia and type 2 diabetes. The co-primary endpoints for these studies will evaluate the differences between treatments in mean percent weight loss from baseline to the end of the treatment period and the differences between treatments in the percentage of subjects achieving weight loss of 5% or more. Patient enrollment for both pivotal Phase 3 trials, OB-302 and OB-303, are complete.

A pharmacokinetic-pharmacodynamic (PK/PD) study has confirmed that the once-a-day formulation is comparable to the twice-a-day formulation used in the Phase 2 study.

The Phase 3 program also includes a six-month confirmatory factorial-design study, known as EQUATE (OB-301), including obese subjects with BMI's from 30 to 45. This trial was initiated in December 2007 and completed enrollment in March 2008. The EQUATE study will evaluate two dose levels of Qnexa, compared to both placebo and the individual constituents of the combination. The primary endpoints at six months are similar to those evaluated in the pivotal studies.

Safety and tolerability of Qnexa will be determined by reporting adverse events, physical exam, clinical laboratory data, electrocardiogram, cognitive function tests, psychological assessments, and clinical assessment of clinical laboratory variables. The Phase 3 studies are fully enrolled and include approximately 4,500 subjects.

***Qnexa for Diabetes***

On June 10, 2008, the results of the Phase 2 study with Qnexa in diabetes were presented at the American Diabetes Association annual scientific meeting. Patients treated with Qnexa for 28 weeks had a reduction in HbA1c of 1.2% and lost on average 8% of their baseline body weight, or approximately 17 pounds. Qnexa patients also had significant improvement in cardiovascular risk factors including blood pressure, triglycerides levels and waist circumference. In the diabetes study (OB-202), subjects underwent a 4-week dose escalation period followed by 24 weeks of treatment. The study was a randomized, double-blind, placebo-controlled prospective trial, with subjects randomized to receive Qnexa or placebo. The study included 206 subjects (141 females, 65 males) with an average age of 49 years. Baseline BMIs were greater than 35 in both groups, and baseline body weight was 94.7 kg in the Qnexa group and 98.1 kg in the placebo group. At baseline, subjects had glycosylated hemoglobin (HbA1c) of 8.7%. Patients in the Qnexa group reduced systolic blood pressure from 122.8 mmHg to 118.9 mmHg, as compared to a neutral effect in the placebo group from 124.4 mmHg to 124.5 mmHg ($p<0.005$). Patients in the Qnexa group reduced diastolic blood pressure from 74.7 mmHg to 73.7 mmHg, as compared to a marginal increase in the placebo group from 75.7 mmHg to 76.6 mmHg ($p<0.018$). Patients in the Qnexa group also had a significant reduction in triglycerides from 162 mg/dL to 143 mg/dL, as compared to subjects in the placebo group that had a slight reduction from 172.2 mg/dL to 171.6 mg/dL ($p<0.016$). Most of the subjects had been diagnosed with diabetes for more than five years (59%). Sixty percent of subjects were on two or more oral diabetic medications. Patients on antidepressant medications such as SSRIs and SNRIs were allowed to participate in the study. Subjects were instructed to follow a simple diet and lifestyle modification program throughout the study. The primary endpoint was change



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in glycemic control as reflected by measurements of hemoglobin A1c. Investigators were allowed to intervene and add/adjust anti-diabetic and anti-hypertensive medications during the study based on predetermined rescue criteria and nationally recognized standards of care. The incidence of hypoglycemia in the treatment and placebo arms were comparable (6% versus 5%, respectively). Qnexa was well-tolerated, with no treatment-related serious adverse events (SAEs). The most common treatment-related adverse events were nausea, paresthesias, constipation, dry mouth and dizziness.

A subset analysis of the Phase 2 OB-202 study with Qnexa in diabetes of subjects with higher cardiovascular risk factors at baseline demonstrated that these subjects had significantly greater improvements in these risk factors on Qnexa as compared to placebo. This analysis population is comprised of subjects with elevated baseline risk factors that were in the upper quartile of the overall study population. Specifically, these higher-risk subjects treated with Qnexa reduced their systolic blood pressure (SBP) by 11.2 mmHg from a baseline mean of 138.1 mmHg, as compared to a reduction of 1.9 mmHg from a baseline mean of 140.7 mmHg in the placebo group ($p=0.006$). Similarly, diastolic blood pressure (DBP) was reduced by 7.9 mmHg from a baseline mean of 83.5 mmHg in the Qnexa group, as compared to a reduction of 3.3 mmHg from a baseline mean of 86.3 mmHg in the placebo group ($p=0.015$). Current standard of care for diabetics includes a target SBP < 130 and DBP < 80 mmHg. Higher-risk subjects with elevated triglyceride levels at baseline that were treated with Qnexa experienced a reduction of 86.9 mg/dL or 32% from baseline as compare to a reduction of 25.3 mg/dL or 8.7% in the placebo group ($p=0.022$). Fasting plasma glucose (FPG) in the higher-risk subjects was reduced by 85.2 mg/dL or 35% from a baseline mean of 245 mg/dL in the Qnexa group as compared to a reduction of 42.2 mg/dL or 17% from a baseline mean of 242.4 mg/dL in the placebo group ($p=0.006$).

In January 2008, we announced that we had initiated a six-month extension study for patients previously enrolled in the OB-202 diabetes study. The extension study, DM-230, will allow subjects to continue, in a blinded fashion as randomized, in the study for an additional 28 weeks. The DM-230 study will measure the OB-202 endpoints after an additional 28 weeks, for a total time on treatment of one year.

The primary endpoint of the diabetes studies is improvement of glycemic control as measured by a reduction of glycosylated hemoglobin (HbA1c) levels. The studies also measure the effects of Qnexa on associated metabolic and cardiovascular risk factors as well as changes in total body weight, percent of baseline body weight lost, and a change in waist circumference. OB-202 with the extension is intended to assess both safety and efficacy of Qnexa in subjects with type 2 diabetes controlled with diet or oral medications. Subjects have baseline BMIs between 27 to 42 kg/m2. Patients on antidepressants such as SSRI's or SNRI's have been allowed to participate in the studies.

Our first patent covering Qnexa was issued on June 6, 2006. In addition, Qnexa is the subject of multiple U.S. and international patent applications.

**Male Sexual Health**

Erectile dysfunction, or ED, or the inability to attain or maintain an erection sufficient for intercourse, was reported by 35% of men between the ages of 40 to 70 in the United States, according to an independent study, with the incidence increasing with age. ED, frequently associated with vascular problems, is particularly common in men with diabetes and in those who have had a radical prostatectomy for prostate cancer. PDE5 inhibitors such as sildenafil citrate (Viagra®), vardenafil (Levitra®) and tadalafil (Cialis®), which inhibit the breakdown of cyclic guanosine monophosphate, have been shown to be effective treatments for ED.

The worldwide sales in 2007 of PDE5 inhibitor products for ED were in excess of $3.5 billion, including approximately $1.8 billion in sales of Viagra, approximately $1.2 billion in sales of Cialis and approximately $495 million in sales of Levitra. Based on the aging baby boomer population and the desire to maintain an active sexual lifestyle, we believe the market for PDE5 inhibitors will continue to grow.

**Avanafil**

*Our Clinical Candidate*

Avanafil is our orally administered, PDE5 inhibitor investigational product candidate, which we licensed from Tanabe Seiyaku Co., Ltd., or Tanabe, in 2001. We have exclusive worldwide development and commercialization rights for avanafil with the exception of certain Asian markets.



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Pre-clinical and clinical data suggest that avanafil:

- is highly selective to PDE5, which we believe may result in a favorable side effect profile;
- has a shorter plasma half-life than the current commercially available PDE5 inhibitors; and
- is fast-acting.

Avanafil possesses a shorter plasma half-life than other PDE5 inhibitors currently on the market. The plasma half-life of a drug is the amount of time required for 50% of the drug to be removed from the bloodstream. We believe avanafil's short half-life and fast onset of action are ideal characteristics for the treatment of ED.

*Clinical Status*

We have conducted a number of clinical trials with avanafil, including pharmacokinetic and in-clinic studies as well as at-home efficacy trials in men with ED.

We previously announced positive results from a Phase 2, multi-center, double-blind, randomized, parallel-design study conducted to assess the safety and efficacy of different doses of avanafil for the treatment of ED. Patients in this study were instructed to attempt sexual intercourse 30 minutes after taking avanafil, with no restrictions on food or alcohol consumption. Results showed that up to 84% of avanafil doses resulted in erections sufficient for vaginal penetration, as compared to those who received a dosage of placebo. No serious adverse events were reported during this study.

We previously released the results from an open-label, pharmacokinetic study designed to evaluate the feasibility of allowing avanafil to be taken twice in a 24-hour period. This study compared blood levels of avanafil in healthy volunteer subjects after taking a single dose of avanafil and after taking avanafil every 12 hours for seven days. The results showed no significant plasma accumulation of avanafil after the twice-a-day treatment regimen when compared to the single dose.

We also previously announced the results of a clinical pharmacology study conducted to evaluate the hemodynamic responses (blood pressure and heart rate) to glyceryl trinitrate in subjects pretreated with placebo, avanafil, and sildenafil citrate (Viagra). Results revealed that avanafil had less impact on blood pressure and heart rate than Viagra. The clinical significance of this data is unknown.

An End-of-Phase 2 meeting with the FDA for avanafil took place in November 2005. We discussed the Phase 2 results and the proposed protocol for the Phase 3 trials. Based on feedback from the FDA at this meeting, we anticipate completing several non-clinical studies prior to the initiation of the Phase 3 trials. The Phase 3 protocol and the SPA process for avanafil have been completed.

**Female Sexual Health**

We believe that the market for the treatment of sexual disorders in women is large and underserved. A paper published in the *Journal of the American Medical Association* in 1999 noted 43% of women between the ages of 18 and 59 identified themselves as afflicted with a sexual disorder, reporting hypoactive sexual desire disorder as one of the most common conditions of female sexual dysfunction, or FSD. Currently, there are no pharmaceutical treatments on the market that have been approved by the FDA for the treatment of this sexual disorder in women.

**Testosterone MDTS**

*Hypoactive Sexual Desire Disorder*

Hypoactive Sexual Desire Disorder, or HSDD, the persistent or recurrent lack of interest in sexual activity resulting in personal distress, is reported to be the most common type of female sexual dysfunction, affecting as many as 30% of women in the United States. Several studies over the last several decades have demonstrated that testosterone is an important component of female sexual desire. As a woman ages, there is a decline in testosterone production. The administration of testosterone has been associated with an increase in sexual desire in both pre- and post-menopausal women. In addition to the gradual decline in testosterone that accompanies aging and natural menopause, the surgical removal of a woman's ovaries rapidly results in a decrease of approximately one half of the woman's testosterone production capability. Hence, HSDD can occur much faster, and at a younger age, in women who have undergone this type of surgically induced menopause. Furthermore, HSDD has been observed in pre-menopausal women with naturally occurring low levels of testosterone.



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There are no FDA-approved medical treatments for HSDD; however, OB/GYNs have been prescribing Androgel®, an approved testosterone treatment for hypogonadism in males. In addition, Intrinsa™, a transdermal testosterone patch, is currently approved and available for sale in Europe.

Double-blind, multi-center, placebo-controlled clinical trials conducted by The Procter & Gamble Company to assess the effects of Intrinsa (a twice-weekly testosterone patch) demonstrated a statistically significant increase in the number of satisfying sexual events in surgically induced menopausal women. In addition, an independent clinical study, conducted by Acrux in 261 patients, demonstrated that testosterone transdermally applied with a spray has the ability to increase the number of sexually satisfying events in pre-menopausal women with HSDD.

*Our Clinical Candidate*

Luramist™ (Testosterone MDTS) is our patent protected, transdermal investigational product candidate being developed for the treatment of HSDD in women. The active ingredient in Luramist is the synthetic version of the testosterone that is present naturally in humans.

Luramist utilizes a proprietary, metered-dose transdermal spray, or MDTS, applicator that delivers a precise amount of testosterone to the skin. We licensed the U.S. rights for this product from Acrux in 2004. The metered spray enables patients to apply a precise dose of testosterone for transdermal delivery. The applied dose dries in approximately 60 seconds and becomes invisible. Acrux's independent studies have demonstrated that the Luramist system delivers sustained levels of testosterone in women over a 24-hour period and achieves an increasing number of satisfying sexual events.

We believe that our Luramist product candidate has significant advantages over patches and other transdermal gels that are being developed for this indication. The Luramist spray allows for discreet application, unlike patches that are visible and topical gels that can be messy. We believe that the patented MDTS delivery technology should prevent others from commercializing competitive therapies utilizing a spray delivery technology.

*Clinical Status*

Previously, we announced positive Phase 2 results for Luramist which showed a statistically significant improvement in the number of satisfying sexual events in pre-menopausal patients with HSDD. We met with the FDA to share results from our Phase 2 clinical study and to discuss the Phase 3 study requirements. We submitted a Phase 3 safety and efficacy protocol under the SPA process and met with the FDA in March 2007 to resolve the issues they raised regarding the details of the protocol. In April 2008, we successfully completed and reached agreement with the FDA regarding the SPA for the Phase 3 efficacy trials for Luramist. In addition, we reached agreement with the FDA on the safety requirements necessary for approval.

Under the SPA, we have agreed with the FDA to design features for the pivotal Phase 3 efficacy studies including the primary endpoints, the scope and size of the patient population to be studied, inclusion/exclusion criteria, duration of the trials and elements of the statistical analysis plan. The pivotal Phase 3 program will include two double-blind, placebo-controlled trials that will enroll menopausal women for six months of treatment. The primary endpoints in the clinical trials are an increase in sexual desire and the number of satisfying sexual events, with a secondary endpoint of a decrease in sexual distress.

In addition to the two pivotal Phase 3 efficacy trials, we have reached agreement with the FDA on the safety study. The safety study will be a randomized, double-blind, placebo-controlled, multi-center, cardiovascular event-based outcomes study. Subjects will be required to have an average exposure of 12 months. The study will enroll approximately 5,200 postmenopausal women, aged 50 years or older, who have at least one cardiovascular risk factor. As an event-driven study, analysis of outcomes may occur when there is an average exposure of 12 months and a sufficient number of cardiovascular events have occurred. Subjects enrolled in the safety study will remain in the study for up to five years to allow longer term assessments of cardiovascular and breast cancer risks. These longer term assessments out to five years are not required for NDA submission.

With the successful completion of the two pivotal Phase 3 efficacy studies along with achieving the primary endpoint of the safety study, we currently anticipate submitting an NDA seeking approval of Luramist within two years from initiation of the safety study.



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**Our Marketed Product**

**MUSE**

In 1997, we commercially launched MUSE in the United States. MUSE was the first minimally invasive therapy for erectile dysfunction approved by the FDA. With MUSE, an erection is typically produced within 15 minutes of administration and lasts approximately 30 to 60 minutes. Alprostadil is the active pharmacologic agent used in MUSE. Alprostadil is the generic name for the synthetic version of prostaglandin E1, a naturally-occurring vasodilator present in the human body and at high levels in seminal fluid.

Because therapeutic levels of drug are delivered locally to the erectile tissues with minimal systemic drug exposure, MUSE is a relatively safe, local treatment that minimizes the chances of systemic interactions with other drugs or diseases. Over 13 million units of MUSE have been sold since we introduced MUSE to the market.

In May 2005, results were reported from an independent study conducted by the Cleveland Clinic, which focused on an individual's ability to restore sexual function following radical prostatectomy, a common treatment for prostate cancer. The study showed that 74% of patients who completed six months of MUSE treatment were able to resume sexual activity and 39% were able to achieve natural erections sufficient for intercourse.

**Other Programs**

We have licensed and intend to continue to license from third parties the rights to other products to treat various diseases and medical conditions. We also sponsor early stage clinical trials at various research institutions and intend to conduct early stage proof of concept studies on our own. We expect to continue to use our expertise in designing clinical trials, formulation and product development to commercialize pharmaceuticals for unmet medical needs or for disease states that are underserved by currently approved products. We intend to develop products with a proprietary position or that complement our other products currently under development.

**Sale of Evamist to K-V Pharmaceutical Company**

On March 30, 2007, we entered into a definitive agreement with K-V, to transfer our assets and grant a sublicense of our rights under the Evamist Agreement to K-V, or the Transaction. The closing of the Transaction occurred on May 15, 2007. Under the terms of the Transaction, we received an upfront payment of $10 million upon the closing. On July 27, 2007, we received FDA approval of the NDA for Evamist. On August 1, 2007, we transferred and assigned the Evamist FDA submissions, and all files related thereto to K-V and on August 8, 2007, K-V paid us the additional $140 million milestone payment due upon FDA approval of the Evamist NDA. In August 2008, the Company assigned all of its rights and obligations under the Evamist license agreement to K-V. We may also receive certain one-time payments of up to $30 million based on achieving certain annual net sales thresholds for Evamist. In connection with the Transaction, in order to obtain Tanabe's blanket release of liens against our assets including the Evamist assets and intellectual property, we repaid the Tanabe line of credit.

In May 2006, we announced positive results from the pivotal Phase 3 clinical trial of Evamist. The study showed a statistically significant reduction in the number and severity of moderate and severe hot flashes. We submitted the NDA for Evamist to the FDA in the third quarter of 2006 and made a $1 million clinical development milestone payment to Acrux in October 2006 under the terms of our licensing agreement, related to this submission. Upon approval of the NDA for Evamist, a $3 million product approval milestone became due and was paid to Acrux in August 2007. Under the terms of the Transaction, K-V paid $1.5 million of this $3 million milestone.

**Deerfield Financing**

On April 3, 2008, we entered into several agreements with Deerfield Management Company, L.P., or Deerfield, a healthcare investment fund, and its affiliates, Deerfield Private Design Fund L.P. and Deerfield Private Design International, L.P. (collectively, the Deerfield Affiliates). Under the agreements, Deerfield and its affiliates agreed to provide us with $30 million in funding. The $30 million in funding consists of $20 million from the FARA entered into with a newly incorporated subsidiary of Deerfield, or the Deerfield Sub, and $10 million from the sale of our common stock. Under the FARA, the Deerfield Affiliates made $3.3 million payments to us in April and August 2008 and will make four quarterly payments of approximately $3.3 million, thereafter. Such payments are referred to as the Funding Payments. We will pay royalties on the current net sales of MUSE and if approved, future sales of avanafil, an investigational product candidate to Deerfield Sub. The term of the FARA is 10 years. The FARA includes covenants requiring us to use commercially reasonable efforts to preserve our intellectual property, manufacture, promote and sell MUSE, and develop avanafil. At the closing on April 15, 2008, under the securities purchase agreement, the



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Deerfield Affiliates purchased 1,626,017 shares of our common stock for an aggregate purchase price of $10 million and we paid to the Deerfield Affiliates a $500,000 fee and reimbursed approximately $200,000 in certain expenses incurred in this transaction. The number of shares was determined based on the volume weighted average price on the Nasdaq Global Market of the Company's common stock on the three days prior to the execution of the securities purchase agreement dated as of April 3, 2008. The agreements also provided us with an option to purchase, and the Deerfield Affiliates with an option to compel us to purchase, the Deerfield Sub holding the royalty rights. If either party exercises its option, any further royalty payments would be effectively terminated. Collectively, these transactions are referred to as the Deerfield Transactions.

Also in connection with the Deerfield Transactions, VIVUS, the Deerfield Affiliates and Deerfield Sub entered into the Option and Put Agreement, dated April 3, 2008, or the OPA. Pursuant to the OPA, the Deerfield Affiliates have granted us an option to purchase all of the outstanding shares of common stock of Deerfield Sub from the Deerfield Affiliates, referred to as the Option, and we have agreed to grant the Deerfield Affiliates an option to require us to purchase all of the outstanding shares of common stock of Deerfield Sub from the Deerfield Affiliates, referred to as the Put Right.

If we exercise the Option, base consideration for the Option exercise, or Base Option Price, will be:

- $25 million, if the Option is exercised on or prior to the third anniversary of the execution of the OPA; or
- $28 million, if the Option is exercised subsequent to the third anniversary but prior to the fourth anniversary of the execution of the OPA.

The aggregate consideration payable by VIVUS upon exercise of the Option, or the Option Purchase Price, would be equal to the sum of the Base Option Price, plus: (i) the cash and cash equivalents held by Deerfield Sub at the date of the closing of the resulting sale of the common stock of Deerfield Sub; (ii) accrued and unpaid royalties; and minus (i) the option premium of $2 million which was paid at the closing of the transaction (referred to as the Option Premium); (ii) accrued but unpaid taxes; (iii) unpaid Funding Payments; and (iv) any other outstanding liabilities of Deerfield Sub. The Option terminates on the fourth anniversary of the execution of the OPA.

In consideration of the grant of the Option, at closing we paid $2 million to the Deerfield Affiliates. As indicated in the calculation of the Option Purchase Price, if the Option is exercised by us the Option Premium will be applied to reduce the Option Purchase Price.

The Put Right terminates on the tenth anniversary of the execution of the OPA and will become exercisable on the earliest of:

- the third anniversary of the execution of the OPA;
- any date on which:
  - (1) the market capitalization of the Company falls below $50 million; or
  - (2) the amount of cash and cash equivalents as defined, held by the Company falls below $15 million; or
  - (3) the fifteenth day following the delivery of written notice to the Company that we have failed to make Royalty Payments in accordance with the provisions of the FARA unless we make such Royalty Payments prior to such fifteenth day; or
  - (4) a Major Transaction, as defined below, closes.

If the Deerfield Affiliates exercise the Put Right, base consideration for the put exercise, or the Base Put Price, will be:

- $23 million, if the Put Right is exercised on or prior to the third anniversary of the execution of the OPA and we have notified the Deerfield Affiliates of our intent to enter into a Major Transaction (such notice is referred to as a Major Transaction Notice); or

- $26 million, if the Put Right is exercised subsequent to the third anniversary of the execution of the OPA and we have provided the Deerfield Affiliates a Major Transaction Notice; or

- $17 million, in all other cases.



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The aggregate consideration payable by the Company upon exercise of the Put Right, or the Put Purchase Price, would be equal to the sum of the Base Put Price, plus: (i) the cash and cash equivalents held by Deerfield Sub at the date of the closing of the resulting sale of the common stock of Deerfield Sub; (ii) accrued and unpaid royalties; and minus (i) accrued but unpaid taxes; (ii) unpaid Funding Payments; and (iii) any other outstanding liabilities of Deerfield Sub.

Pursuant to the OPA, the following events would qualify as Major Transactions:

- a consolidation, merger, exchange of shares, recapitalization, reorganization, business combination or similar event:

  (1) following which the holders of the Company's common stock immediately preceding such event either:

    (a) no longer hold a majority of the shares of the Company's common stock; or

    (b) no longer have the ability to elect a majority of the the Company's Board of Directors;

  (2) as a result of which shares of the Company's common stock are changed into (or the shares of common stock become entitled to receive) the same or a different number of shares of the same or another class or classes of stock or securities of the Company or another entity, collectively referred to as Change in Control Transactions;

  - a sale or transfer of the Company's assets in one transaction or a series of related transactions for a purchase price of more than $350 million where the consideration to be payable at or within 30 days of closing of such transaction or transactions has a value of more than $350 million, or a sale, transfer or license of all or substantially all the Company's assets or proprietary rights that relate specifically to MUSE or avanafil; or

  - a purchase, tender or exchange offer made to the holders of outstanding shares of the Company's common stock, such that following such purchase, tender or exchange offer a Change in Control Transaction shall have occurred; or

  - an issuance or series of issuances in a series of related transactions by the Company of an aggregate number of shares of common stock in excess of 20% of the Company's outstanding common stock on the date hereof if, immediately prior to such issuance, the market capitalization of the Company is less than $300 million.

In connection with the FARA, Deerfield Sub and the Company have entered into a Royalty Security Agreement, whereby we have granted Deerfield Sub a security interest in certain collateral related to MUSE and avanafil including: all of our drug applications; all existing and future licenses relating to the development, manufacture, warehousing, distribution, promotion, sale, importing or pricing of MUSE and avanafil; our intellectual property and all of the accounts, inventory and equipment arising out of or relating to Muse and avanafil. In connection with the OPA, the Deerfield Affiliates and the Company have entered into a security agreement, whereby we have granted the Deerfield Affiliates a security interest in the same Collateral as defined by the Royalty Security Agreement. The security interest granted to the Deerfield Affiliates has priority to that granted to Deerfield Sub by the Royalty Security Agreement.

**CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

The discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to product returns, rebates and sales reserves, research and development expenses, doubtful accounts, income taxes, inventories, contingencies and litigation and stock-based compensation. We base our estimates on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.



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We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our condensed consolidated financial statements:

*Revenue Recognition*

*Product Revenue:* Product sales are recognized as revenues when persuasive evidence of an arrangement exists, shipment has occurred, the sales price is fixed or determinable and collectibility is reasonably assured.

*Sales Allowances and Reserves:* Revenues from product sales are recorded net of product sales allowances for expected returns of expired product, government chargebacks and other rebate programs, and cash discounts for prompt payment. These sales allowances are deducted from gross product revenues at the time such revenues are recognized along with the recording of a corresponding reserve, or liability. In making these estimates we take into consideration our historical information, current contractual and statutory requirements, shelf life of our products, estimated customer inventory levels and information received from outside parties. Significant judgments and estimates must be made and used in estimating the reserve balances in any accounting period. Our product sales allowances and reserves include:

- Product Returns: We have estimated reserves for product returns from wholesalers, hospitals and pharmacies in the United States in accordance with our product returns policy. Our returns policy allows product returns within the period beginning six months prior to and twelve months following product expiration. We sell one pharmaceutical product, MUSE, which is sold in four dosages. Three of these dosages have a 24-month shelf-life. The fourth, which has a small sales volume, has an 18-month shelf-life. As of September 30, 2008, the shipments of MUSE in the United States made in 2008, 2007, and a portion of the shipments in 2006 remain subject to future returns.

  We record reserves for anticipated returns of expired product in the United States. We follow this method since reasonably dependable estimates of product returns can be made based on historical experience. There is no right-of-return on expired product sold internationally subsequent to shipment; thus, no returns reserve is needed.

  We estimate our returns reserve by utilizing historical information and returns data obtained from external sources, along with the shelf life of the product. We believe that the information obtained from external sources is reliable, but we are unable to independently verify the accuracy of such data. We track the actual returns on a lot-by-lot basis along with date of production and date of expiration. We review the actual returns experience for trends. We calculate our returns reserve by applying an estimated return rate to the quantity of units sold that is subject to future return. We routinely assess our experience with product returns and adjust the reserves accordingly. Revisions in returns estimates are charged to income in the period in which the information that gives rise to the revision becomes known.

- Chargebacks: Chargebacks include government chargebacks which are contractual commitments by us to provide MUSE to federal government organizations including the Veterans Administration at specified prices and other rebate programs, primarily with Medicaid, Medicare Part D and managed care organizations, for the reimbursement of portions of the prescriptions filled that are covered by these programs. Allowances for chargebacks are recorded at the time of sale to the wholesaler distributors and accrued as a reserve. In estimating the chargeback reserve, we analyze actual government chargeback and rebate amounts paid and apply chargeback rates to estimates of the quantity of units subject to chargeback. We estimate this reserve by utilizing historical information, contractual and statutory requirements, end-customer prescription demand data, estimated quantities sold to these organizations and estimated wholesaler inventory levels based upon data obtained from our larger wholesaler customers. We believe that the information received from the wholesaler customers regarding inventory levels and information received from external sources regarding end-customer prescription demand are reliable, but we are unable to independently verify the accuracy of such data. Effective January 1, 2006, MUSE no longer qualifies for Medicaid reimbursement and effective January 1, 2007, MUSE no longer qualifies for Medicare Part D. We routinely reassess the chargeback estimates and adjust the reserves accordingly.

- Cash Discounts: We offer cash discounts to wholesaler distributors, generally 2% of the sales price as an incentive for prompt payment. The estimate of cash discounts is recorded at the time of sale. We account for the cash discounts by reducing accounts receivable by the full amount of the discounts we expect wholesaler distributors to take.

All of the aforementioned categories of sales allowances are evaluated each reporting period and adjusted when trends or significant events indicate that a change in estimate is appropriate. Changes in actual experience or changes in other qualitative factors could cause our sales allowance adjustments to fluctuate. If actual returns, government chargebacks, rebates and cash



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discounts are greater than our estimates, additional reserves may be required which could have an adverse effect on financial results in the period of adjustment. Revisions to estimates are charged to income in the period in which the facts that give rise to the revision become known.

*License and Other Revenue:* We recognize license revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 104, *Revenue Recognition*. When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force, or EITF, Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, or EITF 00-21. In accordance with EITF 00-21, we recognize revenue for delivered elements only when the delivered element has stand-alone value and we have objective and reliable evidence of fair value for each undelivered element. If the fair value of any undelivered element included in a multiple element arrangement cannot be objectively determined, revenue is deferred until all elements are delivered and services have been performed, or until fair value can objectively be determined for any remaining undelivered elements, or such elements are insignificant. Application of this standard requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

Revenue from non-refundable, upfront license fees where we have continuing involvement is recognized ratably over the development or agreement period. Revenue associated with performance milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements.

On May 15, 2007, we closed our transaction with K-V Pharmaceutical Company, or K-V, for the sale of our product candidate, Evamist, a metered dose transdermal spray for the treatment of menopause symptoms. At the time of the sale, Evamist was an investigational product and was not yet approved by the FDA for marketing. The sale transaction contained multiple deliverables, including: the delivery at closing of the Evamist assets (mainly raw material inventory and certain fixed assets), a grant of a sublicense of our rights under a license related to Evamist, and a license to the MDTS applicator; the delivery upon receipt of regulatory approval of Evamist, along with all regulatory submissions; and, lastly, the delivery after FDA approval of certain transition services and a license to improvements to the MDTS applicator. We received approval from the FDA to market Evamist on July 27, 2007, or FDA Approval, and on August 1, 2007, we transferred and assigned the Evamist FDA submissions, and all files related thereto to K-V. In August 2008, the Company assigned all of its rights and obligations under the Evamist license agreement to K-V.

We received an upfront payment of $10 million in May 2007 upon the closing and received an additional $140 million milestone payment in August 2007 upon FDA Approval. These payments are non-refundable.

We evaluated this multiple deliverable arrangement under EITF 00-21 to determine whether the deliverables are divided into separate units of accounting.

Upon FDA Approval, the two remaining deliverables are the transition services to be performed under the Transition Services Agreement, or TSA, and a license to improvements to the MDTS applicator, or Improvement License, during the two-year period commencing with the closing, or May 15, 2007, and ending on May 15, 2009. We are able to establish fair value for the TSA.

As it relates to the Improvement License, no specific value was assigned in the agreement. We have no obligation to develop improvements to the MDTS applicator and have no plans to expend significant resources in this endeavor. However, as required under EITF 00-21, we do not have objective, reliable evidence of fair value or evidence of inconsequential value to the customer of the Improvement License. Accordingly, the delivered items, together with the undelivered items, are bundled together and are treated as one unit of accounting.

As a result, the initial $10 million paid at closing and the $140 million paid upon FDA Approval have been recorded as deferred revenue and will be recognized as license revenue, together with the future billings under the TSA, if any, ratably over the remaining 21.5-month term of the Improvement License, from August 1, 2007 to May 15, 2009. The revenue related to the transaction recognized in the year ended December 31, 2007 was $34.9 million and for the nine months ended September 30, 2008 was $62.8 million. Such revenue in future quarters is expected to be recognized as follows (in thousands):

| Quarter ending | License revenue |
|---|---|
| December 31, 2008 | $ 20,930 |
| March 31, 2009 | $ 20,930 |
| June 30, 2009 | $ 10,465 |

We may also receive milestone payments of up to $30 million based upon sales of Evamist through the term of the agreements. Revenues associated with these performance milestones will be recognized when they are earned and collectability is reasonably assured.



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*Research and Development Expenses*

Research and development, or R&D, expenses include license fees, related compensation, consultants fees, facilities costs, administrative expenses related to R&D activities and clinical trial costs at other companies and research institutions under agreements which are generally cancelable, among other related R&D costs. We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by clinical research organizations, or CROs, and clinical sites. These costs are recorded as a component of R&D expenses. Under our agreements, progress payments are typically made to investigators, clinical sites and CROs. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

*Accounts Receivable and Allowance for Doubtful Accounts*

We extend credit to our customers for product sales resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. The accounts receivable are reported on the balance sheet, net of the allowance for doubtful accounts.

*Income Taxes*

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes.

As part of the process of preparing our condensed consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included in our condensed consolidated balance sheets.

We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that we will recover our deferred tax assets, we will increase our provision for taxes by recording a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable. As a result of our analysis of all available evidence, both positive and negative, as of September 30, 2008, it was not considered more likely than not that our deferred tax assets would be realized.

As of September 30, 2008, we believed that the amount of the deferred tax assets recorded on our condensed consolidated balance sheet would not ultimately be recovered. However, should there be a change in our ability to recover our deferred tax assets; we would recognize a benefit to our tax provision in the period in which we determine that it is more likely than not that we will recover our deferred tax assets.

In July 2006, the Financial Accounting Standards Board, or FASB issued FASB Interpretation No. 48, or FIN No. 48, *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109,* to clarify certain aspects of accounting for uncertain tax positions, including issues related to the recognition and measurement of those tax positions. FIN No. 48 prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN No. 48 also provides guidance on derecognizing, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. This interpretation is effective for fiscal years beginning after December 15, 2006. The cumulative effect of adopting FIN No. 48 on January 1, 2007 was recognized as a change in accounting principle,

recorded as an adjustment to the opening balance of accumulated deficit on the adoption date. As a result of the implementation of FIN No. 48, we recognized a decrease of approximately $1.2 million in our income tax liability, which resulted in a decrease of $1.2 million in accumulated deficit on January 1, 2007.



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*Inventories*

We record inventory reserves for estimated obsolescence, unmarketable or excess inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. During the quarter ended September 30, 1998, we established significant reserves against our inventory to align with the then new estimates of expected future demand for MUSE. In 2007, we disposed of $2.8 million of fully reserved alprostadil. The disposal had no impact on cost of goods sold. As of September 30, 2008, the remaining inventory reserve balance is $1.6 million relating to raw materials and components. In the first quarter of 2005, we determined that we likely would continue to use some portion of the fully reserved component parts inventory in production. When we record inventory reserves, we establish a new, lower cost basis for the inventory for accounting purposes. Accordingly, to the extent that this fully reserved inventory was used in production in the first nine months of 2008 and 2007, it was charged to cost of goods sold at a zero basis, which had a favorable impact on cost of goods sold.

*Cash and Cash Equivalents*

The Company considers highly liquid investments with maturities from the date of purchase of three months or less to be cash equivalents. All cash equivalents are in money market funds, U.S. Treasury securities and debt securities of U.S. government agencies, certificates of deposit, corporate bonds and commercial paper. These amounts are recorded at cost, which approximates fair value.

Cash with restrictions for a period of greater than 12 months is classified as restricted cash, a non-current asset.

*Available-for-Sale Securities*

We focus on liquidity and capital preservation in our investments in available-for-sale securities. Through February 28, 2008, we restricted our investments to:

- Direct obligations of the United States Treasury;
- Federal agency securities which carry the direct or implied guarantee of the United States government; and
- Corporate and asset-backed securities, including commercial paper, rated A1/P1/F1 or better.

The weighted average maturity of our portfolio was not to exceed 18 months.

On February 29, 2008, the Audit Committee of the Board of Directors approved a change to the investment policy to be more restrictive in the focus on liquidity and capital preservation in our investments in available-for-sale securities. Future cash investments are restricted to:

- Direct obligations of the United States Treasury;
- Federal agency securities which carry the direct or implied guarantee of the United States government; and
- Corporate debt obligations rated AA3/AA- or A-1+/P-1 or better or asset-backed commercial paper rated A-1+/P-1 or better.

The weighted average maturity of our portfolio for new investments is not to exceed nine months.

We invest our excess cash balances in money market and marketable securities, primarily U.S. Treasury securities and debt securities of U.S. government agencies, corporate debt securities and asset-backed securities in accordance with our investment policy. The investment policy has the primary investment objectives of preservation of principal while at the same time maximizing yields without significantly increasing risk; however, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. If those securities are downgraded or impaired we would experience losses in the value of our portfolio which would have an adverse effect on our results of operations, liquidity and financial condition. Certain of these securities are subject to general credit, liquidity, market and interest rate risks, which may be exacerbated by U.S. sub-prime mortgage defaults that have affected various sectors of the financial markets and caused credit and liquidity issues.



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We determine the appropriate classification of marketable securities at the time of purchase and reevaluate such designation at each balance sheet date. Our marketable securities have been classified and accounted for as available-for-sale. These securities are carried at fair value, based on market prices obtained from a number of pricing methods used to derive the fair value of the securities on a recurring basis, which include the use of independent pricing services, brokers quotes and discussions with portfolio managers. We hold certain securities with stated maturities greater than 12 months until maturity. In response to changes in the availability of and the yield on alternative investments as well as liquidity requirements, we will occasionally sell these securities prior to their stated maturities. As these securities are viewed by us as available to support current operations, based on the provisions of Accounting Research Bulletin No. 43, Chapter 3A, *Working Capital—Current Assets and Liabilities*, securities with maturities beyond 12 months are classified as current assets, except for certain securities that we expect to recover their full or substantial values beyond the next 12 months due to the current lack of a readily available market, and the continued uncertainty in the capital markets. Consequently, we have classified those available-for-sale securities as non-current in our condensed consolidated balance sheets.

Our policy is to record investments in marketable securities as available-for-sale because the sale of such securities may be required prior to maturity. Any gains and losses on the sale of marketable securities are determined on a specific identification basis and are included in other-than-temporary loss on impaired securities in the accompanying condensed consolidated statements of operations and other comprehensive income (loss).

The difference between amortized cost (cost adjusted for amortization of premiums and accretion of discounts which are recognized as adjustments to interest income) and fair value, representing unrealized holding gains or losses, are recorded in accumulated other comprehensive income (loss), a separate component of stockholders' equity until realized. We recognize all realized gains and losses on our available-for-sale securities in income before provision for income taxes.

From 2005 and until December 2007 we had an investment in Columbia Strategic Cash Portfolio, or Strategic Cash, offered by our investment advisor, Columbia Management LLC, or Columbia. Strategic Cash is an enhanced money market fund in which the fund sought to maintain a $1 per share net asset value. We used Strategic Cash for the investment of excess cash, and periodic transfers were made from Strategic Cash to the operating cash account to fund our current operations.

In early December 2007, we were notified by Columbia that the Strategic Cash fund was closed and that the fund was to be liquidated. The fund no longer supported the $1 per share net asset value and switched to a market value fund in which all investments were marked to market. We were given the option of staying in the fund and receiving cash proceeds from the fund as its holdings were liquidated or receiving a pro-rata share of the investments held by the fund. Upon advice from our investment advisor, we took redemption-in-kind consisting of cash, interest receivable and a pro-rata distribution of the underlying securities, consisting principally of high quality corporate debt and asset-backed securities. Prior to the redemption our investment in Strategic Cash was $84.4 million. On December 20, 2007 and December 21, 2007, we received our redemption-in-kind consisting of securities with a market value of $68.7 million, interest receivable of $300,000 and cash of $14.4 million. The difference between our investment in Strategic Cash of $84.4 million and the fair value of the securities, cash and interest receivable totaling $83.4 million received in-kind resulted in a loss of $1 million. This loss of $1 million was reflected in interest income in the consolidated statement of operations and other comprehensive income (loss) for the year ended December 31, 2007.

The securities distributed to us from Strategic Cash included corporate bonds, commercial paper, asset-backed securities and other securities. Certain of the securities transferred to us from Strategic Cash, totaling $3.9 million in fair value at transfer, did not comply with our investment policy in effect at that time due to either credit ratings, length of maturities or sectors not allowed under the policy. These securities were approved by the Audit Committee of the Board of Directors for acceptance into our portfolio. The securities received on redemption will be subject to changes in value depending on market conditions.

We monitor our investment portfolio for impairment on a quarterly basis. In the event that the carrying value of an investment exceeds its fair value and the decline in value is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis for the investment is established. In order to determine whether a decline in value is other-than-temporary, we evaluate, among other factors: the duration and extent to which the fair value has been less than the carrying value; our financial condition and business outlook, including key operational and cash flow metrics, current market conditions and future trends in our industry; our relative competitive position within the industry; and our intent and ability to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value.

*Contingencies and Litigation*

We are periodically involved in disputes and litigation related to a variety of matters. When it is probable that we will experience a loss, and that loss is quantifiable, we record appropriate reserves.



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*Share-Based Payments*

We follow the fair value method of accounting for share-based compensation arrangements in accordance with the Financial Accounting Standards Board Statement of Financial Accounting Standards, or SFAS, 123R, *Share-Based Payment*, or SFAS 123R. We adopted SFAS 123R effective January 1, 2006 using the modified prospective method of transition. Under SFAS 123R, the estimated fair value of share-based-compensation, including stock options and restricted stock units granted under our Stock Option Plan and purchases of common stock by employees at a discount to market price under the Employee Stock Purchase Plan, or the ESPP, is recognized as compensation expense. Compensation expense for purchases under the ESPP is recognized based on the estimated fair value of the common stock purchase rights during each offering period and the percentage of the purchase discount.

We recorded $1 million and $3.7 million of share-based compensation expense for the quarter and nine months ended September 30, 2008, respectively, and $910,000 and $2.8 million of share-based compensation expense for the quarter and nine months ended September 30, 2007, respectively. Share-based compensation expense is allocated among cost of goods sold and manufacturing, research and development and selling, general and administrative expenses based on the function of the related employee. This charge had no impact on our cash flows for the periods presented.

We use the Black-Scholes option pricing model to estimate the fair value of the share-based awards as of the grant date. The Black-Scholes model, by its design, is highly complex, and dependent upon key data inputs estimated by management. The primary data inputs with the greatest degree of judgment are the estimated lives of the share-based awards and the estimated volatility of our stock price. The Black-Scholes model is highly sensitive to changes in these two data inputs. The expected term of the options represents the period of time that options granted are expected to be outstanding and is derived by analyzing the historical experience of similar awards, giving consideration to the contractual terms of the stock-based awards, vesting schedules and expectations of future employee behavior. We determine expected volatility using the historical method, which is based on the daily historical trading data of our common stock over the expected term of the option. Management selected the historical method primarily because we have not identified a more reliable or appropriate method to predict future volatility. For more information about SFAS 123R, see Note 3: Share-Based Compensation to the notes to condensed consolidated financial statements included in this Form 10-Q.

*Fair Value Measurements*

On January 1, 2008, we adopted SFAS No. 157 *Fair Value Measurements*. Adoption of the provisions of this standard did not have a material effect on our financial position. For assets that are measured using quoted prices in active markets, total fair value is the published market price per unit multiplied by the number of units held without consideration of transaction costs.

*Financial Instruments Measured at Fair Value*. Our available-for-sale financial instruments are carried at fair value and we make estimates regarding valuation of these assets measured at fair value in preparing the condensed consolidated financial statements.

*Fair Value Measurement—Definition and Hierarchy.* SFAS No. 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date.

*Valuation Technique.* SFAS No. 157 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of VIVUS. Unobservable inputs are inputs that reflect our assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. SFAS No. 157 prescribes three valuation techniques that shall be used to measure fair value as follows:

1. Market Approach—uses prices or other relevant information generated by market transactions involving identical or comparable assets or liabilities.

2. Income Approach—uses valuation techniques to convert future amounts to a single present amount (discounted).

3. Cost Approach—the amount that currently would be required to replace the service capacity of an asset (i.e., current replacement cost).



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One or a combination of the approaches above can be used to calculate fair value, whichever results in the most representative fair value.

In addition to the three valuation techniques, SFAS No. 157 prescribes a fair value hierarchy in order to increase consistency and comparability in fair value measurements and related disclosures. The hierarchy is broken down into three levels based on the reliability of inputs as follows:

- Level 1—Valuations based on quoted prices in active markets for identical assets. Valuation adjustments and block discounts are not applied to Level 1 instruments. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment.

Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded equity securities that are actively traded.

- Level 2—Valuations based on quoted prices in markets that are not active or for which all significant inputs are observable, directly or indirectly. Quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models are primarily industry-standard models that consider various assumptions, including time value, yield curve, volatility factors, prepayment speeds, default rates, loss severity, current market and contractual prices for the underlying financial instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

- Level 3—Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

Level 3 is comprised of unobservable inputs that are supported by little or no market activity. Financial assets are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable. Level 3 financial assets include securities for which there is limited market activity such that the determination of fair value requires significant judgment or estimation. At September 30, 2008, these securities were valued primarily using broker and portfolio manager pricing models that incorporate transaction details such as contractual terms, maturity, timing and amount of future cash inflows, as well as assumptions about liquidity.

The availability of observable inputs can vary from product to product and is affected by a wide variety of factors, including, for example, the type of product, whether the product is new and not yet established in the marketplace, and other characteristics particular to the transaction. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for disclosure purposes the level in the fair value hierarchy within which the fair value measurement in its entirety falls is determined based on the lowest level input that is significant to the fair value measurement in its entirety. Investment securities priced using non-binding broker quotes are included in Level 3.

Fair value is a market-based measure considered from the perspective of a market participant who holds the asset or owes the liability rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, our own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date. We use prices and inputs that are current as of the measurement date, including during periods of market dislocation. In periods of market dislocation, the observability of prices and inputs may be reduced for many instruments. This condition could cause an instrument to be reclassified from Level 1 to Level 2 or Level 2 to Level 3.

*Deerfield Financing*

On April 3, 2008, we entered into several agreements with Deerfield Management Company, L.P., or Deerfield, a healthcare investment fund, and its affiliates, Deerfield Private Design Fund L.P. and Deerfield Private Design International, L.P. (collectively, the Deerfield Affiliates). Please refer to Note 7: Deerfield Financing and Note 8: Notes Payable to the notes to

condensed consolidated financial statements included in this Form 10-Q for additional information on these agreements. Under the agreements, Deerfield and its affiliates agreed to provide $30 million in funding to the Company. The $30 million in funding consists of $20 million from the FARA, and $10 million from the sale of the Company's common stock. Under the FARA, the Deerfield Affiliates made $3.3 million payments to us in April and August 2008 and will make four quarterly payments of approximately $3.3 million, thereafter. We have agreed to pay royalties on the current net sales of MUSE and once approved, future sales of avanafil, an investigational product candidate, to the Deerfield Sub. The agreements also provide us with an option to purchase, and the Deerfield Affiliates with an option to compel us to purchase, the Deerfield Sub holding the royalty rights. If either party exercises its option, any further royalty payments would be effectively terminated. In exchange for the option right, we paid $2 million to the Deerfield Affiliates.

We have evaluated the Deerfield financing in accordance with FASB Financial Interpretation No., or FIN, 46(R), *Consolidation of Variable Interest Entities*, or FIN 46R, and determined that the Deerfield Sub may constitute a Variable Interest Entity, or VIE; however, we have also determined that the Company is not the primary beneficiary of this VIE at this time and we therefore have concluded that we are not required to consolidate the Deerfield Sub.

In accordance with Emerging Issues Task Force (EITF) Issue 88-18, *Sale of Future Revenues*, the transaction is in substance a financing arrangement, or loan that will be repaid by us. The minimum repayment amount would be $17 million, the amount of the unconditional put option held by Deerfield Affiliates, plus royalties paid on MUSE sales, and avanafil sales if approved, during the term of the agreement. Accordingly, we will record the advances from the Deerfield Affiliates, net of the $2 million option right payment and related fees and expenses, as a loan. Using the interest method under APB Opinion No. 21, *Interest on Receivables and Payables*, interest on the loan will be recognized over three years, which is the estimated term of the loan based on the earliest date that the Deerfield Affiliates could require us to repay the amounts advanced.

**Recent Accounting Pronouncements**

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162, which defines the category and order of authority of accounting principles that are generally accepted, including rules and interpretations of the Securities and Exchange Commission, or SEC. SFAS No. 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board, or PCAOB, amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles.* Management is currently evaluating the impact of adopting this Statement, but we do not expect the adoption of SFAS 162 to have a material impact on our condensed consolidated financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, or SFAS 141(R). SFAS 141(R) changes several underlying principles in applying the purchase method of accounting. Among the significant changes, SFAS 141(R) requires a redefining of the measurement date of a business combination, expensing direct transaction costs as incurred, capitalizing in-process research and development costs as an intangible asset and recording a liability for contingent consideration at the measurement date with subsequent re-measurements recorded in the results of operations. SFAS 141(R) also requires that costs for business restructuring and exit activities related to the acquired company will be included in the post-combination financial results of operations and also provides new guidance for the recognition and measurement of contingent assets and liabilities in a business combination. In addition, SFAS 141(R) requires several new disclosures, including the reasons for the business combination, the factors that contribute to the recognition of goodwill, the amount of acquisition related third-party expenses incurred, the nature and amount of contingent consideration, and a discussion of pre-existing relationships between the parties. SFAS 141(R) is effective for the Company as of January 1, 2009. Management is currently evaluating the impact of adopting this Statement, but we do not expect it to have a material impact on our condensed consolidated financial position or results of operations.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51*, or SFAS 160. SFAS 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 requires noncontrolling interests in subsidiaries initially to be measured at fair value and classified as a separate component of equity. SFAS 160 also requires a new presentation on the face of the condensed consolidated financial statements to separately report the amounts attributable to controlling and noncontrolling interests. SFAS 160 is effective for the Company as of January 1, 2009. Management is currently evaluating the impact of adopting this Statement, but we do not expect it to have a material impact on our condensed consolidated financial position or results of operations.

In September 2007, the FASB ratified Emerging Issues Task Force Issue No. 07-01, *Accounting for Collaborative Agreements*, or EITF 07-01. EITF 07-01 defines collaborative agreements as contractual arrangements that involve a joint operating activity.





These arrangements involve two (or more) parties who are both active participants in the activity and that are exposed to significant risks and rewards dependent on the commercial success of the activity. EITF 07-01 provides that a company should report the effects of adoption as a change in accounting principle through retrospective application to all periods and requires additional disclosures about a company's collaborative arrangements. EITF 07-01 is effective for the Company as of January 1, 2009. The adoption of EITF 07-01 is not expected to have a material impact on our condensed consolidated financial position or results of operations.

In June 2007, the FASB ratified EITF 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-03, which requires nonrefundable advance payments for future R&D activities to be capitalized and recognized as an expense as the goods are delivered or services are performed. Earlier application is not permitted. EITF 07-03 is effective for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. On January 1, 2008, we adopted this Statement which did not have a material impact on our condensed consolidated financial position or results of operations.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115*, or SFAS 159. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. This statement provides entities the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. This Statement is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. We did not elect to measure any additional assets or liabilities at fair value that are not already measured at fair value under existing standards. Therefore, the adoption of this standard had no impact on our condensed consolidated financial statements.

## RESULTS OF OPERATIONS

### Executive Overview

For the three months ended September 30, 2008, we reported net income of $266,000, or $0.00 net income per share, as compared to $1.3 million, or $0.02 net income per share, during the same period in 2007. The lower net income in the third quarter of 2008 as compared to the third quarter of 2007 is primarily due to an increase in operating expenses and from the loss due to an other-than-temporary decline in the market value of certain investments, partially offset by the recognition of additional K-V deferred license revenue in the third quarter of 2008. The increase in operating expenses was primarily attributable to spending related to our Phase 3 clinical trials of Qnexa for the treatment of obesity. In addition, we recorded a provision for income taxes of $4.4 million as a result of the $150 million received from K-V in the third quarter of 2007.

On April 3, 2008, we entered into several agreements with Deerfield Management Company, L.P., or Deerfield, a healthcare investment fund, and its affiliates. Under the agreements Deerfield and its affiliates agreed to provide $30 million in funding to us. The $30 million in funding consists of $20 million from the FARA, and $10 million from the sale of the Company's common stock at the closing on April 15, 2008 in connection with the registered direct offering mentioned above under a securities purchase agreement. Under the FARA, the Deerfield Affiliates made $3.3 million payments to us in April and August 2008 and will make four quarterly payments of approximately $3.3 million thereafter. The amounts of funding provided under the FARA, net of certain amounts, represent a financial obligation, a loan payable by the Company in which the principal and interest will be repaid through royalty payments and the exercise of the option or put rights.

In connection with the sale of Evamist, we received $150 million. The sale of Evamist was a unique transaction. As discussed in Note 11: Sale of Evamist Product, an initial $10 million was paid at closing and $140 million was paid upon FDA approval of Evamist. These payments are non-refundable and have been recorded as deferred revenue and will be recognized as license and other revenue ratably over a 21.5-month period, from August 1, 2007 to May 15, 2009, which is the remaining term of a license to improvements to the MDTS applicator. As compared to revenues from product sales, license and other revenue will be significant on a quarterly basis until all of the revenue from the sale of Evamist is recognized, currently expected to be May 2009. Since the $150 million has been received and we have no related contingencies, the future recognition of revenue and the corresponding reduction of deferred revenue related to the Evamist sale will have no impact on our cash flows from operations in future periods through May 2009.



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The revenue related to the transaction recognized in the third quarter of 2008 was $20.9 million and the revenue in future quarters is expected to be recognized as follows (in thousands):

| Quarter ending | License revenue |
|---|---|
| December 31, 2008 | $ 20,930 |
| March 31, 2009 | $ 20,930 |
| June 30, 2009 | $ 10,465 |

With the exception of income generated from the revenue recognition of the $150 million received from K-V, we may have continued losses in future years, depending on the timing of our research and development expenditures, because we expect MUSE sales to remain consistent with prior years and we plan to continue to invest in clinical development of our current research and investigational product candidates to bring those potential products to market.

*Revenue. (Unaudited)*

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2008 | 2007 | 2008 vs. 2007 | 2008 | 2007 | 2008 vs. 2007 |
| | (In thousands, except percentages) | | | | | |
| United States product, net | $ 3,774 | $ 4,075 | (7)% | $ 7,785 | $ 7,572 | 3% |
| International product | 657 | 944 | (30)% | 2,511 | 3,003 | (16)% |
| Other revenue | 21,046 | 14,069 | 50% | 63,138 | 14,300 | 342% |
| Total revenues | $ 25,477 | $ 19,088 | 33% | $ 73,434 | $ 24,875 | 195% |

Product revenues for the quarters ended September 30, 2008 and September 30, 2007, were $4.4 million and $5 million, respectively. In the nine months ended September 30, 2008 and September 30, 2007, product revenues totaled $10.3 million and $10.6 million, respectively.

U.S. product revenues decreased slightly in the third quarter of 2008 as compared to the prior year period primarily due to a small decrease in shipments of MUSE and the increase to sales in the third quarter 2007 resulting from an adjustment to our sales allowances of $519,000 and partially offset by a price increase for 2008. The sales adjustment in the third quarter 2007 was the result of updated information received from certain wholesaler customers of the inventory in the distribution channel. The increase in U.S. product revenues in the nine months ended September 30, 2008 as compared to the same period in 2007 is primarily due to a modest increase in shipments and increased prices in the nine months ended September 30, 2008 as compared to the prior year period. The fluctuation in international revenues in the three and nine months ended September 30, 2008 as compared to the same periods in 2007 was due to the timing of orders from our international partners. The change in MUSE domestic shipments in the three and nine months ended September 30, 2008 as compared to the prior year periods is a result of fluctuations in inventory levels at the wholesale level and is not indicative of any trend.

Although the demand for MUSE has stabilized, we are not able to anticipate if wholesalers will continue their historical pattern of making purchases in the fourth quarter that exceed expected quarterly demands. If wholesalers do not repeat this pattern of purchasing quantities of MUSE that exceed quarterly demands, revenues from the sale of MUSE in 2008 may be lower as compared to 2007. We have been notified that one of our larger wholesaler customers will not purchase quantities that exceed expected demand in the fourth quarter 2008 as they have in prior years.

On March 30, 2007, we announced that we had entered into a definitive agreement with K-V, to transfer our assets and grant a sublicense of our rights under the Evamist Agreement to K-V, or the Transaction. In August 2008, the Company assigned all of its rights and obligations under the Evamist license agreement to K-V. The closing of the Transaction occurred on May 15, 2007 and on July 27, 2007, we received FDA approval of the Evamist NDA. An initial

$10 million was paid at closing and $140 million was paid upon FDA approval. These payments have been recorded as deferred revenue and will be recognized as revenue ratably over the remaining 21.5-month term of the Improvement License, from August 1, 2007 to May 15, 2009.

*Cost of goods sold and manufacturing. (Unaudited)*

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2008 | 2007 | 2008 vs. 2007 | 2008 | 2007 | 2008 vs. 2007 |
| | (In thousands, except percentages) | | | | | |
| Cost of goods sold and manufacturing | $ 2,547 | $ 2,736 | (7)% | $ 8,263 | $ 8,498 | (3)% |



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Cost of goods sold and manufacturing, or cost of goods sold, in the third quarter of 2008 decreased $189,000, or 7%, to $2.5 million, as compared to $2.7 million for the third quarter of 2007. Cost of goods sold decreased in the three months ended September 30, 2008 as compared to the same period in 2007 primarily due to decreased shipments, materials and manufacturing costs in the third quarter of 2008 as compared to the third quarter of 2007.

In the nine months ended September 30, 2008 costs of goods sold decreased $235,000, or 3%, to $8.3 million, as compared to $8.5 million in the same period last year. In the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007, the balance of cost of goods sold is lower primarily due to a one-time charge of $559,000 for the sale of Evamist assets in May 2007 partially offset by $444,000 in costs incurred due to the non-conformance of certain raw materials in 2008.

We anticipate cost of goods sold and manufacturing for the year 2008 will be similar to costs incurred in 2007.

*Research and development. (Unaudited)*

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2008 | 2007 | 2008 vs. 2007 | 2008 | 2007 | 2008 vs. 2007 |
| | (In thousands, except percentages) | | | | | |
| Research and development | $ 15,590 | $ 8,644 | 80% | $ 54,296 | $ 15,610 | 248% |

Research and development expenses in the third quarter of 2008 increased $7 million, or 80%, to $15.6 million, as compared to $8.6 million for the third quarter of 2007. In the third quarter of 2008, this included increased spending for Qnexa in obesity of $7.4 million, avanafil of $643,000 and increased spending of $812,000 (primarily due to increases in non-cash stock based compensation expense of $89,000, compensation and related expense of $436,000 due to an increase in headcount, increased consulting expense of $177,000 and a net increase in other non-project related spending of $110,000) partially offset by decreased Qnexa for diabetes spending of $313,000 and Evamist spending of $1.6 million as compared to the third quarter of 2007.

In the nine months ended September 30, 2008, research and development expenses increased $38.7 million, or 248%, to $54.3 million, as compared to $15.6 million in the same period last year. This increase was primarily due to increased Qnexa for obesity spending of $36.5 million, and a net increase in non-project related expenses of $2.2 million (primarily attributable to $851,000 in increased compensation and related expense due to an increase in headcount, increased consulting expense of $567,000, increased non-cash stock based compensation expense of $452,000 and a net increase in other non-project related spending of $295,000). In the nine months ended September 30, 2008, we spent $37.1 million on Qnexa Phase 3 trials performed by our primary contract research organization which represented 68% of our total research and development expenses.

We anticipate that our research and development expenses will continue to increase significantly in 2008 over the expenses in 2007, as we continue to advance the clinical program for Qnexa for the treatment of obesity and our other investigational products. The current remaining contractual obligation for payments to our primary contract research organization for the Phase 3 Qnexa trials totals $32.6 million. There are likely to be additional research and development expenses related to Qnexa and our other investigational products under development. Our research and development expenses may fluctuate from period to period due to the timing and scope of our development activities and the results of clinical and preclinical studies. Regardless, if we are successful in obtaining FDA regulatory approval for any new investigational product candidates being developed through our research and development efforts, we do not expect to recognize revenue from sales of such new products, if any, for several years due to the length of time required to develop investigational product candidates into commercially viable products.

*Selling, general and administrative.(Unaudited)*

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2008 | 2007 | 2008 vs. 2007 | 2008 | 2007 | 2008 vs. 2007 |
| | (In thousands, except percentages) | | | | | |
| Selling, general and administrative | $ 4,502 | $ 3,691 | 22% | $ 13,099 | $ 11,988 | 9% |



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Selling, general and administrative expenses in the three months ended September 30, 2008 of $4.5 million increased $811,000, or 22% as compared to the three months ended September 30, 2007. In the quarter ended September 30, 2008, this increase is primarily due to incremental increases in compensation expense of $236,000, investor relations expenses of $230,000, corporate legal fees of $262,000, and other net selling, general and administrative expenses net increases of $254,000 partially offset by decreased MUSE related marketing expense of $171,000, as compared to the quarter ended September 30, 2007.

In the nine months ended September 30, 2008, selling, general and administrative expenses increased $1.1 million, or 9%, to $13.1 million as compared to the same period in 2007. The increase is primarily due to incremental increases in non-cash stock based compensation expense of $444,000, compensation expense of $750,000, investor relations expense of $274,000, corporate legal fees of $163,000, and other net selling, general and administrative expenses net increases of $321,000 partially offset by a decrease in MUSE related marketing expense of $841,000, as compared to the nine months ended September 30, 2007.

We anticipate that our selling, general and administrative expenses for the year 2008 will be similar to 2007.

*Interest income and expense.*

Interest income for the quarter ended September 30, 2008 was $1.2 million, as compared to $1.8 million for the quarter ended September 30, 2007 and $4.7 million for the nine months ended September 30, 2008, as compared to $3.3 million for the nine months ended September 30, 2007. The decrease in interest income in the quarter ended September 30, 2008 as compared to the same period last year is primarily due to lower investment yields in the three months ended September 30, 2008 as compared to the same period in 2007. The increase in interest income in the nine months ended September 30, 2008 as compared to the same period last year is primarily due to the increase in our average investment cash balance.

Interest expense for the quarter ended September 30, 2008 was $282,000 as compared to $125,000 during the same period last year and $589,000 in the nine months ended September 30, 2008 as compared to $409,000 during the same period last year. The net increase in interest expense in the three and nine months ended September 30, 2008 as compared to the same period in 2007 is primarily due to interest expense on the Deerfield financing partially offset by a reduction in interest expense on both the Crown note and the Tanabe line of credit. On April 24, 2007, in connection with the sale of Evamist to K-V, we paid off the $6.7 million outstanding balance on the Tanabe line of credit, including all accrued interest and terminated the line of credit.

The other-than-temporary loss on impaired securities was $3.5 million in the third quarter of 2008 and $5.1 million in the nine months ended September 30, 2008. Included in the $3.5 million charge taken in the third quarter was $2.2 million related to corporate bonds issued by Lehman Brothers Holdings Inc., or Lehman (or their respective subsidiaries, as appropriate). On September 15, 2008, Lehman filed for bankruptcy protection under Chapter 11 of the United States Bankruptcy Code. Accordingly, recovery of the full value of our Lehman bonds, if any, is deemed remote and we recognized an other-than-temporary impairment in the three months ended September 30, 2008. This primarily represents unrealized impairment losses recorded on securities that are classified as available-for-sale securities on our condensed consolidated balance sheet as of September 30, 2008. There was no impairment loss recorded for the quarter and nine months ended September 30, 2007. With the current volatility and turmoil in the economy and financial markets there can be no assurance that additional impairment losses will not be recognized in future periods.

LIQUIDITY AND CAPITAL RESOURCES

*Cash.* Unrestricted cash, cash equivalents and available-for-sale securities totaled $204.1 million at September 30, 2008, as compared to $179.5 million at December 31, 2007. The increase in cash, cash equivalents and available-for-sale securities of $24.6 million is the net result of cash provided by financing activities, partially offset by cash used for operating activities for the first nine months of 2008. Included in these amounts are cash receipts from the sale of common stock and the Deerfield financing, including $73.4 million in net proceeds from the issuance of common stock and $4.2 million from the FARA, as well as $1.4 million from stock option exercises and $141,000 from the sale of common stock through our ESPP.

Since inception, we have financed operations primarily from the issuance of equity securities. Through September 30, 2008, we raised $300 million from financing activities, received $150 million from the sale of Evamist and had an accumulated deficit of $173.1 million at September 30, 2008.

*Available-for-sale securities.* We focus on liquidity and capital preservation in our investments in available-for-sale securities. Through February 28, 2008, we restricted our investments to:

- Direct obligations of the United States Treasury;
- Federal Agency securities which carry the direct or implied guarantee of the United States government; and
- Corporate securities, including commercial paper, rated A1/P1/F1 or better.

The weighted average maturity of our portfolio was not to exceed 18 months.



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On February 29, 2008, the Audit Committee of the Board of Directors approved a change to the investment policy to be more restrictive in the focus on liquidity and capital preservation in our investments in available-for-sale securities. Future investments are restricted to:

- Direct obligations of the United States Treasury;
- Federal agency securities which carry the direct or implied guarantee of the United States government; and
- Corporate debt obligations rated AA3/AA- or A-1+/P-1 or better or asset-backed commercial paper rated A-1+/P-1 or better.

The weighted average maturity of our portfolio for new investments is not to exceed nine months.

At September 30, 2008, we had $96.2 million in cash and cash equivalents and $107.9 million in available-for-sale securities. We invest our excess cash balances in money market and marketable securities, primarily U.S. Treasury securities and debt securities of U.S. government agencies, corporate debt securities and asset-backed securities, in accordance with our investment policy. The investment policy has the primary investment objectives of preservation of principal while at the same time maximizing yields without significantly increasing risk; however, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. If those securities are downgraded or impaired, we would experience losses in the value of our portfolio which would have an adverse effect on our results of operations, liquidity and financial condition. Certain of these securities are subject to

general credit, liquidity, market and interest rate risks, which may be exacerbated by U.S. sub-prime mortgage defaults that have affected various sectors of the financial markets and caused credit and liquidity issues.

The current economic environment and recent volatility of securities markets increase the difficulty of assessing investment impairment and the same influences tend to increase the risk of potential impairment of these assets. During the nine months ended September 30, 2008, we recorded charges for other-than-temporary impairment of securities of $5.1 million. We believe we have adequately reviewed our investment securities for impairment and that our investment securities are carried at fair value. However, over time, the economic and market environment may provide additional insight regarding the fair value of certain securities, which could change our judgment regarding impairment. This could result in realized losses relating to other-than-temporary declines being charged against future income. Given the current market conditions and the significant judgments involved, there is continuing risk that further declines in fair value may occur and additional material other-than-temporary impairments may be charged to income in future periods.

We currently believe we will be able to realize the par value of our investments without significant loss; however, it could take until the final maturity of the underlying securities or an improvement in the liquidity of the financial markets to realize the par value. Based on our expected operating cash flows, and our other sources of cash, we do not anticipate the potential lack of liquidity on certain of these investments will affect our ability to execute our current business plan; however, these market risks associated with our investment portfolio could cause the loss of a significant portion of our investments which would have an adverse effect on our results of operations, liquidity and financial condition.

*Accounts Receivable.* Accounts receivable (net of allowance for doubtful accounts) at September 30, 2008 was $2.5 million, as compared to $4.2 million at December 31, 2007. The 40% decrease in the accounts receivable balance at September 30, 2008 is primarily due to lower sales in the month of September 2008 as compared to December 2007. Currently, we do not have any significant concerns related to accounts receivable or collections.

*Liabilities.* Total liabilities were $86.2 million at September 30, 2008; $53.3 million lower than at December 31, 2007. The change in total liabilities includes a $63.1 million net decrease in deferred revenue primarily due to the amortization of the $150 million in deferred license revenue received from K-V on the sale of Evamist, offset by a $5.4 million increase in accrued research and clinical expenses related to the Qnexa for obesity development effort and a $4.2 million increase in note payable due to borrowings under the FARA.

We have entered into manufacturing agreements with suppliers to purchase raw materials. As of September 30, 2008, our remaining commitment under these agreements is to purchase a minimum of $2.3 million of product from 2008 through 2011. Should our inventory of raw materials exceed our future production needs, it may be necessary to write-off additional excess inventory.



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In February 2004, we entered into exclusive licensing agreements with Acrux Limited and a subsidiary of Acrux under which we have agreed to develop and commercialize Luramist and Evamist in the United States for various female health applications. Under the terms of the agreements, we agreed to pay to Acrux combined licensing fees of $3 million, up to $4.3 million for the achievement of certain clinical development milestones, up to $6 million for achieving product approval milestones, and royalties on net sales in the United States upon commercialization of each product. We made a $1 million clinical development milestone payment to Acrux in October 2006 related to the submission of an NDA to the FDA for Evamist and we made an additional $3 million product approval milestone payment for the approval of this NDA in August 2007. Under the terms of our Asset Purchase Agreement with K-V for the sale of our Evamist product, K-V paid $1.5 million of this milestone obligation.

*Operating Activities.* Our operating activities used $47.7 million of cash and provided $134 million of cash during the nine months ended September 30, 2008 and 2007, respectively. During the first nine months of 2008, our net operating loss of $3.2 million was offset by a $5.1 million other-than-temporary loss on impaired securities, $3.7 million in non-cash stock based compensation expense, a $5.4 million increase in accrued research and clinical expenses primarily due to the Qnexa for obesity development effort, a $1.7 million increase in accounts payable due to the timing of payments, a $1.6 million reduction in our accounts receivable, due to the collection of monies owed to us, and a $1.8 million decrease in prepaid and other assets. These positive cash flows to our net operating loss were in turn offset by the recognition of $63.1 million in revenue primarily due to the amortization of deferred license revenue from the receipt of $150 million from K-V for the sale of Evamist. During the first nine months of 2007, our net operating loss of $12.7 million was offset by the deferral of $135.7 million of license revenue due to the receipt of $150 million from K-V for the sale of Evamist, a $3.3 million increase in accounts payable due to the timing of payments, a $2.7 million reduction in our accounts receivable, due to the collection of monies owed to us, $2.8 million in non-cash stock-based compensation expense, and a $4.4 million increase in income taxes payable related to the Evamist license revenue. In addition, the increase in prepaid and other assets decreased operating cash by $1.7 million in the nine months ended September 30, 2007.

*Investing Activities.* Our investing activities provided $27.6 million and used $13.8 million in cash during the nine months ended September 30, 2008 and 2007, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities.

*Financing Activities.* Financing activities provided $78.4 million and used $3.6 million during the nine months ended September 30, 2008 and 2007, respectively. In the first nine months of 2008, the cash provided by financing activities included cash receipts from the Deerfield financing including $9.7 million in net proceeds from the issuance of common stock and $4.2 million from the FARA, net proceeds of $63.7 million from the registered direct offering of our common stock, $1.4 million in proceeds from the exercise of stock options and $141,000 from the sale of common stock through our ESPP partially offset by $738,000 in principal payments under our notes payable. In the first nine months of 2007, the cash used by financing activities was primarily due to the $6.7 million payoff of the Tanabe loan in the second quarter of 2007, partially offset by $1.7 million in proceeds from the exercise of stock options.

On December 22, 2005, we purchased from our landlord our principal manufacturing facility, which was previously leased, for $7.1 million. The purchase price was funded in part by $3.3 million, which was being held by the landlord as cash collateral for renovations to the facility upon the termination of the lease and the remainder with cash. On January 4, 2006, we obtained a $5.4 million loan from Crown Bank, N.A., or Crown. The land and buildings, among other assets, located at our principal manufacturing facility and a $700,000 Certificate of Deposit held by Crown serve as collateral for the Crown loan. The loan is payable over a 10-year term. The interest rate is adjusted annually to a fixed rate for the year equal to the prime rate plus 1%, with a floor of 7.5%. Principal and interest are payable monthly based upon a 20-year amortization schedule and are adjusted annually at the time of the interest rate reset. All remaining principal is due on February 1, 2016. The interest rate was 7.5% and 9.25% for the first nine months of 2008 and 2007, respectively.

On April 15, 2008, we closed the Deerfield Transaction in which Deerfield and its affiliates agreed to provide us with $30 million in funding. The $30 million in funding consists of $20 million from the FARA entered into with the Deerfield Sub, and $10 million from the sale of our common stock under a securities purchase agreement. Under the FARA, the Deerfield Affiliates made $3.3 million payments to us in April and August 2008 and will make four

quarterly payments of approximately $3.3 million, thereafter. We will pay royalties on the current net sales of MUSE and if approved, future sales of avanafil, an investigational product candidate, to Deerfield Sub. The term of the FARA is 10 years. The FARA includes covenants requiring us to use commercially reasonable efforts to preserve our intellectual property, manufacture, promote and sell MUSE, and develop avanafil. At the closing on April 15, 2008, in connection with the registered direct offering under the securities purchase agreement, the Deerfield Affiliates purchased 1,626,017 shares of our common stock for an aggregate purchase price of $10 million and we paid to the Deerfield Affiliates a $500,000 fee and reimbursed certain expenses incurred in this transaction of approximately $200,000. The number of shares was determined based on the volume weighted average price on the Nasdaq Global Market of the Company's common stock on the three days prior to the execution of the securities purchase agreement dated as of April 3, 2008.



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The agreements also provided us with an option to purchase, and the Deerfield Affiliates with an option to compel us to purchase, or put right, the Deerfield Sub holding the royalty rights. If we exercise our right to purchase the Deerfield Sub, the net price will be $23 million if exercised within three years or $26 million if exercised after three years but before four years (the purchase price is subject to other adjustments, as defined in the agreement). After three years from the closing the Deerfield Affiliates may exercise the right to compel us to purchase the Deerfield Sub at a price of $17 million. This price could increase up to $26 million, and the timing of the sale of the shares could be accelerated under certain conditions including a change-in-control, sale of MUSE or avanafil, sale of major assets and the sale of securities in a transaction or a series of related transactions by the Company that exceed 20% of our outstanding common stock at the date the Option and Put Agreement was signed if at the time of the sale the Company's market capitalization is below $300 million (each, a Major Transaction). Under these conditions, the cost of the shares of Deerfield Sub would be $23 million on or before the third anniversary and $26 million from the third through tenth anniversary. The sale of the shares of Deerfield Sub could also accelerate if the Company's cash, cash equivalents and available for sale securities falls below $15 million or the Company's market capitalization falls below $50 million. The purchase prices under the put right are subject to other adjustments as defined in the agreements. If either party exercises its option, any further royalty payments would be effectively terminated. In exchange for the option right, we paid $2 million to the Deerfield Affiliates. Our intellectual property and all of the accounts receivable, inventory and equipment arising out of or relating to MUSE and avanafil are collateral for this transaction.

On May 5, 2008, we filed with the SEC a shelf Registration Statement on Form S-3 (File Number 333-150649) and was declared effective by the SEC on May 29, 2008, providing the us with the ability to offer and sell up to an aggregate of $150 million of our common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering.

On May 6, 2008, we filed with the SEC a Post-Effective Amendment No. 1 to Form S-3 (File No. 333-135793), or the Registration Statement, which was filed with the SEC on July 14, 2006, to amend the Registration Statement to deregister any securities registered pursuant to the Registration Statement and not otherwise sold thereunder.

On August 6, 2008, we sold $65 million of our common stock in a registered direct offering. Under the terms of the financing, we sold 8,365,508 shares of our common stock at a price of $7.77 per share. On August 5, 2008, the Company filed a prospectus supplement with the SEC relating to this registered direct offering under the existing shelf Registration Statement (File Number 333-150649).

The funding necessary to execute our business strategies is subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of an investigational product candidate. It is also important to note that if an investigational product candidate is identified, the further development of that candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, lack of efficacy or safety or change in market demand.

The nature and efforts required to develop our investigational product candidates into commercially viable products include research to identify a clinical candidate, preclinical development, clinical testing, FDA approval and commercialization. This process is very costly and can take in excess of 10 years to complete for each investigational product candidate. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of matters arising during the clinical studies, including, among others, the following:

- we or the FDA may suspend trials;
- we may discover that an investigational product candidate may cause harmful side effects or is not effective;
- patient recruitment may be slower than expected; and
- patients may drop out of the trials.

For each of our investigational product programs, we periodically assess the scientific progress and the merits of the programs to determine if continued research and development is economically viable. Certain of our programs have been terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. As such, the ultimate timeline and costs to commercialize a product cannot be accurately estimated.



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Our investigational product candidates have not yet achieved FDA regulatory approval, which is required before we can market them as therapeutic products. In order to achieve regulatory approval, the FDA must conclude that our clinical data establish substantial evidence of safety and efficacy. The results from preclinical testing and early clinical trials may not be predictive of results in later clinical trials. It is possible for a candidate to show promising results in early clinical trials, but subsequently fail to establish safety and efficacy data necessary to obtain regulatory approvals.

As a result of the uncertainties discussed above, among others, the duration and completion of our investigational product programs are difficult to estimate and are subject to considerable variation. Our inability to complete our research and investigational product programs in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our

liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. Our inability to raise capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

We may also be required to make further substantial expenditures if unforeseen difficulties arise in other areas of our business. In particular our future capital and additional funding requirements will depend upon numerous factors, including:

- the progress and costs of our research and development programs;
- the scope, timing and results of pre-clinical testing and clinical trials;
- patient recruitment and enrollment in current and future clinical trials;
- the costs involved in seeking regulatory approvals for our investigational product candidates;
- the costs involved in filing and pursuing patent applications and enforcing patent claims;
- the establishment of collaborations, sublicenses and strategic alliances;
- the cost of manufacturing and commercialization activities and arrangements;
- the results of operations;
- demand for MUSE;
- the potential forced purchase of the royalty streams we previously sold to Deerfield;
- the cost, timing and outcome of regulatory reviews;
- the rate of technological advances;
- ongoing determinations of the potential commercial success of our products under development;
- the level of resources devoted to sales and marketing capabilities; and
- the activities of competitors.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs at least through the end of 2009. However, we anticipate that we may require additional funding to continue our research and investigational product development programs, to conduct preclinical studies and trials, for operating expenses, to pursue regulatory approvals for our investigational product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, and we may require additional funding to establish additional manufacturing and marketing capabilities in the future. In particular, we expect to make other substantial payments to Acrux and Tanabe, in accordance with our agreements with them in connection with the licensing of certain compounds. These payments are based on certain development, regulatory and sales milestones. In addition, we are required to make royalty payments on any future product sales. Similar to the transaction with Evamist, we may consider selling or licensing any of our products in development or our commercial product in order to raise additional funding. We may seek to access the public or private equity



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markets whenever conditions are favorable. The sale of additional equity securities would result in additional dilution to our stockholders. We may also seek additional funding through strategic alliances and other financing mechanisms. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. If adequate funds are not available, we may be required to curtail significantly one or more of our investigational product development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies or investigational product candidates. To the extent that we are unable to obtain third party funding for such expenses, we expect that increased expenses may result in future losses from operations. We are continually evaluating our existing portfolio and we may choose to divest or spin-off one or more of our products or investigational product candidates at any time. We cannot assure you that we will successfully develop our products under development or that our products, if approved for sale, will generate revenues sufficient to enable us to earn a profit.

***Contractual Obligations***

The following table summarizes our contractual obligations at September 30, 2008, excluding amounts already recorded on our condensed consolidated balance sheet as accounts payable, and the effect such obligations are expected to have on our liquidity and cash flow in future fiscal years. These do not include milestones and assume non-termination of agreements. These obligations, commitments and supporting arrangements represent payments based on current operating forecasts, which are subject to change:

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| **Contractual obligations** | **Total** | **2008 (3 months)** | **2009-2011** | **2012-2013** | **Thereafter** |
| | | | (in thousands) | | |
| Operating leases | $ 457 | $ 137 | $ 320 | $ — | $ — |
| Manufacturing and other agreements | 9,393 | 6,009 | 3,341 | 7 | 36 |
| Clinical trials | 42,782 | 21,961 | 20,821 | — | — |
| Notes payable | 8,659 | 35 | 4,050 | 378 | 4,196 |
| Interest payable | 4,403 | 96 | 1,340 | 670 | 2,297 |
| Total contractual obligations | $ 65,694 | $ 28,238 | $ 29,872 | $ 1,055 | $ 6,529 |

*Operating Leases*

We purchased our previously leased manufacturing facilities in Lakewood, New Jersey on December 22, 2005. In November 2006, we entered into a new 30-month lease for our existing Mountain View corporate headquarters location with our existing landlord. The new lease commenced on February 1, 2007. The lease expires on July 31, 2009 and allows us one option to extend the term of the lease for a period of one year from the expiration of the lease.

*Manufacturing and Other Purchases*

Purchase obligations consist of agreements to purchase goods or services that are enforceable and legally binding on us and that specify all significant terms, including: fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. These include obligations for minimum inventory purchase contracts, research and development, general and administrative services, and media/market research contracts.

Manufacturing Agreements

In November 2002, we entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. In May 2007, the terms of this agreement were amended to require the purchase of a minimum total of $2.3 million of product from 2007 through 2011. Our remaining commitment is to purchase a minimum total of $1.5 million of product from 2008 through 2011.

In January 2004, we entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. In February 2006, we amended the terms of this agreement to require the purchase of a minimum total of $1.5 million of product from 2006 through 2008. Our remaining commitment under this agreement is $765,000.

Other Agreements

We have remaining commitments under various general and administrative services agreements totaling $1.9 million at September 30, 2008, including $1.2 million related to Mr. Wilson's Employment Agreement (see paragraph below). We have also entered into various agreements with research consultants and other contractors to perform regulatory services, drug research,



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testing and manufacturing including animal studies and, at September 30, 2008, our remaining commitment under these agreements totaled $4.4 million. In addition, we have entered into marketing promotion and related agreements for our erectile dysfunction product, MUSE. At September 30, 2008, our remaining commitment under the MUSE agreements totaled $779,000.

On December 19, 2007, the Compensation Committee of the Board of Directors of the Company approved an employment agreement, or the Employment Agreement, with Leland F. Wilson, the Company's President and Chief Executive Officer. The Employment Agreement includes salary, incentive compensation, retirement benefits and length of employment, among other items, as agreed to with Mr. Wilson. The Employment Agreement has an initial term of two years commencing on the effective date, June 1, 2007, or the Effective Date. On the second anniversary of the Effective Date, the Employment Agreement will automatically renew for an additional one-year term unless either party provides the other party with a notice of non-renewal.

*Clinical Trials*

We have entered into various agreements with clinical consultants, investigators, clinical suppliers and clinical research organizations to perform clinical trial management and clinical studies on our behalf and, at September 30, 2008, our remaining commitment under these agreements totaled $42.8 million. We make payments to these providers based upon the number of patients enrolled and the length of their participation in the trials. These obligations, however, are contingent on future events, e.g. the rate of patient accrual in our clinical trials. This amount represents the remaining contractual amounts due under various contracts, although all of these contracts could be cancelled by us, in which case we would only be liable to the vendors for work performed to the date of cancellation.

*Notes Payable and Interest Payable*

Crown Loan

On January 4, 2006, we obtained a $5.4 million loan from Crown. The land and buildings, among other assets, located at our principal manufacturing facility and a $700,000 Certificate of Deposit held by Crown serve as collateral for these Agreements. The loan is payable over a 10-year term. The interest rate is adjusted annually to a fixed rate for the year equal to the prime rate plus 1%, with a floor of 7.5%. Principal and interest are payable monthly based upon a 20-year amortization schedule and are adjusted annually at the time of the interest rate reset. All remaining principal is due on February 1, 2016. The interest rate was 7.5% and 9.25% for the nine months ended September 30, 2008 and 2007, respectively. As of September 30, 2008, we have a principal balance of $5.1 million remaining on the Crown loan.

We have included in the above table the estimated interest payments based upon current interest rates that we expect to make in accordance with the terms of the loan agreement. However, should we decide to prepay the loan, there would be a prepayment premium, in lieu of the interest payable in the above table, which would have been 3% at September 30, 2008 (the third year of the loan term). If prepayment occurs in the fourth year the premium would be 2%, and if it occurs in the fifth year or thereafter, the premium would be 1%.

Deerfield Financing

On April 3, 2008, we entered into several agreements with Deerfield Management Company, L.P., or Deerfield, a healthcare investment fund, and its affiliates, Deerfield Private Design Fund L.P. and Deerfield Private Design International, L.P. (collectively, the Deerfield Affiliates). Under the agreements Deerfield and its affiliates agreed to provide us with $30 million in funding. The $30 million in funding consists of $20 million from the FARA entered into with the Deerfield Sub and $10 million from the sale of our common stock. Under the FARA, the Deerfield Affiliates made $3.3 million payments to us in

April and August 2008 and will make four quarterly payments of approximately $3.3 million thereafter. Such payments are referred to as the Funding Payments. We will pay royalties on the current net sales of MUSE and if approved, future sales of avanafil, an investigational product candidate to Deerfield Sub. The term of the FARA is 10 years. The FARA includes covenants requiring us to use commercially reasonable efforts to preserve our intellectual property, manufacture, promote and sell MUSE, and develop avanafil. At the closing on April 15, 2008, under the securities purchase agreement, the Deerfield Affiliates purchased 1,626,017 shares of our common stock for an aggregate purchase price of $10 million and we paid to the Deerfield Affiliates a $500,000 fee and reimbursed approximately $200,000 in certain expenses incurred in this transaction. The number of shares was determined based on the volume weighted average price on the Nasdaq Global Market of the Company's common stock on the three days prior to the execution of the securities purchase agreement dated as of April 3, 2008. The agreements also provided us with an option to purchase, and the Deerfield Affiliates with an option to compel us to purchase, the Deerfield Sub holding the royalty rights. If either party exercises its option, any further royalty payments would be effectively terminated. Collectively, these transactions are referred to as the Deerfield Transactions.



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Also in connection with the Deerfield Transactions, the Company, the Deerfield Affiliates and Deerfield Sub entered into the Option and Put Agreement, dated April 3, 2008, or the OPA. Pursuant to the OPA, the Deerfield Affiliates have granted us an option to purchase all of the outstanding shares of common stock of Deerfield Sub from the Deerfield Affiliates, referred to as the Option, and we have agreed to grant the Deerfield Affiliates an option to require us to purchase all of the outstanding shares of common stock of Deerfield Sub from the Deerfield Affiliates, referred to as the Put Right.

If we exercise the Option, base consideration for the Option exercise, or Base Option Price, will be:

- $25 million, if the Option is exercised on or prior to the third anniversary of the execution of the OPA; or
- $28 million, if the Option is exercised subsequent to the third anniversary but prior to the fourth anniversary of the execution of the OPA.

The aggregate consideration payable by VIVUS upon exercise of the Option, or the Option Purchase Price, would be equal to the sum of the Base Option Price, plus: (i) the cash and cash equivalents held by Deerfield Sub at the date of the closing of the resulting sale of the common stock of Deerfield Sub; (ii) accrued and unpaid royalties; and minus (i) the option premium of $2 million which was paid at the closing of the transaction (referred to as the Option Premium); (ii) accrued but unpaid taxes; (iii) unpaid Funding Payments; and (iv) any other outstanding liabilities of Deerfield Sub. The Option terminates on the fourth anniversary of the execution of the OPA.

In consideration of the grant of the Option, at closing we paid $2 million to the Deerfield Affiliates. As indicated in the calculation of the Option Purchase Price, if the Option is exercised by us the Option Premium will be applied to reduce the Option Purchase Price.

The Put Right terminates on the tenth anniversary of the execution of the OPA and will become exercisable on the earliest of:

- the third anniversary of the execution of the OPA;
- any date on which:
  - (1) the market capitalization of the Company falls below $50 million; or
  - (2) the amount of cash and cash equivalents as defined, held by the Company falls below $15 million; or
  - (3) the fifteenth day following the delivery of written notice to the Company that we have failed to make Royalty Payments in accordance with the provisions of the FARA unless we make such Royalty Payments prior to such fifteenth day; or
  - (4) a Major Transaction, as defined below, closes.

If the Deerfield Affiliates exercise the Put Right, base consideration for the put exercise, or the Base Put Price, will be:

- $23 million, if the Put Right is exercised on or prior to the third anniversary of the execution of the OPA and we have notified the Deerfield Affiliates of our intent to enter into a Major Transaction (such notice is referred to as a Major Transaction Notice); or
- $26 million, if the Put Right is exercised subsequent to the third anniversary of the execution of the OPA and we have provided the Deerfield Affiliates a Major Transaction Notice; or
- $17 million, in all other cases.

The aggregate consideration payable by VIVUS upon exercise of the Put Right, or the Put Purchase Price, would be equal to the sum of the Base Put Price, plus: (i) the cash and cash equivalents held by Deerfield Sub at the date of the closing of the resulting sale of the common stock of Deerfield Sub; (ii) accrued and unpaid royalties; and minus (i) accrued but unpaid taxes; (ii) unpaid Funding Payments; and (iii) any other outstanding liabilities of Deerfield Sub.



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Pursuant to the OPA, the following events would qualify as Major Transactions:

- a consolidation, merger, exchange of shares, recapitalization, reorganization, business combination or similar event:
  - (1) following which the holders of the Company's common stock immediately preceding such event either:

(a) no longer hold a majority of the shares of the the Company's common stock; or

(b) no longer have the ability to elect a majority of the Board of Directors of the Company;

(2) as a result of which shares of the Company's common stock are changed into (or the shares of common stock become entitled to receive) the same or a different number of shares of the same or another class or classes of stock or securities of the Company or another entity, collectively referred to as Change in Control Transactions;

- a sale or transfer of assets of the Company in one transaction or a series of related transactions for a purchase price of more than $350 million where the consideration to be payable at or within 30 days of closing of such transaction or transactions has a value of more than $350 million, or a sale, transfer or license of all or substantially all assets or proprietary rights of the Company that relate specifically to MUSE or avanafil; or

- a purchase, tender or exchange offer made to the holders of outstanding shares of the Company's common stock, such that following such purchase, tender or exchange offer a Change in Control Transaction shall have occurred; or

- an issuance or series of issuances in a series of related transactions by the Company of an aggregate number of shares of common stock in excess of 20% of our outstanding common stock on the date hereof if, immediately prior to such issuance, the market capitalization of the Company is less than $300 million.

In connection with the FARA, Deerfield Sub and the Company have entered into a Royalty Security Agreement, whereby we have granted Deerfield Sub a security interest in certain collateral related to MUSE and avanafil including: all of our drug applications; all existing and future licenses relating to the development, manufacture, warehousing, distribution, promotion, sale, importing or pricing of MUSE and avanafil; our intellectual property and all of the accounts, inventory and equipment arising out of or relating to Muse and avanafil. In connection with the OPA, the Deerfield Affiliates and the Company have entered into a security agreement, whereby we have granted the Deerfield Affiliates a security interest in the same Collateral as defined by the Royalty Security Agreement. The security interest granted to the Deerfield Affiliates has priority to that granted to Deerfield Sub by the Royalty Security Agreement.

In accordance with Emerging Issues Task Force (EITF) Issue 88-18, *Sale of Future Revenues*, the FARA transaction is in substance a financing arrangement, or loan that will be repaid by us. The minimum repayment amount would be $17 million, the amount of the unconditional put option held by Deerfield Affiliates, plus royalties paid on MUSE sales, and avanafil sales if approved, during the term of the agreement. Accordingly, we will record the advances from the Deerfield Affiliates, net of the $2 million option right payment and related fees and expenses, as a loan. The loan balance will increase as the advances are received. The loan balance will increase quarterly up to the minimum amount owed of $17 million. The minimum amount to be recorded is lower than the contractual amounts owed if we exercise our call option of $23 million to $26 million, or if the Deerfield Affiliates require us to purchase the shares as a result of a Major Transaction (see Note 7: Deerfield Financing). Using the interest method under APB Opinion No. 21, *Interest on Receivables and Payables*, interest on the loan will be calculated and recognized over three years, which is the estimated term of the loan based on the earliest date that the Deerfield Affiliates could require us to repay the amounts advanced. The Deerfield Affiliates will receive a quarterly payment based on net sales of MUSE.

***Additional Payments***

We have entered into development, license and supply agreements which contain provisions for payments upon completion of certain development, regulatory and sales milestones. Due to the uncertainty concerning when and if these milestones may be completed or other payments are due, we have not included these potential future obligations in the above table.

*Tanabe*

In January 2001, we entered into an exclusive development, license and supply agreement with Tanabe for the development and commercialization of avanafil, a PDE5 inhibitor compound for the oral and local treatment of male and female sexual dysfunction. Under the terms of the agreement, Tanabe agreed to grant an exclusive license to us for products containing avanafil



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outside of Japan, North Korea, South Korea, China, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Vietnam and the Philippines. We agreed to grant Tanabe an exclusive, royalty-free license within those countries for oral products that we develop containing avanafil. In addition, we agreed to grant Tanabe an exclusive option to obtain an exclusive, royalty-bearing license within those countries for non-oral products that we develop containing avanafil. Further, we granted Tanabe the option to obtain co-promotional rights for oral products that we develop under our license for up to 25% of the promotional activity in our territory. Tanabe agreed to manufacture and supply us with avanafil for use in clinical trials, which will be our primary responsibility.

We have paid upfront licensing fees of $5 million to Tanabe and have agreed to make additional payments upon the completion of certain development, regulatory and sales milestones. During the first quarter of 2004, we initiated a Phase 2 clinical trial with avanafil, which triggered one of the clinical development milestone criteria above. We paid Tanabe $2 million in connection with this milestone in 2006. We have further agreed to pay royalties on net sales of products containing avanafil. No payments were made under this agreement with Tanabe in the nine months ended September 30, 2008. We expect to make other substantial payments to Tanabe in accordance with our agreements with Tanabe as we continue to develop and, if approved for sale, commercialize avanafil for the oral treatment of male sexual dysfunction. Such potential future milestone payments total $19 million and include payments upon: the enrollment of the first patient in the first Phase 3 clinical studies; the first submission of an NDA; obtainment of the first regulatory approval in the United States and any major European country; and achievement of $250 million or more in calendar year sales.

The term of the Tanabe agreement is based on a country-by-country and on a product-by-product basis. The term shall continue until the later of (i) ten years after the date of the first sale for a particular product, or (ii) the expiration of the last to expire patents within the Tanabe patents covering such product in such country. In the event that our product is deemed to be (i) insufficiently effective or insufficiently safe relative to other PDE5 inhibitor compounds based on published information, or (ii) not economically feasible to develop due to unforeseen regulatory hurdles or costs as measured by standards common in the pharmaceutical industry for this type of product, we have the right to terminate the agreement with Tanabe with respect to such product.

*Acrux*

In February 2004, we entered into exclusive licensing agreements with Acrux Limited, or Acrux, and its subsidiary under which we have agreed to develop and, if approved, commercialize Luramist and Evamist in the United States for various female health applications. Acrux's metered-dose transdermal spray, or MDTS, technology is a patented, simple to use spray that is being developed to deliver testosterone and estradiol effectively to women when applied to the skin. We agreed to grant Acrux's subsidiary a non-exclusive, royalty-free license outside the United States for any MDTS products containing improvements we have made to the licensed intellectual property and the option to obtain a non-exclusive, worldwide license for our intellectual property related to MDTS products. We have paid $3 million in upfront licensing fees to Acrux and have agreed to make additional payments upon the completion of certain development, regulatory and sales milestones. Under the terms of the agreements, we agreed to pay to Acrux combined licensing fees up to $4.3 million for the achievement of certain clinical development milestones, up to $6 million for achieving product approval milestones, and royalties on net sales in the United States following approval and commercialization of each product. Future potential milestone payments to Acrux for Luramist total $5.5 million and are payable upon (1) the dosage of the first patient in the Phase 3 clinical studies, (2) the first submission of an NDA, and (3) obtainment of the first regulatory approval in the United States. We have paid $4.8 million in clinical development milestone payments to date, including the $1 million milestone payment we made to Acrux in October 2006 related to the submission of an NDA to the FDA for Evamist and the $3 million product approval milestone payment for approval of this NDA, which was paid in August 2007. Under the terms of our Asset Purchase Agreement with K-V for the sale of our Evamist product, we granted a sublicense of our rights under the Evamist Agreement to K-V and K-V paid $1.5 million of this $3 million obligation. In August 2008, the Company assigned all of its rights and obligations under the Evamist license agreement to K-V. See Note 11: Sale of Evamist Product to the unaudited notes to condensed consolidated financial statements included in this Form 10-Q for additional information concerning the terms of this agreement.

***Off-Balance Sheet Arrangements***

We have not entered into any off-balance sheet financing arrangements and have not established any special purpose entities. We have not guaranteed any debt or commitments of other entities or entered into any options on non-financial assets.



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***Indemnifications***

In the normal course of business, the Company provides indemnifications of varying scope to customers against claims of intellectual property infringement made by third parties arising from the use of its products and to its clinical research organizations and investigators sites against liabilities incurred in connection with any third-party claim arising from the work performed on behalf of the Company. Historically, costs related to these indemnification provisions have not been significant and we are unable to estimate the maximum potential impact of these indemnification provisions on our future results of operations.

Pursuant to the terms of the K-V transaction for the sale of Evamist, we made certain representations and warranties concerning our rights and assets related to Evamist and our authority to enter into and consummate the transaction. We also made certain covenants that survive the closing date of the transaction, including a covenant not to operate a business that competes, in the United States, and its territories and protectorates, with the Evamist product.

Pursuant to the terms of the Funding and Royalty Agreement with Deerfield, we made certain representations, warranties and covenants related to MUSE and avanafil. Covenants include that we will maintain all registrations and regulatory rights to sell and promote MUSE in the United States, we will continue to manufacture and promote MUSE and will continue the development of avanafil. We also entered into a covenant that we will not manufacture, promote or sell any product that competes with avanafil in the United States other than MUSE.

To the extent permitted under Delaware law, we have agreements whereby we indemnify our officers and directors for certain events or occurrences while the officer or director is, or was, serving at our request in such capacity. The indemnification period covers all pertinent events and occurrences during the officer's or director's lifetime. The maximum potential amount of future payments we could be required to make under these indemnification agreements is unlimited; however, we have director and officer insurance coverage that reduces our exposure and enables us to recover a portion of any future amounts paid. We believe the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Securities and Exchange Commission's rule related to market risk disclosure requires that we describe and quantify our potential losses from market risk sensitive instruments attributable to reasonably possible market changes. Market risk sensitive instruments include all financial or commodity instruments and other financial instruments that are sensitive to future changes in interest rates, currency exchange rates, commodity prices or other market factors.

### Market Risk

Market risk represents the risk of loss that may impact our financial position, results of operations or cash flows due to adverse changes in financial and commodity market prices and rates. We are exposed to market risk in the area of changes in United States interest rates. We do not have any material foreign currency or other derivative financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to increase the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in investment grade securities.

### Interest Rate Risk

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in widely diversified investments consisting of investment grade securities. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the interest rate later rises, the principal amount of our investment will probably decline. A hypothetical 100 basis point increase in interest rates reduces the fair value of our available-for-sale securities at September 30, 2008 by approximately $474,000. To minimize this risk in the future, we intend to maintain our portfolio of cash equivalents and marketable securities in a variety of securities.

We hold investments in both fixed rate and floating rate interest earning instruments, and both carry a degree of interest rate risk. Fixed rate securities may have their fair market value adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectations due to changes in market conditions and in interest rates or we may suffer losses in principal if forced to sell securities which may have declined in market value due to changes in interest rates.



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We have investments in commercial paper, corporate bonds, asset-backed securities, and other securities. While we now earn a premium interest rate on these investments, some of these investments are not liquid. We presently do not need to access these funds for operating purposes. We have the ability to generally hold our investments until maturity and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our securities portfolio. In the event we need to access these funds, we may not be able to do so without a loss of principal.

We are also exposed to interest rate risk on the $5.1 million loan payable to Crown Bank, N.A. as of September 30, 2008. The loan is payable over a 10-year term. The interest rate is adjusted annually to a fixed rate for the year equal to the prime rate plus 1%, with a floor of 7.5%. The interest rate was 7.5% and 9.25% for the first nine months of 2008 and 2007, respectively.

***Fair Value of Financial Instruments***

Our financial instruments consist primarily of cash and cash equivalents, and available for sale securities. The estimated fair values of the financial instruments have been determined by us using available market information and appropriate valuation techniques. Considerable judgment is required, however, to interpret market data to develop the estimates of fair value. Accordingly, the estimates presented are not necessarily indicative of the amounts that we could realize in a current market exchange. This determination of the fair value of our holdings in the investment account requires significant judgment or estimation. At September 30, 2008, these securities were valued primarily using broker pricing models that incorporate transaction details such as contractual terms, maturity, timing and amount of future cash inflows, as well as assumptions about liquidity. The use of different market assumptions and/or estimation methodologies may have a material effect on the estimated fair value amounts.

**ITEM 4. CONTROLS AND PROCEDURES**

(a.) Evaluation of disclosure controls and procedures. We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the rules and forms of the Securities and Exchange Commission, or SEC, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of VIVUS' disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

(b.) Changes in internal controls. There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



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**PART II: OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

In the normal course of business, the Company receives and makes inquiries regarding patent infringement and other legal matters.

The Company and Acrux Limited, or Acrux, are parties to the Testosterone Development and Commercialization Agreement, or the Testosterone Agreement, and the Estradiol Development and Commercialization Agreement, or the Evamist Agreement, each dated February 12, 2004, or collectively, the Acrux Agreements. The Acrux Agreements cover the Company's investigational product candidate, Luramist, and the Company's former investigational product candidate, Evamist, both of which are licensed from Acrux under the Acrux Agreements. The Company received a letter dated November 13, 2006 from legal counsel for Acrux containing various claims of breach under the Acrux Agreements. The Company responded that there is no merit to Acrux's claims and that it has meritorious defenses to such claims. Acrux has since approved the Company's assignment of the Company's rights and obligations under the Evamist Agreement to K-V as part of K-V's purchase of Evamist and released the Company from any claims or liabilities arising from the Evamist Agreement. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding its claims related to Luramist. Acrux's demand seeks a reversion of all rights assigned to the Company related to Luramist, monetary damages, a portion of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. The Company continues to believe that it is in compliance with all material aspects of the Testosterone Agreement and that it does not owe monetary damages or any milestone payment under the Testosterone Agreement. The Company also believes that it has valid counterclaims against Acrux and has requested that it be allowed to include such counterclaims in the arbitration. Otherwise, the arbitration process is proceeding, with the parties having selected and qualified a panel of three arbitrators and having agreed to a schedule of pre-hearing discovery. Absent a resolution to the dispute, the arbitration hearing is currently scheduled to commence in January 2009. In the event that Acrux should prevail in this matter, it could have a material adverse effect on the Company's business, financial condition and results of operations and cash flow.

We are not aware of any other asserted or unasserted claims against us where the resolution would have an adverse material impact on our operations or financial position.

**ITEM 1A. RISK FACTORS AFFECTING OPERATIONS AND FUTURE RESULTS**

Set forth below and elsewhere in this Form 10-Q and in other documents we file with the Securities and Exchange Commission, or the SEC, are risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this Quarterly Report on Form 10-Q. These are not the only risks and uncertainties facing the Company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

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

**Risks Relating to our Product Development Efforts**

**We face significant risks in our product development efforts.**

The process of developing new drugs and/or therapeutic products is inherently complex, time-consuming, expensive and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will result in products that will receive regulatory approval and achieve market acceptance. Investigational product candidates that appear to be promising at all stages of development may not reach the market for a number of reasons. Investigational product candidates may be found ineffective or may cause harmful side effects during clinical trials, may take longer to progress through clinical trials than had been anticipated, may not be able to achieve the pre-defined clinical endpoint due to statistical anomalies even though clinical benefit may have been achieved, may fail to receive necessary regulatory approvals, may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality, or may fail to achieve market acceptance. Historically, our development efforts have been focused on products for sexual and postmenopausal health. While we have experience in managing Phase 1 through Phase 3 clinical trials in support of various indications, we do not have any experience in managing Phase 3 clinical trials for obesity or diabetes. There can be no assurance that we will be successful with the limited experience and resources we have available at the present time relating to obesity or diabetes.



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**The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current investigational product candidates may not have favorable results in later studies or trials.**

Pre-clinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of an investigational product candidate in the general population, but rather to test initial safety, to study pharmacokinetics and pharmacodynamics, to study limited efficacy in a selected disease population, and to identify and attempt to understand the investigational product candidate's side effects at various doses and schedules. Success in pre-clinical studies or completed clinical trials does not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. Favorable results in early studies or trials may not be repeated in later studies or trials, and investigational product candidates in later stage trials may fail to show acceptable safety and efficacy despite having progressed through initial-stage trials. In addition, the placebo rate in larger studies may be higher than expected.

Our investigational product candidates, Qnexa, Luramist and avanafil, have not completed the large, pivotal Phase 3 trials for efficacy and safety that are required for approval by the FDA and other worldwide regulatory authorities. Pre-clinical data and the limited clinical results that we have obtained for these investigational product candidates may not predict results from studies in larger numbers of subjects in multiple sites drawn from more diverse populations treated for longer periods of time. The smaller and shorter clinical trials also may not predict the ability of these investigational products to achieve or sustain the desired effects in the broad intended population or to do so safely. We may also decide to not conduct additional Phase 2 studies prior to the initiation of pivotal Phase 3 studies. In addition, we may elect to enter into pivotal Phase 3 studies with a new formulation, delivery system or choose to study different populations than had been used or studied in previous clinical trials.

Qnexa is our proprietary capsule formulation investigational product candidate containing the active ingredients phentermine and topiramate. Phentermine was approved for the short-term treatment of obesity by the FDA in 1959. Topiramate is approved for seizures and migraine prevention. Published studies on topiramate reported that topiramate produced weight loss. By combining the activity of each of these compounds, Qnexa attempts to simultaneously address excessive appetite and a high threshold for satiety, the two main mechanisms believed to impact eating behavior. Although we believe Qnexa affects both of the two major causes of overeating, excessive hunger and the inability to feel satisfied, we may not be correct in our assessment of the impact the combination of these two ingredients may have on weight loss or their mechanism of action. Our Phase 2 obesity study was a single center trial conducted at Duke University in only 200 patients. The twice-a-day dose and timing of the administration of the active ingredients was determined by the inventor through the treatment of patients in his private practice. We have completed the formulation development of Qnexa and have initiated Phase 3 studies of Qnexa with a once-a-day formulation. We have completed various pharmacokinetic studies of the once-a-day formulations to characterize the pharmacokinetic profile of the once-a-day formulation of Qnexa; however, there can be no assurance that we will be able to achieve any weight loss effects with the once-a-day formulation or that we will be able to duplicate the weight loss seen in the Phase 2 obesity study. The FDA has also asked us to study the effects of a lower dose of Qnexa, which we plan to do in the Phase 3 obesity trials. We are unable to predict the effect of the inclusion of a lower dose group in the Phase 3 obesity trials on the overall development program of Qnexa.

We will be required to demonstrate through larger-scale clinical trials that our investigational product candidates are safe and effective for use in a broad population before we can seek regulatory approvals for their commercial sale. There is typically a high rate of attrition from the failure of investigational product candidates proceeding through clinical trials. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our current investigational product candidates. If any of our investigational product candidates fails to demonstrate sufficient safety and efficacy in any clinical trial, we will experience potentially significant delays in, or decide to abandon development of, that investigational product candidate. If we abandon or are delayed in our development efforts related to any of our investigational products we may not be able to generate sufficient revenues to continue our operations and clinical studies at the current level or become profitable, our reputation in the industry and in the investment community would likely be significantly damaged, it may not be possible for us to complete financings, and our stock price would likely decrease significantly.

**If the results of current or future pre-clinical studies, clinical testing and/or clinical trials indicate that our proposed investigational product candidates are not safe or effective for human use, our business will suffer.**

Unfavorable results from ongoing pre-clinical studies, clinical testing and/or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in late stage clinical trials, even after promising results in initial-stage trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated, modified or terminated. In addition, failure to design appropriate clinical trial protocols could result in the test or control group experiencing a disproportionate number of adverse events and could cause a clinical trial to be delayed, repeated, modified or terminated.



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All of the investigational product candidates that we are currently developing require extensive pre-clinical and/or clinical testing before we can submit any application for regulatory approval. Before obtaining regulatory approvals for the commercial sale of any of our investigational product candidates, we must demonstrate through pre-clinical testing and/or clinical trials that our investigational product candidates are safe and effective in humans. Conducting clinical trials is a complex, lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. Our ability to complete clinical trials may be delayed by many factors, including, but not limited to:

· inability to obtain or manufacture sufficient quantities of drugs for use in clinical trials;

· failure to receive approval by the FDA of our clinical trial protocols;

· changes in clinical trial protocols made by us or imposed by the FDA;

· the safety or effectiveness of our investigational product candidates;

· slower than expected rate of and higher than expected cost of patient recruitment;

· inability to adequately follow patients after treatment;

· unforeseen safety issues;

· government or regulatory delays; or

· our ability to raise the necessary cash to start or complete the trials.

Many of these factors may also ultimately lead to denial of regulatory approval of our investigational product candidates. If we experience delays, suspensions or terminations in our clinical trials for a particular investigational product candidate, the commercial prospects for that investigational candidate will be harmed, and we may be unable to raise additional funds, or generate product revenues from that investigational candidate or revenues would be delayed.

**Prior association with fen-phen could lead to increased scrutiny of our investigational product candidate, Qnexa.**

One of the active ingredients in Qnexa, phentermine, had previously been used in combination with fenfluramine and dexfenfluramine. Phentermine is the most commonly prescribed anti-obesity product. As phentermine is an older drug, no new efficacy trials have been conducted with the exception of several trials on the combination of phentermine and fenfluramine in the early and mid 1990s. The combination of fenfluramine or PONDIMIN, or fen, and phentermine, or phen, was known as fen-phen. Fenfluramine received FDA approval in 1973 for the short-term treatment of obesity. Together, phentermine and fenfluramine were used by doctors to treat obesity. The FDA never approved the fen-phen combination; however, since the FDA approved fenfluramine, doctors were able to prescribe it as needed. The use of these drugs together for treatment of obesity was considered an off-label and unapproved use. In 1992, a published study cited fen-phen as a more effective method than dieting or exercise in reducing the weight of the chronically obese.

Neither combination, however, was ever tested for safety. By the summer of 1997, the Mayo Clinic reported 24 cases of heart valve disease in patients that had taken the fen-phen combination. The cluster of unusual cases of heart valve disease in fen-phen users suggested a co-relation between fen-phen use and heart valve disease. On July 8, 1997, the FDA issued a Public Health Advisory to report the Mayo findings. The FDA continued to receive additional reports of heart valve disease, including reports from patients who had taken only fenfluramine or dexfenfluramine. Further evaluations of patients taking fenfluramine or dexfenfluramine showed that approximately 30% had abnormal valve findings. This figure was much higher than expected for abnormal test results and suggests fenfluramine and dexfenfluramine as the likely causes of Primary Pulmonary Hypertension, or PPH, and valvular heart disease.

In September 1997, the FDA requested drug manufacturers to voluntarily withdraw fenfluramine and dexfenfluramine. At the same time, the FDA recommended that patients using either fenfluramine or dexfenfluramine stop taking them. The FDA did not, however, request the withdrawal of phentermine. Although studies to date have demonstrated that phentermine does not cause PPH and valvular heart disease, there can be no assurance that Qnexa will not have any significant cardiovascular or other detrimental side effects. Moreover, the adverse clinical history of fen-phen and dexfen-phen combinations for obesity may result in increased FDA regulatory scrutiny of the safety or the risk/benefit profile of Qnexa and may raise potential adverse publicity in the marketplace, which could affect clinical enrollment or ultimately market acceptance if Qnexa is approved for commercial sale.



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**Adverse side effects associated with topiramate, an ingredient in Qnexa, could result in patient drop outs and increased scrutiny.**

Previously published studies suggest that the administration of topiramate alone, in conjunction with diet and a behavioral modification program, results in weight reduction in obese patients. The most prominent side effect seen in the published studies was paresthesia, (tingling of the extremities) experienced by 42% to 59% of patients. Drop outs due to paresthesia were 5% or less. In the Phase 2 obesity study, paresthesia was experienced in 38% of the patients on

Qnexa. In the Phase 2 diabetes study, paresthesia was experienced by 17% of the patients. There were no drop outs in the Qnexa group in either study due to paresthesia. The other common adverse events reported in the published topiramate monotherapy studies were also central nervous system, or CNS, related including fatigue, difficulty with attention, memory and concentration and depression. In our Phase 2 obesity and diabetes studies, these CNS related side effects were also experienced but the difference was not statistically significant when compared to placebo. The pharmaceutical company performing research of topiramate alone announced they had discontinued development of a time-release formulation due to side effects at high doses.

The FDA has also recently issued an alert on the use of antiepileptic drugs and a potential risk of increased suicidal ideation. There were no reports of suicidal ideation in our Phase 2 studies of Qnexa. The FDA has requested that as part of our Phase 3 obesity trials for Qnexa, a standard analysis of patients' suicidal tendencies be performed. On July 10, 2008, the FDA held a Joint Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee and the Psychopharmacologic Drugs Advisory Committee. The advisory committee and representatives from the Pediatric Advisory Committee, and the Drug Safety and Risk Management Advisory Committee considered the results of FDA's analysis of suicidality (both suicidal ideation and behavior) from placebo-controlled clinical studies of 11 antiepileptic drugs. One of the drugs included in the discussion was topiramate (marketed as TOPAMAX, Ortho-McNeil-Janssen Pharmaceuticals Inc.). The FDA discussed with the committee, in light of the results, whether any additional actions are necessary. The committee recognized that there is an increased risk of suicidality and recommended to the FDA that additional information should be provided to patients regarding the risks and benefits of antiepileptic drugs; however, the committee strongly recommended against a Black Box warning to be applied to antiepileptic drugs.

The preliminary experience from an observational registration study conducted in the United Kingdom on women with epilepsy who became pregnant, published in the July 22, 2008 edition of Neurology, stated that the major congenital malformations, or MCM, rate observed in the study among infants born to women who were taking topiramate and other antiepileptics during their pregnancy raised some concerns. The UK Epilepsy and Pregnancy Register is a voluntary registry in the United Kingdom that collects information in order to gather and publish information on the relative safety of antiepileptic drugs in this population. In the study, 203 pregnancies were followed of which 13 (9%) had an MCM on polytherapy and three (4.8%) had an MCM on topiramate monotherapy. The MCMs included oral clefts and hypospadias. It has been reported that prenatal exposure to certain antiepileptic drugs increases the risk of MCM from a background risk of between 1% and 2% to between 4% and 9%.

Pregnant women or women who plan on becoming pregnant are not eligible to participate in the Qnexa clinical trials. Women are advised to use and agree to use two forms of birth control during the study. Subjects that become pregnant during the study period will immediately discontinue study medication. We are unable to predict the effect or use of Qnexa on study subjects who become pregnant or their fetuses.

**There are additional adverse side effects to the individual use of topiramate and phentermine.**

Topiramate and phentermine are approved for sale by the FDA and have been on the market for several years. Adverse events and side effects observed in pre-clinical and post-marketing studies are included in the label for each drug. The label for TOPAMAX contains reports of side effects, warnings and precautions including metabolic acidosis, acute myopia and secondary angle closure glaucoma, decreased sweating and hyperthermia, cognitive related dysfunction, psychiatric and behavioral disturbances including one completed suicide in a patient during a bipolar trial, somnolence and fatigue, sudden unexplained death in epileptics, kidney stones, parasthesia and various drug interactions. The label for ADIPEX, a popular branded form of phentermine, contains reports of side effects, warnings and precautions including recommendation against coadministration of phentermine with other drugs for weight loss, reports of pulmonary hypertension, valvular heart disease, drug abuse and dependence, overstimulation, restlessness, dizziness, insomnia, euphoria, dysphoria, tremor, headache, dryness of the mouth, diarrhea, constipation, impotence and changes in libido. The labels for both of these products are often updated and should be reviewed for the most current warnings and precautions. We are unable to determine which, if any, of these side effects and warnings will be contained in the label for Qnexa if approved. We are also unable to determine the impact on the future commercial potential of Qnexa, and ultimately the Company, if any of these side effects and warnings is included in the label for Qnexa.



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To date, the clinical results we have obtained do not necessarily predict that the results of further testing, including larger, late-stage controlled human clinical testing, will be successful. If our trials are not successful or are perceived as not successful by the FDA or physicians, our business, financial condition and results of operations will be materially harmed.

**Our investigational product candidate, Qnexa, is a combination of drugs approved individually by the FDA that are commercially available and marketed by other companies. As a result, our product may be subject to substitution and competition.**

We anticipate that each of the approved drugs that are combined to produce our investigational product candidate, Qnexa, will be commercially available at prices lower than the price at which we would seek to market our investigational product candidate. We cannot be sure that physicians will view Qnexa as sufficiently superior to a treatment regime of the individual active pharmaceutical ingredients as to justify the significantly higher cost we expect to seek for Qnexa, and they may prescribe the individual drugs already approved and marketed by other companies instead of our combination product. Even though our U.S. patent contains composition, product formulation and method-of-use claims that we believe protect Qnexa, that patent may be ineffective as a practical matter to protect against physicians prescribing the individual drugs marketed by other companies instead of our combination product. To the extent that the price of Qnexa is significantly higher than the prices of the individual components as marketed by other companies, physicians may have a greater incentive to write prescriptions for the individual components instead of for our combination product, and this may limit how we price or market Qnexa. Similar concerns could also limit the reimbursement amounts private health insurers or government agencies in the U.S. are prepared to pay for Qnexa, which could also limit market and patient acceptance of our product, and could negatively impact our revenues. A physician could seek to prescribe off-label generics in place of Qnexa. Off-label use occurs when a drug that is approved by the FDA for one indication is legally prescribed by physicians for a different, unapproved indication. Topiramate, one of the ingredients in Qnexa, is not approved for obesity treatment.

In many countries where we may plan to market Qnexa, including Europe, Japan and Canada, the pricing of prescription drugs is controlled by the government or regulatory agencies. Regulatory agencies in these countries could determine that the pricing for Qnexa should be based on prices for its active pharmaceutical ingredients when sold separately, rather than allowing us to market Qnexa at a premium as a new drug.

**The FDA and other regulatory agencies will likely require more extensive or expensive trials for our combination investigational product candidate, Qnexa, than may be required for single agent pharmaceuticals.**

To obtain regulatory approval for Qnexa, we will be required to show that each active pharmaceutical ingredient in our investigational product candidate makes a contribution to the combined investigational product candidate's claimed effects and that the dosage of each component, including amount,

frequency and duration, is such that the combination is safe and effective. As a result, we will be required to include in our clinical trials an evaluation of each component drug as well as for the component drug in combination. This would likely require us to conduct more extensive and more expensive clinical trials than would be the case for many single agent pharmaceuticals. The need to conduct such trials could make it more difficult and costly to obtain regulatory approval of Qnexa than of a new drug containing only a single active pharmaceutical ingredient. The OB-301, or EQUATE trial, is designed to meet the combination guidelines set by the FDA. This trial was fully enrolled in March 2008. Data from this study is expected to be available in December 2008.



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**We are exposed to risks related to collaborative arrangements, licenses or strategic alliances.**

We have and will continue to in-license investigational product candidates from third parties. The United States rights to Evamist and Luramist were licensed from Acrux and its related affiliates. The rights to avanafil were licensed from Tanabe. The rights to Evamist were sublicensed to K-V upon closing of the sale of Evamist to K-V and in August 2008, we assigned all of our rights and obligations under the Evamist license agreement to K-V. These types of licensing agreements contain certain obligations. Failure to comply with the terms of the agreements could result in the early termination of these agreements. We believe we are in compliance with all the material terms of our current agreements; however, there can be no assurance that this compliance will continue or that the licensors would not have a differing interpretation of the material terms of the agreements. If the license agreements were terminated early or if the terms of the license were contested for any reason, it would have a material adverse impact on our ability to commercialize products subject to these agreements, our ability to raise funds to finance the company, our stock price and our overall financial condition.

VIVUS and Acrux Limited, or Acrux, are parties to the Testosterone Development and Commercialization Agreement, or the Testosterone Agreement, and the Estradiol Development and Commercialization Agreement, or the Evamist Agreement, each dated February 12, 2004, or collectively, the Acrux Agreements. The Acrux Agreements cover our investigational product candidate, Luramist, and our former investigational product candidate, Evamist, both of which were in-licensed from Acrux under the Acrux Agreements. We received a letter dated November 13, 2006 from legal counsel for Acrux containing various claims of breach under the Acrux Agreements. We responded that there is no merit to Acrux's claims and that we have meritorious defenses to such claims. Acrux has since approved the Company's assignment of the Company's rights and obligations under the Evamist Agreement to K-V as part of K-V's purchase of Evamist and released the Company from any claims or liabilities arising from the Evamist Agreement. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding its claims related to Luramist. Acrux's demand seeks a reversion of all rights assigned to VIVUS related to Luramist, monetary damages, a portion of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. We continue to believe that we are in compliance with all material aspects of the Testosterone Agreement and that we do not owe monetary damages or any milestone payment under the Testosterone Agreement. We also believe that we have valid counterclaims against Acrux and we have requested that we be allowed to include such counterclaims in the arbitration. Otherwise, the arbitration process is proceeding, with the parties having selected and qualified a panel of three arbitrators and having agreed to a schedule of pre-hearing discovery. Absent a resolution of the dispute, the arbitration hearing is currently scheduled to commence in January 2009. The arbitration proceedings have also appeared to have a detrimental impact on our discussions with potential partners. We may have to await the outcome of the arbitration process before proceeding with our partnering discussions. In the event that Acrux should prevail in this matter, it could have a material adverse effect on our business, financial condition and results of operations and cash flow.

**We are dependent upon collaborative arrangements and strategic alliances.**

We are, and in the future expect to be, dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of some of our investigational product candidates, particularly after the Phase 2 stage of clinical testing. These arrangements may place the development of our investigational product candidates outside of our control, may require us to relinquish important rights, or may otherwise be on terms unfavorable to us. In October 2007, Tanabe and Mitsubishi Pharma Corporation completed their merger and announced their name change to Mitsubishi Tanabe Pharma Corporation, or Mitsubishi Tanabe. We currently have a collaboration agreement with Mitsubishi Tanabe and it is unclear at this time what effect, if any, the merger will have on our agreement with Tanabe. There can be no guarantee that the merger of Tanabe and Mitsubishi will not have an adverse material effect on our agreement with Tanabe, which in turn could lead to a material adverse effect on our business, financial condition and results of operations.

We may be unable to locate and enter into favorable agreements with third parties, which could delay or impair our ability to develop and commercialize our investigational product candidates and could increase our costs of development and commercialization. Dependence on collaborative arrangements or strategic alliances will subject us to a number of risks, including the risk that:

· we may not be able to control the amount and timing of resources that our collaborators may devote to the investigational product candidates;

· our collaborators may experience financial difficulties;

· we may be required to relinquish important rights such as marketing and distribution rights;



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· business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;

· a collaborator could independently move forward with a competing investigational product candidate developed either independently or in collaboration with others, including our competitors; and

· collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our investigational product candidates.

**We face significant governmental regulation during our product development activities.**

The research, testing, manufacturing, selling and marketing of investigational product candidates are subject to extensive regulations by the FDA and other regulatory agencies in the United States and other countries. We cannot predict with certainty if or when we might submit for regulatory review those investigational product candidates currently under development. The FDA can suspend or modify clinical studies at any time if the agency believes that the subjects participating in such studies are being exposed to unacceptable health risks.

Regulatory approval is never guaranteed, and the approval process typically takes several years and is extremely expensive. The FDA has substantial discretion in the drug approval process. Despite the time and expense involved, failure can occur at any stage.

In July 2008, an FDA advisory panel discussed the role of cardiovascular outcomes assessment in the pre-approval and post-approval settings for drugs and biologics developed for the treatment of type 2 diabetes mellitus. The panel recommended that sponsors conduct a long-term cardiovascular trial or to provide other equivalent evidence to rule out an unacceptable cardiovascular risk; however, the panel did not reach consensus as to the timing of the study. A long-term cardiovascular study would take several years to complete and would require resources that may be beyond our current capabilities. Qnexa, in development for obesity and diabetes, may be subject to this requirement. If we are required to complete a long-term cardiovascular study for Qnexa, the ultimate approval may be delayed for several years and the overall cost of the program will increase.

In June 2007, an FDA advisory panel recommended against approval of rimonabant, an oral obesity treatment targeting the CB1 receptor system being developed by another company. Rimonabant is a centrally acting drug that reduces patients' desire to eat. The advisory panel expressed concerns about the impact of the drug on depressed patients and also expressed concerns about patients having thoughts about suicide. In addition, concerns about rimonabant's mechanism of action and interference with the CB1 receptor pathway were also voiced. The company withdrew its NDA for rimonabant shortly after the advisory panel meeting.

In December 2004, an FDA advisory panel recommended against approval of a testosterone patch under development by another company to address female sexual dysfunction, specifically hypoactive sexual desire disorder. The FDA indicated that more safety data would be required before it would be in a position to recommend approval. Subsequently, this company withdrew its NDA. We are developing an investigational transdermal testosterone product candidate, Luramist, which is designed to address hypoactive sexual desire disorder. We recently reached agreement with the FDA regarding the long-term cardiovascular event study that we must complete prior to submitting Luramist for approval. We estimate we will have to enroll a minimum of 5,200 patients, over the age of 50, with one cardiovascular risk factor. The average minimum exposure to Luramist in the safety study is 12 months. The safety study is an events-driven study and patients will be followed until the minimum number of pre-defined cardiovascular events has occurred. Despite the agreement with the FDA on the size and scope of the safety study, we may be required to undertake additional or expanded clinical trials, which could be expensive and the cause of significant delays in our ability to submit our investigational product candidate to the FDA for consideration. In the end, we may be unsuccessful in obtaining FDA approval of Luramist or any of our investigational product candidates.

We are not permitted to market any of our investigational product candidates in the United States until we receive approval from the FDA. As a consequence, any failure to obtain or delay in obtaining FDA approval for our investigational product candidates would delay or prevent our ability to generate revenue from our investigational product candidates, which would adversely affect our financial results and our business.



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**Our applications for regulatory approval could be delayed or denied due to problems with studies conducted before we licensed some of our investigational product candidates from third parties.**

We currently license some of our investigational product candidates from third parties. Our present development programs involving these investigational product candidates rely in part upon previous development work conducted by third parties over whom we had no control and before we licensed the investigational product candidates. In order to receive regulatory approval of an investigational product candidate, we must present to the FDA for its review all relevant data and information obtained during research and development, including research conducted prior to our license of the investigational product candidate. Although we are not currently aware of any such problems, any problems that emerge with research and testing conducted prior to our licensing an investigational product candidate may affect future results or our ability to document prior research and to conduct clinical trials, which could delay, limit or prevent regulatory approval for our investigational product candidates.

**Following regulatory approval of any investigational product candidates, we would be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our potential drugs.**

If one of our investigational product candidates is approved by the FDA or by another regulatory authority for a territory outside of the United States, we will be held to extensive regulatory requirements over product manufacturing, labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the investigational product candidates or who we may distribute to. Potentially costly post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. For example, the safety study for Luramist will require us to follow patients for five years in order to assess potential cardiovascular risks and breast cancer. While we may submit an NDA for Luramist after patients have had an average exposure of 12 months and a minimum number of predefined cardiovascular incidences have occurred, there can be no assurance that Luramist will be approved or, if approved, that safety issues would not arise subsequent to such approval. Previously unknown problems with the investigational product candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could lead to the withdrawal of the drug from the market.

In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our investigational product candidates. We cannot predict the likelihood, nature, extent or effects of government regulation that may arise from future legislation or administrative action, either in the U.S. or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market our products and our business could suffer.

**We rely on third parties to conduct pre-clinical and clinical trials and studies for our investigational product candidates in development and those third parties may not perform satisfactorily.**

We do not have the ability to conduct pre-clinical or clinical studies for our investigational product candidates without the assistance of third parties who conduct the studies on our behalf. These third parties are usually toxicology facilities, safety monitoring companies and clinical research organizations, or

CROs, that have significant resources and experience in the conduct of pre-clinical and clinical studies. The toxicology facilities conduct the pre-clinical safety studies as well as all associated tasks connected with these studies. Safety monitoring companies collect reported adverse events that are reported from subjects during clinical trials. The CROs typically perform patient recruitment, project management, data management, statistical analysis, and other reporting functions. We intend to use several different toxicology facilities and CROs for all of our pre-clinical and clinical studies. We have contracted with a safety monitoring company that we intend to use for all of our clinical trials. If these third party toxicology facilities, the safety monitoring company or CROs do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approvals for our investigational product candidates on a timely basis, if at all, and we may not be able to successfully commercialize these investigational product candidates. If these third party toxicology facilities, the safety monitoring company or CROs do not perform satisfactorily, we may not be able to locate acceptable replacements or enter into favorable agreements with them, if at all.

**We rely on third parties to manufacture sufficient quantities of compounds for use in our pre-clinical and clinical trials and future commercial operations and an interruption to this service may harm our business.**

We do not have the ability to manufacture the materials we use in our pre-clinical and clinical trials and future commercial operations. Rather, we rely on various third parties to manufacture these materials and there may be long lead times to obtain materials. There can be no assurance that we will be able to identify, qualify and obtain prior regulatory approval for additional sources of clinical materials. If interruptions in this supply occur for any reason, including a decision by the third parties to discontinue manufacturing, technical difficulties, labor disputes or a failure of the third parties to follow regulations, we may not be able to obtain regulatory approvals for our investigational product candidates and may not be able to successfully commercialize these investigational product candidates.



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We have completed the development of a once-a-day formulation of Qnexa. The contract manufacturer we have selected to develop a once-a-day formulation is supplying the entire product for the Phase 3 program. In addition, this contract manufacturer is our sole-source of clinical supplies for Qnexa. Stability data of the once-a-day capsule and the active pharmaceutical ingredients is limited. There can be no assurance that the final once-a-day formulation will result in sufficient safety and efficacy for approval. A failure on the stability or manufacturability of our once-a-day formulation or the inability of this contract manufacturer or any of our suppliers involved in the manufacturing of the Phase 3 supplies to carry out its contractual duties or meet expected timelines, our Qnexa clinical studies would be delayed which may have a material adverse impact on our development plan, market price of our common stock and financial condition.

We have requested Mitsubishi Tanabe to manufacture materials for the pivotal Phase 3 trials for avanafil. While the materials have been manufactured and are currently in the U.S. for packaging, we will not be able to initiate the clinical trials of avanafil prior to the receipt of the materials from Mitsubishi Tanabe. The failure to receive the materials on the expected timeline would delay the start of the studies and could have a material adverse effect on our market price for our common stock, our ability to raise additional funds and on the estimated costs of the studies.

**Risks Relating to our Operations**

**If we, or our suppliers, fail to comply with FDA and other government regulations relating to our manufacturing operations, we may be prevented from manufacturing our products or may be required to undertake significant expenditures to become compliant with regulations.**

After regulatory approval for a product is obtained, the product is subject to continual regulatory review. Manufacturing, labeling and promotional activities are continually regulated by the FDA and equivalent foreign regulatory agencies. For example, our third party manufacturers are required to maintain satisfactory compliance with current Good Manufacturing Practices, or cGMP. If these manufacturers fail to comply with applicable regulatory requirements, our ability to manufacture, market and distribute our products may be adversely affected. In addition, the FDA could issue warning letters or could require the seizure or recall of products. The FDA could also impose civil penalties or require the closure of our manufacturing facility until cGMP compliance is achieved.

We obtain the necessary raw materials and components for the manufacture of MUSE as well as certain services, such as testing and sterilization, from third parties. We currently contract with suppliers and service providers, including foreign manufacturers. We and these suppliers and service providers are required to follow cGMP requirements and are subject to routine and unannounced inspections by the FDA and by state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Upon inspection of these facilities, the FDA or foreign regulatory agencies may find the manufacturing process or facilities are not in compliance with cGMP requirements and other regulations.

We are required to obtain FDA, European Medicines and Healthcare products Regulatory Agency, and other regulatory agency approvals for any change in suppliers or service providers. For example, MUSE is supplied to the market with the MUSE applicator, containing the MUSE dosage, enclosed within a sealed foil pouch. Our previous supplier of the MUSE laminated foil has closed its business. The laminated foil is used to make the sealed foil pouch, described above, which is used to make the MUSE primary product container. Before this previous supplier closed its business, the supplier produced a bulk-quantity of foil that currently is expected to be sufficient to support the production of MUSE for our international markets through the end of the fourth quarter of 2008. There can be no assurance that as this bulk supply is used through the end of the fourth quarter of 2008 for international product, that there will be a sufficient yield in the final quantity of foil with acceptable quality to support the international MUSE demand. Although the foil supplier produced this bulk unprinted foil, the label printing will be done periodically. As a consequence, if there are unacceptable quality issues with the bulk foil, they may not be discovered as the bulk material is used through the end of the fourth quarter of 2008. If such foil quality issues do occur, we may be unable to meet international MUSE demand through the end of the fourth quarter of 2008.

We have a new vendor for the MUSE laminated foil and the use of this new vendor for the production of MUSE has been approved by regulatory agencies in both our U.S. and international markets. However, as supplies from this new vendor are introduced into the MUSE manufacturing process once the supplies from our previous foil vendor become exhausted, there can be no assurance that unforeseen supply, quality or production issues will not occur that may disrupt or cause the suspension of MUSE manufacturing. If we are unable to successfully integrate the foil from our new vendor into the MUSE manufacturing process, it could have a material adverse effect on our business, financial condition and results of operations.

Non-conformance issues may occur in our manufacturing operations or in the operations of our vendors and suppliers which could have an adverse impact on our ability to manufacture our products and investigational product candidates. For example, in late March 2008, we identified a non-conformance issue in one container of a raw material for MUSE, as supplied by the raw material vendor. All MUSE units manufactured from this bottle were within the VIVUS held inventory, were separated from our other inventory and will not be distributed. As required, we appropriately notified the FDA of this raw material incident. In a timely manner, we completed an investigation of this non-conformance which concluded that the impact of this raw material non-conformance was limited to those units of MUSE produced from the one subject container. All of these units had already been identified and separated out of our normal inventory. We have also shared our findings and actions directly with the FDA. Although we believe this incident to be complete from a product impact point of view, there can be no assurance that any further raw material non-conformance would not have a much greater negative impact to production, inventory supply, market demand supply, or even require a recall of previously distributed MUSE units. Additionally, as the financial impact of this non-conformance has not yet been negotiated with the raw material vendor, there can be no assurance that such negotiations would not avert raw material supply problems, which could then lead to a long-term interruption in our ability to manufacture MUSE and an adverse impact on the sales of MUSE and the resultant amounts collected or to be collected from the sales of MUSE. In addition, the costs associated with the interruption in supply could be great and our future financial results could be adversely affected.

Failure to achieve satisfactory cGMP compliance as confirmed by routine and unannounced inspections could have a material adverse effect on our ability to continue to manufacture and distribute our products and, in the most serious case, result in the issuance of a regulatory warning letter or seizure or recall of products, injunction and/or civil penalties or closure of our manufacturing facility until cGMP compliance is achieved.

**If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.**

As a manufacturer of pharmaceuticals, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third party payors, certain federal and state healthcare laws and regulations pertaining to fraud, abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud, abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, but are not limited to:

· the federal healthcare program Anti-Kickback Law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

· federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers or promoting our commercial products for "off-label" use;

· the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

· state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.





**Our marketing activities for our products are subject to continued governmental regulation.**

After product approval by the FDA, our marketing activities will be subject to FDA and other regulatory review. If products are marketed in contradiction with FDA mandates, the FDA may issue warning letters that require specific remedial measures to be taken, as well as an immediate cessation of the impermissible conduct resulting in adverse publicity. The FDA may also order that all future promotional materials receive prior agency review and approval before use. For example, the FDA issued a warning letter to us in May 2004 in which the FDA objected to a specific television commercial as well as information contained on our website promoting MUSE, our FDA approved product for the treatment of erectile dysfunction. The letter indicated that we had failed to disclose or had minimized certain risks associated with MUSE. Through discussions with the FDA, we agreed to produce and have released a television commercial that we believe corrected the prior message and addressed the FDA's concerns. We incurred costs in providing this corrective information, which would have otherwise been utilized by us in a different manner. In March 2005, we received a letter from the FDA indicating that the matter had been closed.

**We must continue to monitor the use of our approved products and may be required to complete post-approval studies mandated by the FDA.**

Even if we receive regulatory approval of our investigational product candidates, such approval may involve limitations on the indicated uses or marketing claims we may make for our products. For example, the safety study for Luramist requires that we follow subjects for five years in total to detect cardiovascular events and breast cancer. Further, later discovery of previously unknown problems for Luramist or any of our investigational product candidates could result in additional regulatory restrictions, including withdrawal of products. The FDA may also require us to commit to perform lengthy

post-approval studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results, financial condition and stock price. Failure to comply with the applicable regulatory requirements can result in, among other things, civil penalties, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition, results of operations and stock price.

**We depend exclusively on third party distributors outside of the United States and we have very limited control over their activities.**

We entered into an agreement granting Meda exclusive marketing and distribution rights for MUSE in member states of the European Union. Meda currently sells MUSE in the United Kingdom, Ireland, Sweden, Norway, Germany, Switzerland, Denmark, Finland, France and the Netherlands. This agreement does not have minimum purchase commitments and we are entirely dependent on Meda's efforts to distribute and sell MUSE effectively in all these markets. There can be no assurance that such efforts will be successful or that Meda will continue to support MUSE.

We entered into an agreement granting Paladin Labs, Inc. exclusive marketing and distribution rights for MUSE in Canada. This agreement does not have minimum purchase commitments and we are entirely dependent on Paladin Labs' efforts to distribute and sell our product effectively in Canada. There can be no assurance that such efforts will be successful or that Paladin Labs will continue to support the product.

**Sales of our current and any future products are subject to continued governmental regulation, our ability to accurately forecast demand and our ability to produce sufficient quantities to meet demand.**

Sales of our products both inside and outside the United States will be subject to regulatory requirements governing marketing approval. These requirements vary widely from country to country and could delay the introduction of our proposed products in those countries. After the FDA and international regulatory authorities approve a product, we must manufacture sufficient volumes to meet market demand. This is a process that requires accurate forecasting of market demand. There is no guarantee that there will be market demand for any future products or that we will be able to successfully manufacture or adequately support sales of any future products.

**We have limited sales and marketing capabilities in the United States.**

We support MUSE sales in the United States through a small direct sales force targeting major accounts. Telephone marketers also focus on urologists who prescribe MUSE. Physician and patient information/help telephone lines are available to answer additional questions that may arise after reading the inserts or after actual use of the product. There can be no assurance that our MUSE sales programs will effectively maintain or potentially increase current sales levels. There can be no assurance that demand for MUSE will continue or that we will be able to adequately support sales of MUSE in the United States in the future.





If we are unable to establish capabilities to sell, market and distribute our investigational product candidates, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully launch our investigational product candidates upon FDA approval. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need. We may not be able to enter into any marketing or distribution agreements with third party providers on acceptable terms, if at all. In that event, we will not be able to generate significant revenues.

**We have little or no control over our wholesalers' buying patterns, which may impact future revenues, returns and excess inventory.**

For domestic sales we sell our product primarily to major wholesalers located in the United States. As a result, most of our revenues are derived from the three major wholesalers. We rely solely on our wholesaler customers to effect the distribution allocation of our product. There can be no assurance that these customers will adequately manage their local and regional inventories to avoid outages, build-ups or result in excessive returns for expiration.

We do not control or significantly influence the purchasing patterns of wholesale customers. These are highly sophisticated customers that purchase products in a manner consistent with their industry practices and perceived business interests. Our sales are subject to the purchasing requirements of our major customers, which presumably are based upon projected volume levels. Purchases by any customer, during any period may be above or below the actual prescription volumes of our product during the same period, resulting in increases or decreases in inventory existing in the distribution channel.

Although the demand for MUSE has stabilized, given the loss of coverage under Medicare Part D we are not able to anticipate if wholesalers will continue their historical pattern of making purchases in the fourth quarter that exceed expected quarterly demands. If wholesalers do not repeat this pattern of purchasing quantities of MUSE that exceed quarterly demands, revenues from the sale of MUSE in 2008 may be lower as compared to 2007. We have been notified that one of our larger wholesaler customers will not purchase quantities that exceed expected demand in the fourth quarter 2008 as they have in prior years.

**The markets in which we operate are highly competitive and we may be unable to compete successfully against new entrants or established companies.**

Competition in the pharmaceutical and medical products industries is intense and is characterized by costly and extensive research efforts and rapid technological progress. We are aware of several pharmaceutical companies also actively engaged in the development of therapies for the treatment of obesity, diabetes and sexual health. These companies have substantially greater research and development capabilities as well as substantially greater marketing, financial and human resources than we do. In addition, many of these companies have significantly greater experience than us in undertaking pre-clinical testing, human clinical trials and other regulatory approval procedures. Our competitors may develop technologies and products that are more effective than those we are currently marketing or researching and developing. Such developments could render our products less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

Current anti-obesity drugs include Xenical (orlistat), marketed by Roche, and Meridia (sibutramine), marketed by Abbott Labs. Orlistat works by inhibiting lipase, thus preventing digestion and absorption of dietary fat in the gastrointestinal tract. There are several drugs in development for obesity including four product candidates in Phase 3 clinical trials being developed by Merck & Co., Inc., Pfizer, Arena Pharmaceuticals, Inc., and Orexigen

Therapeutics, Inc., and approximately 20 product candidates in Phase 2 clinical trials by companies including Amylin Pharmaceuticals, Inc., Alizyme plc, Neurosearch A/S, Novo Nordisk and GlaxoSmithKline, among others.

All of these drugs are or will be marketed by pharmaceutical companies with substantially greater resources than us. In addition, a number of generic pharmaceutical products are prescribed for obesity, including phentermine, phendimetrazine, mazindol, benzphetamine and diethylpropion. Some of these generic drugs, and others, are prescribed in combinations that have shown some level of efficacy. These products are sold at much lower prices than we intend to charge for our investigational product candidate, Qnexa, if approved. The availability of a large number of branded prescription products, generic products and over-the-counter products could limit the demand for, and the price we are able to charge for, our obesity investigational product candidate.

In October 2008, Sanofi-Aventis announced that it is temporarily halting sales of its weight loss drug, Acomplia, in the wake of a recommendation by a European regulatory panel that the product be pulled off the market over safety concerns. The company is also halting all human trials of the Acomplia obesity medicine after health authorities in a few countries requested local tests be stopped. The Food and Drug Administration refused to approve the product last year over concerns it might trigger psychiatric problems in some users. A final decision on Acomplia will be made by the European Medicines Agency.

Significant competitive therapies exist for MUSE and avanafil in the form of oral medications marketed by Pfizer, Inc. under the name Viagra®, Cialis® marketed by Eli Lilly and Company, and Levitra®, which is co-marketed by GlaxoSmithKline plc and Schering-Plough Corp. in the United States.



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Other treatments for erectile dysfunction, or ED, exist, such as needle injection therapies, vacuum constriction devices and penile implants, and the manufacturers of these products will most likely continue to develop or improve these therapies. In November 2007, NexMed, Inc. announced that the NDA filed for its ED product, a topically applied alprostadil cream, was accepted for review by the FDA. NexMed has also announced that they have entered into a licensing arrangement with Warner Chilcott Company, Inc. (a subsidiary of Warner Chilcott, Ltd., Nasdaq:WCRX) granting Warner Chilcott the exclusive U.S. rights to NexMed's topically applied alprostadil cream for the treatment of ED. Under the reported terms of the agreement, Warner Chilcott has exclusive U.S. rights to develop and market NexMed's product. NexMed received an initial, up-front payment and is eligible to receive additional payments upon achievement of certain development and regulatory approval milestones. Further, Warner Chilcott will pay a royalty to NexMed on sales of the product. Specific financial details of the agreement were not disclosed. If the NDA for the NexMed product is approved and Warner Chilcott is successful in commercializing this product, the sales of MUSE will decline, which will have an adverse effect on the results of our operations and cash flows from sales of MUSE.

Several companies are developing products that could compete with our investigational product candidates for the treatment of FSD including: The Proctor & Gamble Company is developing Intrinsa, a testosterone patch for the treatment of HSDD; BioSante Pharmaceuticals, Inc. is developing forms of testosterone gels for HSDD and Palatin Technologies, Inc. is developing a nasal spray to treat FSD. None of these investigational products have been approved by the FDA. In July 2006, the European Medicines Agency granted marketing authorization of Intrinsa for the treatment of HSDD in bilaterally oophorectomized and hysterectomized women and in February 2007, Intrinsa was launched in France and Germany. In March 2007, Intrinsa became available through the National Health Service in the United Kingdom.

New developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical and medical technology industries at a rapid pace. These developments may render our investigational product candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater:

· research and development resources, including personnel and technology;

· regulatory experience;

· drug development and clinical trial experience;

· experience and expertise in exploitation of intellectual property rights; and

· access to strategic partners and capital resources.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our investigational product candidates.

**If our raw material suppliers fail to supply us with the Active Pharmaceutical Ingredients for our products and investigational product candidates, for which availability is limited, we may experience delays in our product development and commercialization.**

We are required to receive regulatory approval for suppliers. We obtained our current supply of alprostadil from two approved sources, NeraPharm, s.r.o., in the Czech Republic and Chinoin Pharmaceutical and Chemical Works Private Co., Ltd., in Hungary. We have manufacturing agreements with Chinoin and NeraPharm to produce additional quantities of alprostadil for us.

Furthermore, our current supply of alprostadil is subject to periodic re-testing to ensure it continues to meet specifications. There can be no guarantees that our existing inventory of alprostadil will pass these re-testing procedures and continue to be usable material.

Non-conformance issues may occur in our manufacturing operations or in the operations of our vendors and suppliers which could have an adverse impact on our ability to manufacture our products and investigational product candidates. For example, in late March 2008, we identified a non-conformance issue in a bottle containing 250 grams of raw material for MUSE, as supplied by the raw material vendor. All MUSE units manufactured from this bottle were within our held inventory and were separated from our other inventory. As required, we appropriately notified the FDA of this raw material incident. In a timely manner, we completed an investigation of this non-conformance which concluded that the impact of this raw material non-conformance was limited to those units of MUSE produced from the one subject container. We have also shared our findings and actions directly with the FDA. Although we believe this incident to be complete from a product impact point of view, there can be no assurance

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that any further raw material non-conformance would not have a much greater negative impact to production, inventory supply, market demand supply, or even require a recall of previously distributed MUSE units. A long-term interruption in our ability to manufacture MUSE or a recall of MUSE previously distributed could have an adverse impact on the sales of MUSE and the resultant amounts collected or to be collected from the sales of MUSE. In addition, the costs associated with the interruption in supply could be great and our future financial results could be adversely affected.

There is a long lead-time for manufacturing alprostadil. A shortage in supply of alprostadil to be used in the manufacture of MUSE would have a material adverse effect on our business, financial condition and results of operations.

In addition, we currently do not have manufacturing agreements in place for topiramate or phentermine. There can be no guarantees that we will be able to enter into such agreements under reasonable terms, if at all. We cannot guarantee that should we be successful in entering into such agreements we will be able to obtain the necessary regulatory approvals for these suppliers.

**We outsource several key parts of our operations and any interruption in the services provided by third parties could harm our business.**

Under our outsourcing agreement with Cardinal Health, Inc. related to MUSE, Cardinal Health warehouses our finished goods for United States distribution; takes customer orders; picks, packs and ships our products; invoices customers; and collects related receivables. As a result of this distribution agreement, we are heavily dependent on Cardinal Health's efforts to fulfill orders and warehouse our products effectively in the United States. There can be no assurance that such efforts will continue to be successful.

Under our testing agreement, Gibraltar Laboratories performs sterility testing on finished product manufactured by us to ensure that it complies with product specifications. Gibraltar Laboratories also performs microbial testing on water and compressed gases used in the manufacturing process and microbial testing on environmental samples to ensure that the manufacturing environment meets appropriate cGMP regulations and cleanliness standards. As a result of this testing agreement, we are dependent on Gibraltar Laboratories to perform testing and issue reports on finished product and the manufacturing environment in a manner that meets cGMP regulations.

We have an agreement with WRB Communications to handle patient and healthcare professional hotlines to answer questions and inquiries about MUSE. Calls to these hotlines may include complaints about our products due to efficacy or quality, as well as the reporting of adverse events. As a result of this agreement, we are dependent on WRB Communications to effectively handle these calls and inquiries. There can be no assurance that such efforts will be successful.

We entered into a distribution agreement with Integrated Commercialization Services, or ICS, a subsidiary of AmerisourceBergen Corporation. ICS provides direct-to-physician distribution of product samples in support of United States marketing and sales efforts. As a result of this distribution agreement, we are dependent on ICS's efforts to distribute product samples effectively.

We rely on two companies, E-Beam Services, Inc., or E-Beam, and Beam One, LLC, or Beam One, for the sterilization of MUSE. However, for some international markets, the MUSE Product License includes approval to use only one of the above listed vendors. If interruptions in these services occur for any reason, including a decision by E-Beam or Beam One to discontinue manufacturing or services, political unrest, labor disputes or a failure of E-Beam or Beam One to follow regulations, the commercial marketing of MUSE and the development of other potential products could be prevented or delayed. An extended interruption in sterilization services would have a material adverse effect on our business, financial condition and results of operations.

**We currently depend on a single source for the supply of plastic applicator components for MUSE and an interruption to this supply source could harm our business.**

We rely on a single injection molding company, Medegen Medical Products, LLC, or Medegen, for our supply of plastic applicator components. In turn, Medegen obtains its supply of resin, a key ingredient of the applicator, from a single source, Huntsman Corporation. Orders to Medegen are made on a periodic basis with purchase orders. We do not have a written agreement with Medegen for the supply of the plastic applicator components. If we are unable to obtain components from Medegen for any reason, there can be no assurance that we will be able to identify and qualify additional sources of plastic components or that Medegen will be able to identify and qualify additional sources of resin. We are required to receive FDA approval for new suppliers. Until we secure and qualify additional sources of plastic components, we are entirely dependent upon Medegen. If interruptions in this supply occur for any reason, including a decision by Medegen to discontinue manufacturing, labor disputes or a failure of Medegen to follow regulations, the manufacture and marketing of MUSE and other potential products could be delayed or prevented. An extended interruption in the supply of plastic components could have a material adverse effect on our business, financial condition or results of operations.



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**All of our manufacturing operations are currently conducted at a single location, and a prolonged interruption to our manufacturing operations could harm our business.**

We own two buildings with a total combined 90,000 square feet in Lakewood, New Jersey. This facility is used for our MUSE manufacturing operation, which includes formulation, filling, packaging, analytical laboratories, storage, distribution and administrative offices, although one of the buildings is used for warehousing component parts. The FDA and the Medicines and Healthcare products Regulatory Agency, the regulatory authority in the United Kingdom, authorized us to begin commercial production and shipment of MUSE from this facility in June and March 1998, respectively. MUSE is manufactured in this facility and we have no plans to construct another manufacturing site. Since MUSE is produced with custom-made equipment under specific manufacturing conditions, the inability of our manufacturing facility to produce MUSE for whatever reason could have a material adverse effect on our business, financial condition and results of operations.

**We are dependent upon a single approved therapeutic approach to treat erectile dysfunction.**

MUSE relies on a single approved therapeutic approach to treat erectile dysfunction, a transurethral system. The existence of side effects or dissatisfaction with this product may impact a patient's decision to use or continue to use, or a physician's decision to recommend, this therapeutic approach as a therapy for the treatment of erectile dysfunction, thereby affecting the commercial viability of MUSE. In addition, competitive products, technological changes or medical advancements could further diminish or eliminate the commercial viability of our product, the results of which could have a material effect on our business operations and results.

**If we fail to retain our key personnel and hire, train and retain qualified employees, we may not be able to compete effectively, which could result in reduced revenues.**

Our success is highly dependent upon the skills of a limited number of key management personnel. To reach our business objectives, we will need to retain and hire qualified personnel in the areas of manufacturing, sales and marketing, research and development, regulatory affairs, clinical trial management and pre-clinical testing. There can be no assurance that we will be able to hire or retain such personnel, as we must compete with other companies, academic institutions, government entities and other agencies. The loss of any of our key personnel or the failure to attract or retain necessary new employees could have an adverse effect on our research, product development and business operations.

**We are subject to additional risks associated with our international operations.**

MUSE is currently marketed internationally. Changes in overseas economic and political conditions, cultural terrorism, currency exchange rates, foreign tax laws or tariffs or other trade regulations could have an adverse effect on our business, financial condition and results of operations. The international nature of our business is also expected to subject us and our representatives, agents and distributors to laws and regulations of the foreign jurisdictions in which we operate or where our products are sold. The regulation of drug therapies in a number of such jurisdictions, particularly in the European Union, continues to develop, and there can be no assurance that new laws or regulations will not have a material adverse effect on our business, financial condition and results of operations. In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as the laws of the United States.

**Any adverse changes in reimbursement procedures by government and other third party payors may limit our ability to market and sell our products or limit our product revenues and delay profitability.**

In the United States and elsewhere, sales of pharmaceutical products are dependent, in part, on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans. Third party payors are increasingly challenging the prices charged for medical products and services. Some third party payor benefit packages restrict reimbursement or do not provide coverage for specific drugs or drug classes. While a large percentage of prescriptions in the United States for MUSE have been reimbursed to some extent by third party payors since our commercial launch in January 1997, there can be no assurance that our products will be considered cost effective and that reimbursement to the consumer will continue to be available or sufficient to allow us to sell our products on a competitive basis.



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In addition, certain healthcare providers are moving towards a managed care system in which such providers contract to provide comprehensive healthcare services, including prescription drugs, for a fixed cost per person. We are unable to predict the reimbursement policies employed by third party healthcare payors. Furthermore, reimbursement for MUSE could be adversely affected by changes in reimbursement policies of governmental or private healthcare payors.

The healthcare industry is undergoing fundamental changes that are the result of political, economic and regulatory influences. The levels of revenue and profitability of pharmaceutical companies may be affected by the continuing efforts of governmental and third party payors to contain or reduce healthcare costs through various means. Reforms that have been and may be considered include mandated basic healthcare benefits, controls on healthcare spending through limitations on the increase in private health insurance premiums and the types of drugs eligible for reimbursement and Medicare and Medicaid spending, the creation of large insurance purchasing groups and fundamental changes to the healthcare delivery system. Due to uncertainties regarding the outcome of healthcare reform initiatives and their enactment and implementation, we cannot predict which, if any, of the reform proposals will be adopted or the effect such adoption may have on us. There can be no assurance that future healthcare legislation or other changes in the administration or interpretation of government healthcare or third party reimbursement programs will not have a material adverse effect on us. Healthcare reform is also under consideration in other countries where we currently or intend to market our product.

The continuing efforts of government and third party payors to contain or reduce the costs of health care through various means may reduce our potential revenues. These payors' efforts could decrease the price that we receive for any products we may develop and sell in the future. In addition, third party insurance coverage may not be available to patients for any products we develop. If government and third party payors do not provide adequate coverage and reimbursement levels for our products, or if price controls are enacted, our product revenues will suffer.

Congress passed legislation that ended federal Medicaid and Medicare payments for erectile dysfunction drugs beginning January 1, 2006 and January 1, 2007, respectively. Historically the volume of MUSE sales to Medicaid and Medicare patients was not a significant portion of our overall MUSE sales volume. We believe there is increasing political pressure to reduce or eliminate reimbursement by the United States government for erectile dysfunction drugs. A reduction or elimination in the reimbursement by the United States government would have a material adverse impact on our revenues and business operations.

One of the active ingredients in Qnexa, phentermine is available as a generic. The other, topiramate, is subject to several patents, the first of which is set to expire in 2008. Based on the research we have completed to date, we are unable to determine if Qnexa, if approved, will be subject to reimbursement or at what level reimbursement may occur. The exact doses of the active ingredients in the final formulation of Qnexa will be different than those currently available. State pharmacy law prohibits pharmacists from substituting drugs with differing doses and formulations. The safety and efficacy of Qnexa is highly dependent on the titration, dosing and formulation which we believe could not be easily duplicated, if at all, with the use of generic substitutes. However, there can be no assurance that we will be able to provide for optimal reimbursement of Qnexa for obesity, if approved, from third party payors or the United States government. Furthermore, there can be no assurance that healthcare providers would not actively seek to provide patients generic versions of the active ingredients in Qnexa in order to treat obesity at a potential lower cost.

**Federal legislation may increase the pressure to reduce prices of pharmaceutical products paid for by Medicare, which could adversely affect our revenues, if any.**

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, expanded Medicare coverage for drug purchases by the elderly and disabled beginning in 2006. Under the MMA, private insurance plans subsidized by the government offer prescription drug coverage to Medicare beneficiaries who elect to enroll in their plans. Although almost all prescription drugs are potentially available to plan enrollees, the plans are allowed to use formularies, preferred drug lists and similar mechanisms to favor selected drugs and limit access to other drugs except in certain circumstances. The price of a drug as negotiated between the manufacturer and a plan is a factor that the plan can consider in determining its availability to enrollees.

As a result, we expect that there will be increased pressure to reduce prices for drugs to obtain favorable status for them under the plans offering prescription drug coverage to Medicare beneficiaries. This pressure could decrease the coverage and price that we receive for our products in the future and could seriously harm our business. It is possible that our investigational product, Qnexa, if approved, could be particularly subject to price reduction initiatives because it is based on combinations of lower priced existing drugs.

In addition, some members of Congress advocate that the federal government should negotiate directly with manufacturers for lower prices for drugs in the Medicare program, rather than rely on private plans. If the law were changed to allow or require such direct negotiation, there could be additional reductions in the coverage of and prices that we receive for our products.

**Recent federal legislation and actions by state and local governments may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could adversely affect our operating results and our overall financial condition.**

We may face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products. The Medicare Prescription Drug Improvement and Modernization Act of 2003 contains provisions that may change United States importation laws and expand consumers' ability to import lower priced versions of our investigational product candidates and competing products from Canada, where there are government price controls. These changes to United States importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The Secretary of Health and Human Services has not yet announced any plans to make this required certification. As directed by Congress, a task force on drug importation conducted a comprehensive study regarding the circumstances under which drug importation could be safely conducted and the consequences of importation on the health, medical costs and development of new medicines for United States consumers. The task force issued its report in December 2004, finding that there are significant safety and economic issues that must be addressed before importation of prescription drugs is permitted. In addition, a number of federal legislative proposals have been made to implement the changes to the United States importation laws without any certification, and to broaden permissible imports in other ways. Even if the changes do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, the United States Customs Service and other government agencies. For example, Pub. L. No. 109-295, which was signed into law in October 2006 and provides appropriations for the Department of Homeland Security for the 2007 fiscal year, expressly prohibits the United States Customs Service from using funds to prevent individuals from importing from Canada less than a 90-day supply of a prescription drug for personal use, when the drug otherwise complies with the Federal Food, Drug, and Cosmetic Act. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our own products could negatively impact our financial condition.

**Defending against claims relating to improper handling, storage or disposal of hazardous materials could be time consuming and expensive.**

Our research and development involves the controlled use of hazardous materials and our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from those materials. Various laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.





**Our business and operations would suffer in the event of system failures.**

Despite the implementation of security measures, our internal computer systems and those of our CROs, safety monitoring company and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs and drug manufacturing operations. For example, the loss of clinical trial data from completed or ongoing clinical trials for our investigational product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our investigational product candidates could be delayed.

**Natural disasters or resource shortages could disrupt our operations and adversely affect results.**

Our MUSE manufacturing operation is conducted in a single location in Lakewood, New Jersey. In the event of a natural disaster in that region, such as a storm, drought or flood, or localized extended outages of critical utilities or transportation systems, we do not have a formal business continuity or disaster plan, and could therefore experience a significant business interruption.

Furthermore, our ongoing or planned clinical trials could be delayed or disrupted indefinitely upon the occurrence of a natural disaster. For example, in 2005, our clinical trials in the New Orleans area were interrupted by Hurricane Katrina. Future natural disasters could further delay our clinical trials process, thus adversely affecting our business and financial results.

**Risks Relating to our Intellectual Property**

**We may be sued for infringing the intellectual property rights of others or others may infringe on our intellectual property rights.**

There can be no assurance that our products do not or will not infringe on the patent or proprietary rights of others. Third parties may assert that we are employing their proprietary technology without authorization. For example, in October 2002, the United States Patent and Trademark Office, or the USPTO, issued to Pfizer a method of use patent, U.S. Patent No. 6,469,012. Pfizer immediately initiated litigation against competitors who were selling PDE5 inhibitors, including ICOS, the maker of Cialis. In September 2003, the USPTO ordered the reexamination of the patent. In a related action, the European Patent Office revoked Pfizer's European patent. However, if the claims under the method of use patent are upheld by the USPTO, we may be prevented from commercializing avanafil, our PDE5 inhibitor, if approved by the FDA.

In addition, third parties may already own or may obtain patents in the future and claim that use of our technologies infringes these patents. We could incur substantial costs and diversion of the time and attention of management and technical personnel in defending ourselves against any such claims. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief that could effectively block our ability to further develop, commercialize and sell products, and such claims could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, if at all. In that case, we could encounter delays in product introductions while we attempt to develop alternative methods or products or be required to cease commercializing affected products and our operating results would be harmed.

The Supreme Court ruling in *KSR International Co. vs. Teleflex, Inc.*, will raise the standards for patentability and ease the ability to show that a patent is obvious. This ruling will make it more difficult to obtain patents for combination pharmaceutical products. At the present time, we are unable to predict the impact, if any, that this ruling will have on our current or future patents. If we are unable to defend the patents currently issued on our commercial product and investigational product candidates, or to obtain new patents for any reason, our ability to commercialize the current and future products would be at risk.

**Our inability to adequately protect our proprietary technologies could harm our competitive position and have a material adverse effect on our business.**

We hold various patents and patent applications in the United States and abroad targeting obesity, diabetes and male and female sexual health among other products. Qnexa is our investigational product candidate involving low doses of topiramate and phentermine. On June 6, 2006, the initial United States patent was issued by the USPTO. This patent contains composition, product, and other claims that should protect Qnexa, if approved, as a proprietary product for the treatment of obesity. The term of



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this patent extends into 2019. The corresponding European patent with similar claims has been approved for grant. We are in the process of prosecuting patent applications in other countries as well, to obtain significant foreign patent coverage for both Qnexa and future generations of Qnexa. Furthermore, we have filed additional patent applications in the United States to expand the coverage that will be provided by U.S. Patent No. 7,056,890 B2. The primary focus of the patent applications is on combination therapy using a sympathomimetic agent (such as phentermine) and an anticonvulsant (such as topiramate) for the treatment of obesity and other related disorders. We are aware of an issued patent for the use of topiramate for obesity. We have worked closely with our patent counsel to put together a cogent patent strategy and are building a strong patent portfolio in an attempt to obtain exclusivity over the life of the patents.

The success of our business depends, in part, on our ability to obtain patents and maintain adequate protection of our intellectual property for our proprietary technology and products in the United States and other countries. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting their proprietary rights in these foreign countries. These problems can be caused by, for example, a lack of rules and processes allowing for meaningful defense of intellectual property rights. If we do not adequately protect our intellectual property, competitors may be able to use our technologies' and erode our competitive advantage, and our business and operating results could be harmed.

The patent positions of pharmaceutical companies, including our patent positions, are often uncertain and involve complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We apply for patents covering our technologies and products, as we deem appropriate. However, we may not obtain patents on all inventions for which we seek patents, and any patents we obtain may be challenged and may be narrowed in scope or extinguished as a result of such challenges. We could incur substantial costs in proceedings before the USPTO, including interference proceedings. These proceedings could also result in adverse decisions as to the priority of our inventions. There can be no assurance that our patents will not be successfully challenged or designed around by others.

Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Others may independently develop similar or alternative technologies or design around our patented technologies or products. These companies would then be able to develop, manufacture and sell products that compete directly with our products. In that case, our revenues and operating results would decline.

We seek to protect our confidential information by entering into confidentiality agreements with employees, collaborators, consultants and potential investors. Nevertheless, employees, collaborators, consultants or potential investors may still disclose or misuse our confidential information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent information or techniques or otherwise gain access to our trade secrets. Disclosure or misuse of our confidential information would harm our competitive position and could cause our revenues and operating results to decline.

**We may be subject to claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of their former employers.**

We employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although we have no knowledge of any pending or overtly threatened claims, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.



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**We may be unable to in-license intellectual property rights or technology necessary to develop and commercialize our products.**

Depending on its ultimate formulation and method of use, before we can develop, clinically test, make, use, or sell a particular investigational product candidate, we may need to obtain a license from one or more third parties who have patent or other intellectual property rights covering components of our investigational product candidate or its method of use. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If a third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable to develop and commercialize one or more of our investigational product candidates.

**Risks Relating to our Financial Position and Need for Financing**

**We require additional capital for our future operating plans, and we may not be able to secure the requisite additional funding on acceptable terms, or at all.**

We expect that our existing capital resources combined with future anticipated cash flows will be sufficient to support our operating activities at least through the end of 2009. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development pipeline in future periods as well as to support the possible launch of any future products. Our future capital requirements will depend upon numerous factors, including:

· the progress and costs of our research and development programs;

· the scope, timing and results of pre-clinical studies and clinical trials;

· patient recruitment and enrollment in planned and future clinical trials;

· the costs involved in seeking regulatory approvals for our investigational product candidates;

· the costs involved in filing and pursuing patent applications, defending and enforcing patent claims;

· the establishment of collaborative and strategic alliances and the related costs;

· the cost of manufacturing and commercialization activities and arrangements;

· the results of operations;

· demand for MUSE;

· the potential forced purchase of the royalty streams we previously sold to Deerfield;

· the cost, timing and outcome of regulatory reviews;

· the rate of technological advances;

· ongoing determinations of the potential commercial success of our investigational product candidates under development;

· the level of resources devoted to sales and marketing capabilities; and

· the activities of competitors.

To obtain additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of equity or debt securities, corporate alliances, joint ventures and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all. The equity capital markets appear to be closed at the present time and we estimate that they will remain closed for several months. As such, our ability to raise capital though the issuance of new equity is extremely limited. We are continually evaluating our existing portfolio and we may choose to divest, sell or spin-off one or more of our products or investigational product candidates at any time. We cannot assure you that we will successfully



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develop our investigational product candidates under development or, if successfully developed or approved, that our products will generate revenues sufficient to enable us to earn a profit. If we are unable to obtain additional capital, management may be required to explore alternatives to reduce cash used by operating activities, including the termination of research and development efforts that may appear to be promising to us, the sale of certain assets and the reduction in overall operating activities.

**We have an accumulated deficit of $173.1 million as of September 30, 2008 and we may continue to incur substantial operating losses for the future.**

We have generated a cumulative net loss of $173.1 million for the period from our inception through September 30, 2008, and we anticipate losses in future years due to increased investment in our research and development programs. There can be no assurance that we will be able to achieve or maintain profitability or that we will be successful in the future.

**Our ability to utilize our net operating loss carryforwards to offset future taxable income may be limited.**

As of December 31, 2007, we had approximately $7 million of net operating loss, or NOL, carryforwards with which to offset our future taxable income for federal and state income tax reporting purposes. We used $121.6 million federal and $38.7 million state NOLs to offset our year ended December 31, 2007 federal and state tax liabilities, which included the $150 million in gain recognized from the Evamist sale. The Internal Revenue Code of 1986, as amended, contains provisions that may limit the net operating loss and credit carryforwards available for use in any given period upon the occurrence of certain events, including significant change in ownership interest. Should this occur, our future ability to use NOLs to offset taxable earnings would be limited in accordance with the Internal Revenue Code.

**We may be unable to collect on our claim for reimbursement of product and establishment and NDA application fees from the FDA.**

We believe we are due a refund pursuant to Section 736(d)(1)(C) of the Federal Food, Drug and Cosmetic Act, or FDC Act from the FDA for product and establishment fees paid in 2006 and 2007 and for the NDA application fee for Evamist paid in 2006 on the basis that the fees paid exceed the anticipated present and future costs incurred by the FDA in conducting the process for the review of human drug applications for VIVUS, Inc. To date, we have collected $767,000 from the FDA. We believe that we will collect these remaining refund amounts from the FDA; however, should we be unable to collect on these claims, we will be required to reverse all or some part of these remaining receivables.

**If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.**

The commercial sale of MUSE and our clinical trials expose us to a significant risk of product liability claims. In addition, pharmaceutical products are subject to heightened risk for product liability claims due to inherent side effects. We identify potential side effects in the patient package insert and the physician package insert, both of which are distributed with MUSE. While we believe that we are reasonably insured against these risks, we may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. A product liability claim in excess of, or excluded from, our insurance coverage would have to be paid out of cash reserves and could have a material adverse effect upon our business, financial condition and results of operations. Product liability insurance is expensive, difficult to maintain, and current or increased coverage may not be available on acceptable terms, if at all.

**Risks Relating to an Investment in our Common Stock**

**Our stock price has been and may continue to be volatile.**

The market price of our common stock has been volatile and is likely to continue to be so. The market price of our common stock may fluctuate due to factors including, but not limited to:

· the clinical trial programs for Qnexa;

· announcements of technological innovations or new products by us or our competitors;

· announcements by licensors of our technology;

· our ability to increase demand for our products in the United States and internationally;



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· our ability to successfully sell our products in the United States and internationally;

· actual or anticipated fluctuations in our financial results;

· our ability to obtain needed financing;

· economic conditions in the United States and abroad;

· the volatility and liquidity of the financial markets;

· comments by or changes in assessments of us or financial estimates by security analysts;

· adverse regulatory actions or decisions;

· any loss of key management;

· the results of our clinical trials or those of our competitors;

· developments or disputes concerning patents or other proprietary rights;

· licensing, product or patent litigation; and

· public concern as to the safety of products developed by us.

These factors and fluctuations, as well as political and market conditions, may adversely affect the market price of our common stock. Securities class action litigation is often brought against a company following periods of volatility in the market price of its securities. We may be the target of similar litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm our business and financial condition, as well as the market price of our common stock.

Additionally, volatility or a lack of positive performance in our stock price may adversely affect our ability to retain or recruit key employees, all of whom have been or will be granted stock options as an important part of their compensation packages.

**Volatility in the stock prices of other companies may contribute to volatility in our stock price.**

The stock market in general, and the NASDAQ Global Market and the market for life sciences companies in particular, have experienced significant price and volume fluctuations. Further, there has been particular volatility in the market prices of securities of early stage and development stage life sciences companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

**Our share ownership is concentrated, and our officers, directors and principal stockholders acting collectively can exert significant control over matters requiring stockholder approval.**

Due to their combined stock holdings, our officers, directors and principal stockholders (stockholders holding greater than 5% of our common stock) acting collectively may have the ability to exercise significant influence over matters requiring stockholder approval including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in control of our company and may make some transactions more difficult or impossible to complete without the support of these stockholders.

**Our operating results may fluctuate from quarter to quarter and this fluctuation may cause our stock price to decline.**

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. Factors contributing to these fluctuations include, among other items, the timing and enrollment rates of clinical trials for our drug candidates, the timing of significant purchases of MUSE by distributors, the timing of recognition of deferred revenue, and our need for clinical supplies. Thus, quarter-to-quarter comparisons of our operating results are not indicative of what we might expect in the future. As a result, in some future quarters our operating results may not meet the expectations of securities analysts and investors, which could result in a decline in the price of our stock.



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**There may not be an active, liquid trading market for our common stock.**

There is no guarantee that an active trading market for our common stock will be maintained on the NASDAQ Global Market. Investors may not be able to sell their shares quickly or at the latest market price if trading in our stock is not active.

**Our charter documents and Delaware law could make an acquisition of our company difficult, even if an acquisition may benefit our stockholders.**

Our Board of Directors has adopted a Preferred Shares Rights Plan. The Preferred Shares Rights Plan has the effect of causing substantial dilution to a person or group that attempts to acquire us on terms not approved by our Board of Directors. The existence of the Preferred Shares Rights Plan could limit the price that certain investors might be willing to pay in the future for shares of our common stock and could discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable.

Some provisions of our Amended and Restated Certificate of Incorporation and Bylaws could delay or prevent a change in control of our company. Some of these provisions:

· authorize the issuance of preferred stock by the Board of Directors without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of common stock;

· prohibit stockholder actions by written consent;

· specify procedures for director nominations by stockholders and submission of other proposals for consideration at stockholder meetings; and

· eliminate cumulative voting in the election of directors.

In addition, we are governed by the provisions of Section 203 of Delaware General Corporate Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These and other provisions in our charter documents could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

**Changes in financial accounting standards related to share-based payments are expected to continue to have a significant effect on our reported results.**

On January 1, 2006, we adopted the revised statement of Financial Accounting Standards No. SFAS 123R, or SFAS 123R, *Share-Based Payment*, which requires that we record compensation expense in the statement of operations for share-based payments, such as employee stock options, using the fair value method. The adoption of this new standard is expected to continue to have a significant effect on our reported earnings, although it will not affect our cash flows, and could adversely impact our ability to provide accurate guidance on our future reported financial results due to the variability of the factors used to estimate the values of share-based payments. If factors change and we employ different assumptions or different valuation methods in the application of SFAS 123R in future periods, the compensation expense that we record under SFAS 123R may differ significantly from what we have recorded in the current period, which could negatively affect our stock price.

**Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses.**

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ Global Market rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors' review and audit of our internal control over financial reporting has required the commitment of significant financial and managerial resources. We expect these efforts to require the continued commitment of significant resources. If we fail to comply with new or changed laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.



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**The investment of our cash balance and our investments in marketable debt securities are subject to risks which may cause losses and affect the liquidity of these investments.**

At September 30, 2008, we had $96.2 million in cash and cash equivalents and $107.9 million in available for sale securities. We invest our excess cash balances in money market and marketable securities, primarily U.S. Treasury securities and debt securities of U.S. government agencies, corporate debt securities and asset-backed securities, in accordance with our investment policy approved by the Board of Directors. The investment policy has the primary investment objectives of preservation of principal while at the same time maximizing yields without significantly increasing risk; however, there may be times when certain of the securities in our portfolio will fall below the credit ratings required in the policy. If those securities are downgraded or impaired we would experience losses in the value of our portfolio which would have an adverse effect on our results of operations, liquidity and financial condition. Certain of these securities are subject to general credit, liquidity, market and interest rate risks, which may be exacerbated by U.S. sub-prime mortgage defaults that have affected various sectors of the financial markets and caused credit and liquidity issues. Money market mutual funds contain investments issued by or guaranteed by the U.S. Government. An investment in money market mutual funds is not insured or guaranteed by the Federal Deposit Insurance Corporation nor any other government agency. Although money market mutual funds seek to preserve the value of the investment at $1.00 per share, it is possible to lose money by investing in money market mutual funds.

From 2005 and until December 2007 the Company had an investment in Columbia Strategic Cash Portfolio, or Strategic Cash, offered by the Company's investment advisor, Columbia Management LLC, or Columbia, an affiliate of Bank of America. Strategic Cash is an enhanced money market fund in which the fund sought to maintain a $1 per share net asset value. The Company used Strategic Cash for the investment of excess cash, and periodic transfers were made from Strategic Cash to the operating cash account to fund current operations.

In early December 2007, we were notified by Columbia that the Strategic Cash fund was closed and that the fund was to be liquidated. The fund no longer supported the $1 per share net asset value and switched to a market value fund in which all investments were marked to market. We were given the option of staying in the fund and receiving cash proceeds from the fund as its holdings were liquidated or receiving a pro-rata share of the investments held by the fund. Upon advice from our investment advisor, we took a redemption-in-kind consisting of cash, interest receivable and a pro-rata distribution of the underlying securities, consisting principally of high quality corporate debt and asset-backed securities. Prior to the redemption, our investment in Strategic Cash was $84.4 million. On December 20, 2007 and December 21, 2007, we received our redemption-in-kind consisting of securities with a market value of $68.7 million, interest receivable of $300,000 and cash of $14.4 million. The difference between our investment in Strategic Cash of $84.4 million and the fair value of the securities, cash and interest receivable totaling $83.4 million received in-kind resulted in a loss of $1 million. This loss of $1 million is reflected in interest income in the consolidated statement of operations and other comprehensive income (loss) for the year ended December 31, 2007. We have reason to believe certain of these securities are in default and others have experienced a decline in market value. In addition, the active market for certain securities is extremely limited.

As a result of the distribution from Strategic Cash, we received securities that fell outside the investment policy at that time. The Audit Committee of the Board of Directors allowed the receipt of the securities and granted an exception to the policy for these specific securities. At the time of distribution, the Strategic Cash held $35 billion in securities. Several other holders in Strategic Cash received a redemption-in-kind as well. Shareholders who remained in Strategic Cash will receive cash as the fund is liquidated. It is our belief that the investors in the Strategic Cash who did not take, or were not allowed to take, a redemption-in-kind will not realize 100% of their holdings. As a result of all of the redemptions-in-kind held by us and others, the liquidation of the fund itself and the general market conditions for these types of securities, the current market value of these securities may be negatively affected.

We currently believe we will be able to realize a significant portion of the par value of our investments without significant loss; however, it could take until the final maturity of the underlying securities or until market conditions improve to realize the par value. Based on our expected operating cash flows, and our other sources of cash, we do not anticipate the potential lack of liquidity on certain of these investments will affect our ability to execute our current business plan; however, these market risks associated with our investment portfolio could cause the loss of a significant portion of our investments which would have an adverse effect on our results of operations, liquidity and financial condition.



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**The value of our investments is influenced by varying economic and market conditions, and a decrease in value may result in a loss charged to income.**

Our available-for-sale investment securities were $107.9 million and represented 49% of our total condensed consolidated assets at September 30, 2008. These assets are carried at fair value, and the unrealized gains or losses are included in accumulated other comprehensive income as a separate component of shareholders' equity, unless the decline in value is deemed to be other-than-temporary and we do not have the intent and ability to hold such securities until their full cost can be recovered. If a decline in value is deemed to be other-than-temporary and we do not have the intent and ability to hold such security until

its full cost can be recovered, the security is deemed to be other-than-temporarily impaired and it is written down to fair value and the loss is charged to income.

In accordance with applicable accounting standards, we review our investment securities to determine if declines in fair value below cost are other-than-temporary. This review is subjective and requires a high degree of judgment. We conduct this review on a quarterly basis, using both quantitative and qualitative factors, to determine whether a decline in value is other-than-temporary. Such factors considered include the length of time and the extent to which market value has been less than cost, financial condition and near term prospects of the issuer, recommendations of investment advisors and forecasts of economic, market or industry trends. This review process also entails an evaluation of our ability and intent to hold individual securities until they mature or full cost can be recovered.

The current economic environment and recent volatility of securities markets increase the difficulty of assessing investment impairment and the same influences tend to increase the risk of potential impairment of these assets. During the nine months ended September 30, 2008, we recorded charges for other-than-temporary impairment of securities of $5.1 million. We believe we have adequately reviewed our investment securities for impairment and that our investment securities are carried at fair value. However, over time, the economic and market environment may provide additional insight regarding the fair value of certain securities, which could change our judgment regarding impairment. This could result in realized losses relating to other-than-temporary declines being charged against future income. Given the current market conditions and the significant judgments involved, there is continuing risk that further declines in fair value may occur and additional material other-than-temporary impairments may be charged to income in future periods.

**Risks Relating to our Transaction with Deerfield Management Company, L.P. and Affiliates**

**Background**

Simultaneously with the sale of securities to funds affiliated with the Deerfield Affiliates, on April 15, 2008, we entered into the FARA, an Option and Put Agreement, or the OPA, and a Security Agreement with Deerfield Sub, a newly incorporated subsidiary of Deerfield Management Company L.P. We also entered into a Security Agreement with the shareholders of Deerfield Sub. Under the terms of the FARA, Deerfield Sub made $3.3 million payments to us in April and August 2008 and will make four quarterly payments of approximately $3.3 million thereafter. As part of the funding arrangement, we have agreed to continue our development of avanafil, our oral PDE5i for Deerfield Sub. The FARA also provides that we will pay royalties on the net MUSE sales on a quarterly basis. Under the FARA, the royalty payments continue for 10 years. There are no minimum royalties due, however, we have agreed to maintain the promotion of MUSE consistent with our prior efforts. The OPA provides that we may purchase all the outstanding shares of Deerfield Sub, thus ending any further royalty payments. The OPA allows for the purchase of the shares of Deerfield Sub by us for $23 million on a net basis through the first three years and $26 million net from the third to fourth year. The purchase amounts are net of the $2 million premium paid to Deerfield Affiliates for the call option. We have no ability to repurchase the shares after the fourth year. The OPA provides that Deerfield Affiliates can force a sale of the shares of Deerfield Sub to us beginning after the third year through the tenth year. The timing on the sale of the shares could be accelerated under certain conditions including a change-in-control, sale of MUSE or avanafil, sale of major assets and the sale of securities in a transaction or a series of related transactions by us that exceed 20% of our outstanding common stock at the date the OPA was signed if at the time of the sale our market capitalization is below $300 million (each, a Major Transaction). Under these conditions, the cost of the shares of Deerfield Sub would be $23 million before the third anniversary and $26 million from the third to tenth anniversary. The sale of the shares of Deerfield Sub could also accelerate if our cash, cash equivalents and available for sale securities falls below $15 million or our market capitalization falls below $50 million. As security for the payment of royalties we have pledged certain unencumbered MUSE and avanafil assets to Deerfield Sub. As security for the payment under the forced purchase of shares of Deerfield Sub to us, we have pledged certain unencumbered MUSE and avanafil assets to Deerfield Affiliates.



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**Risks Related to the FARA**

Under the FARA, the payment of the royalties may result in the MUSE operations being unprofitable. If we fail to exercise the option to repurchase the shares of Deerfield Sub or if Deerfield Affiliates does not force us to purchase the shares of Deerfield Sub, we will continue to pay royalties into 2018. We agreed to continue to promote MUSE at levels consistent with our current efforts. This requirement may force us to allocate resources that could be better utilized for other activities. If we decide to sell the MUSE business line or related assets, we will be forced to purchase the shares of Deerfield Sub. The royalty payments and required commitment under the FARA may have an adverse effect on our cash flows, the market price of our common stock, our ability to raise money, financial position and results of operations.

**Risks Related to the OPA**

Under the OPA, we only have four years to repurchase the shares of Deerfield Sub. If we do not exercise this option within this period of time we will pay royalties through 2018. If exercised by us, the OPA will require us to pay $23 million or $26 million. The payment of these amounts may have an adverse effect on our cash balances, stock price and operations at the time of payment. Deerfield Affiliates has the ability to force us to buy the shares of Deerfield Sub for $17 million, $23 million or $26 million. The payment of any one of these amounts would have a material adverse effect on our cash balance at the time. If our purchase of the Deerfield Sub shares is accelerated due to a Major Transaction, our ability to effectively negotiate and complete such a transaction could be adversely affected. The proceeds from such a transaction will also be reduced by the price paid for the Deerfield Sub shares.



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**Risks Related to the Security Agreement**

We entered into a Security Agreement with Deerfield Sub to secure the royalty payments and with Deerfield Affiliates to secure the forced sale of the Deerfield Sub shares. The Security Agreements severely limit our ability to commercialize the assets covered by the Security Agreement outside the ordinary course of business including a sale of some or all of these assets. These assets would also not be available to serve as collateral for any future purpose.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None

**ITEM 5. OTHER INFORMATION**

None

**ITEM 6. EXHIBITS**

The list of Exhibits as required by Item 601 of Regulation S-K.



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A. EXHIBITS:

| EXHIBIT NUMBER | DESCRIPTION |
|---|---|
| 3.1(1) | Amended and Restated Certificate of Incorporation of the Registrant. |
| 3.2(2) | Amended and Restated Bylaws of the Registrant. |
| 3.3(3) | Amended and Restated Certificate of Designation of the Registrant. |
| 4.1(1) | Specimen Common Stock Certificate of the Registrant. |
| 4.2(4) | Preferred Stock Rights Agreement dated as of March 27, 2007 between the Registrant and Computershare Investor Services, LLC. |
| 31.1 | Certification of Chief Executive Officer, dated November 6, 2008, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended. |
| 31.2 | Certification of Chief Financial Officer, dated November 6, 2008, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended. |
| 32 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

(1) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1996, as amended.

(2) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.

(3) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form 8-A (File No. 001-33389) filed with the Commission on March 28, 2007.

(4) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Registration Statement on Form 8-A (File No. 001-33389) filed with the Commission on March 28, 2007.



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**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.

Date: November 6, 2008

VIVUS, Inc.

/s/ TIMOTHY E. MORRIS
Timothy E. Morris

Vice President, Finance and Chief Financial Officer

/s/ LELAND F. WILSON
Leland F. Wilson
President and Chief Executive Officer



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VIVUS, INC.

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(4) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Registration Statement on Form 8-A (File No. 001-33389) filed with the Commission on March 28, 2007.

**Exhibit 31.1**

CERTIFICATION

I, Leland F. Wilson, President and Chief Executive Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VIVUS, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer 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 6, 2008

By: /s/ LELAND F. WILSON
Leland F. Wilson
President and Chief Executive Officer

**Exhibit 31.2**

CERTIFICATION

I, Timothy E. Morris, Vice President, Finance and Chief Financial Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VIVUS, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer 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 6, 2008

By: /s/ TIMOTHY E. MORRIS
Timothy E. Morris
Vice President, Finance and Chief Financial Officer

**Exhibit 32**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER**
**PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Leland F. Wilson, President and Chief Executive Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended September 30, 2008 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: November 6, 2008

By: /s/ LELAND F. WILSON
Leland F. Wilson

I, Timothy E. Morris, Vice President, Finance and Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended September 30, 2008 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: November 6, 2008

By: /s/ TIMOTHY E. MORRIS
Timothy E. Morris