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

FORM 10-Q

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

For The Quarterly Period Ended March 31, 2009

OR

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

For The Transition Period From to

Commission File Number 001-33389

VIVUS, INC.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	**94-3136179** (IRS employer identification number)
1172 Castro Street **Mountain View, California** (Address of principal executive office)	**94040** (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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

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 ☐	Accelerated filer ☒
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

At April 30, 2009, 69,721,583 shares of common stock, par value $.001 per share, were outstanding.

VIVUS, INC.

Quarterly Report on Form 10-Q

INDEX

PART I: FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

VIVUS, INC.

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

	March 31 2009 (unaudited)	December 31 2008*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 42,723	$ 66,121
Available-for-sale securities	122,482	121,789
Accounts receivable, (net of allowance for doubtful accounts of $53 and $23 at March 31, 2009 and December 31, 2008, respectively)	912	4,157
Inventories, net	3,324	3,041
Prepaid expenses and other assets	4,227	3,744
Total current assets	173,668	198,852
Property, plant and equipment, net	6,480	6,726
Restricted cash	700	700
Available-for-sale securities	631	1,344
Total assets	$ 181,479	$ 207,622
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 14,395	$ 17,205
Accrued product returns	2,781	2,865
Accrued research and clinical expenses	7,216	6,435
Accrued chargeback reserve	1,482	1,379
Accrued employee compensation and benefits	2,170	2,394
Accrued and other liabilities	1,951	1,836
Deferred revenue	10,928	31,858
Total current liabilities	40,923	63,972
Notes payable-net of current portion	13,514	11,177
Deferred revenue	1,145	1,260
Total liabilities	55,582	76,409
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; 69,722 and 69,677 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	70	70
Additional paid-in capital	312,077	310,558
Accumulated other comprehensive income	328	354
Accumulated deficit	(186,578)	(179,769)
Total stockholders' equity	125,897	131,213
Total liabilities and stockholders' equity	$ 181,479	$ 207,622

* Derived from audited consolidated financial statements filed in the Company's 2008 Annual Report on Form 10-K.

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

VIVUS, INC.

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

	Three Months Ended March 31 2009	Three Months Ended March 31 2008
Revenue:		
United States product, net	$ 893	$ 1,088
International product	293	554
License and other revenue	21,046	21,046
Total revenue	22,232	22,688
Operating expenses:		
Cost of goods sold and manufacturing expense	2,603	2,787
Research and development	20,069	23,371
Selling, general and administrative	5,411	4,252
Total operating expenses	28,083	30,410
Loss from operations	(5,851)	(7,722)
Interest (expense) income:		
Interest income, net	208	2,109
Interest expense	(716)	(122)
Other-than-temporary loss on impaired securities	(444)	(1,352)
Total interest (expense) income	(952)	635
Loss before provision for income taxes	(6,803)	(7,087)
Provision for income taxes	(6)	(5)
Net loss	$ (6,809)	$ (7,092)
Other comprehensive loss:		
Unrealized loss on securities	(26)	(305)
Comprehensive loss	$ (6,835)	$ (7,397)
Net loss per share:		
Basic and diluted	$ (0.10)	$ (0.12)
Shares used in per share computation:		
Basic and diluted	69,687	58,882

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Three Months Ended March 31	
	2009	2008
	(unaudited)	(unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (6,809)	$ (7,092)
Adjustments to reconcile net loss to net cash used for operating activities:		
Provision for doubtful accounts	30	(12)
Depreciation	283	278
Net realized loss on investments	257	12
Other-than-temporary loss on impaired securities	444	1,352
Share-based compensation expense	1,334	1,406
Changes in assets and liabilities:		
Accounts receivable	3,215	2,802
Inventories	(283)	(540)
Prepaid expenses and other assets	(483)	1,481
Accounts payable	(2,810)	6,146
Accrued product returns	(84)	(74)
Accrued research and clinical expenses	781	3,331
Accrued chargeback reserve	103	(229)
Accrued employee compensation and benefits	(224)	(698)
Deferred revenue	(21,045)	(21,046)
Accrued and other liabilities	112	(464)
Net cash used for operating activities	(25,179)	(13,347)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(37)	(83)
Investment purchases	(31,406)	—
Proceeds from sale/maturity of securities	30,699	29,220
Net cash provided by (used for) investing activities	(744)	29,137
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from notes payable	3,333	—
Payments of notes payable	(993)	(29)
Exercise of common stock options	185	114
Net cash provided by financing activities	2,525	85
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(23,398)	15,875
CASH AND CASH EQUIVALENTS:		
Beginning of period	66,121	37,838
End of period	$ 42,723	$ 53,713

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2009

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 ended March 31, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009. 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, 2008, as filed on March 11, 2009 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.

Reclassifications

Certain prior year amounts in the condensed consolidated financial statements have been reclassified to conform to the current year presentation.

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 2008, 2007 and 2006 were 93%, 95.8% and 91.7% of international sales, respectively. The balance of international sales was made to Paladin.

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 received a $1.5 million upfront payment in connection with the international supply agreement signed with Meda in September 2002. In January 2006, the Company also 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 Union territories. These amounts were recorded as deferred revenue and are being recognized ratably over the term of the supply agreement. Through March 31, 2009, $2 million has been recognized as revenue.

License and Other Revenue

The Company recognizes license revenue in accordance with the SEC'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, is being 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 is being 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 March 31, 2009, $140 million has been recognized as revenue.

The Company is also eligible to 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.

In February 2009, K-V and certain of its subsidiaries announced a voluntary recall of most of its prescription products. Subsequent to the recall, K-V announced plans to reduce its workforce by 700 employees. In January 2009, K-V voluntarily suspended the manufacturing and shipping of all of its products. Evamist is not manufactured by K-V and was not subject to the recall. Given the uncertainties with K-V, it is difficult to determine the extent of the adverse impact on Evamist. Although the Company is entitled to additional milestone payments from future sales of Evamist by K-V, at the present time the Company does not anticipate receiving any additional milestones for the sales of Evamist.

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 months ended March 31, 2009 and 2008 was comprised as follows (in thousands, except per share data):

	Three Months Ended March 31, 2009	Three Months Ended March 31, 2008
Cost of goods sold and manufacturing expense	$ 172	$ 137
Research and development	292	483
Selling, general and administrative	870	786
Share-based compensation expense before taxes	1,334	1,406
Related income tax benefits	—	—
Share-based compensation expense, net of taxes	$ 1,334	$ 1,406
Basic and diluted per common share	$ 0.02	$ 0.02

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 March 31, 2009 and December 31, 2008 are presented in the tables that follow:

As of March 31, 2009 (in thousands) (unaudited):

Cash and cash equivalents	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
Cash and money market funds	$ 42,723	$ 42,723	$ —	$ —
Total cash and cash equivalents	$ 42,723	$ 42,723	$ —	$ —

Available-for-sale securities	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
U.S. Treasury securities and debt securities of U.S. government agencies	$ 113,643	$ 113,795	$ 159	$ (7)
Corporate bonds	688	688	—	—
Asset backed and other securities	7,823	7,999	176	—
Total available-for-sale securities	$ 122,154	$ 122,482	$ 335	$ (7)

Available-for-sale securities, non-current	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
Corporate bonds	$ 562	$ 562	$ —	$ —
Asset backed and other securities	69	69	—	—
Total available-for-sale securities, non current	$ 631	$ 631	$ —	$ —

As of December 31, 2008 (in thousands):

Cash and cash equivalents	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
Cash and money market funds	$ 66,121	$ 66,121	$ —	$ —
Total cash and cash equivalents	$ 66,121	$ 66,121	$ —	$ —

Available-for-sale securities	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
U.S. Treasury securities and debt securities of U.S. government agencies	$ 100,061	$ 100,412	$ 351	$ —
Corporate bonds	8,393	8,387	—	(6)
Asset backed and other securities	12,981	12,990	10	(1)
Total available-for-sale securities	$ 121,435	$ 121,789	$ 361	$ (7)

Available-for-sale securities, non-current	Amortized Cost	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses
Corporate bonds	$ 1,067	$ 1,067	$ —	$ —
Asset backed and other securities	277	277	—	—
Total available-for-sale securities, non current	$ 1,344	$ 1,344	$ —	$ —

The following table summarizes the Company's available-for-sale securities by the contractual maturity date as of March 31, 2009 (in thousands) (unaudited):

	Amortized Cost	Estimated Fair Value
Due within one year	$ 114,804	$ 114,955
Due within one year to two years	89	89
*No single maturity date	7,892	8,069
	$ 122,785	$ 123,113

* 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	
	March 31, 2009	March 31, 2008
	(unaudited)	(unaudited)
Realized gains	$ 151	$ 37
Realized losses	(408)	(49)
Net realized gains/(losses)	$ (257)	$ (12)

During the three months ended March 31, 2009, we sold and received paydowns totaling $11.8 million of fixed income securities which resulted in net realized losses of $257,000. In the ordinary course of business, we may sell securities at a loss for a number of reasons, including, but not limited to: (i) changes in the investment environment; (ii) expectation that the fair value could deteriorate further; (iii) desire to reduce exposure to an issuer or an industry; (iv) changes in credit quality; or (v) changes in expected cash flow.

At March 31, 2009 and December 31, 2008, 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	
March 31, 2009 (unaudited)	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities and debt securities of U.S. government agencies	$ (7)	$ 26,703	$ —	$ —
Total	$ (7)	$ 26,703	$ —	$ —

	Less Than 12 Months		12 Months or Greater	
December 31, 2008	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
Corporate bonds	$ (6)	$ 231	$ —	$ —
Asset backed and other securities	(1)	1,144	—	—
Total	$ (7)	$ 1,375	$ —	$ —

The gross unrealized losses reported above for March 31, 2009 and December 31, 2008 were primarily 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 the Company owns. Based on the Company's review of these securities, including its assessment of the duration and severity of the related unrealized losses, the Company has not recorded any other-than-temporary impairment losses on these investments.

As of March 31, 2009 and December 31, 2008, the temporary unrealized gains on available-for-sale securities, net of tax, of $328,000 and $354,000, respectively, were included in accumulated other comprehensive income in the accompanying unaudited condensed consolidated balance sheets. As of March 31, 2009, 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. A significant judgment in the valuation of investments is the determination of when an other-than-temporary decline in value has occurred. We follow a consistent and systematic process for recognizing impairments on securities that sustain other-than-temporary declines in value. We have established a policy for the impairment review process. The decision to impair a security incorporates both quantitative criteria and qualitative information. The impairment review process considers a number of factors including, but not limited to: (i) the length of time and the extent to which the fair value has been less than book value, (ii) the financial condition and near term prospects of the issuer, (iii) our intent and ability to retain impaired investments for a period of time sufficient to allow for any anticipated recovery in value, (iv) whether the debtor is current on interest and principal payments and (v) general market conditions and industry or sector specific factors. For securities that are deemed to be other-than-temporarily impaired, the security is adjusted to fair value and the resulting losses are recognized in other-than-temporary loss on impaired securities in the condensed consolidated statements of operations. The new cost basis of the impaired securities is not increased for future recoveries in fair value.

During the Company's quarterly impairment assessment, the Company determined that a decline in value of certain securities was other-than-temporary. Accordingly, the Company recorded other-than-temporary impairment adjustments of $444,000 in the three months ended March 31, 2009. 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). Other-than-temporary impairment losses recognized in 2009 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 $631,000 and the continued uncertainty in the capital markets, the Company expects to recover the carrying values of these securities beyond the next 12 months. Consequently, the Company has classified those available-for-sale securities as non-current in the condensed consolidated balance sheets.

In December 2007, our enhanced money market fund investment, Columbia Strategic Cash Portfolio Fund, or Columbia fund, ceased accepting cash redemption requests and changed to a floating net asset value. In light of the restricted liquidity, the Company elected to receive a pro-rata allocation of the underlying securities in a separately managed account. At March 31, 2009, the market value of securities received in-kind from the Columbia fund investment included in available-for-sale securities was $9.3 million.

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 (cash and cash equivalents, available-for-sale securities) measured at fair value on a recurring basis as of March 31, 2009 (in thousands):

		Basis of Fair Value Measurements		
	Balance at March 31, 2009	Level 1	Level 2	Level 3
Cash and cash equivalents and available-for-sale securities:				
Cash and cash equivalents	$ 42,723	$ 42,723	$ —	$ —
U.S. Treasury securities	109,073	109,073	—	—
Debt securities of U.S. government agencies	4,722	—	4,722	—
Corporate bonds	1,249	—	884	365
Asset backed and other securities	8,069	—	6,376	1,693
Total	$ 165,836	$ 151,796	$ 11,982	$ 2,058
Reported as:				
Cash and cash equivalents	$ 42,723			
Available-for-sale securities	122,482			
Available-for-sale securities, non-current	631			
Total	$ 165,836			

Fair values are based on quoted market prices, where available. These fair values are obtained primarily from third party pricing services, which generally use Level I or Level II inputs for the determination of fair value in accordance with SFAS 157. Third party pricing services normally derive the security prices through recently reported trades for identical or similar securities making adjustments through the reporting date based upon available market observable information. For securities not actively traded, the third party pricing services may use quoted market prices of comparable instruments or discounted cash flow analyses, incorporating inputs that are currently observable in the markets for similar securities. Inputs that are often used in the valuation methodologies include, but are not limited to, benchmark yields, broker quotes, credit spreads, default rates and prepayment speeds. The Company performs a review of the prices received from third parties to determine whether the prices are reasonable estimates of fair value. The Company's analyses include, as needed, a comparison of pricing services' valuations to other pricing services' valuations for the identical security.

The Company generally obtains one price for each investment security. The Company performs a review to assess if the evaluated prices represent a reasonable estimate of their fair value. This process involves quantitative and qualitative analysis by the Company. Examples of procedures performed include, but are not limited to, initial and ongoing review of pricing service methodologies, review of the prices received from the pricing service, and comparison of prices for certain securities with two different appropriate price sources for reasonableness. As a result of this analysis, if the Company determines there is a more appropriate fair value based upon available market data, which happens infrequently, the price of a security is adjusted accordingly. The pricing service provides information to indicate which securities were priced using market observable inputs so that the Company can properly categorize its financial assets in the fair value hierarchy.

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, a prime auto loan asset-backed security and five structured investment vehicles (SIVs).

These Level 3 securities were valued using a number of different sources, namely the use of independent pricing sources which used their proprietary models. The Company reviewed the inputs and assumptions used in these fair value models for reasonableness, and believes that the fair values are consistent with the principles of SFAS 157.

The changes in Level 3 assets measured at fair value on a recurring basis for the three months ended March 31, 2009 were (in thousands):

Activity for the Three Months Ended March 31, 2009 (unaudited)	**Fair Value Measurements Using Significant Unobservable Inputs (Level 3)**
Balance at December 31, 2008	$ 2,314
Total unrealized gains included in other comprehensive income/loss	31
Total (realized/unrealized) losses included in net loss	(207)
Purchases, sales, issuances and settlements, net	(539)
Transfers out of Level 3 securities(a)	—
Transfers into Level 3 securities(a)	459
Balance at March 31, 2009	$ 2,058

(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. Transfers into Level 3 were a result of increased use of input data that could not be validated with other market data, resulting from continued deterioration in the credit markets.

The following table presents the amounts of other-than-temporary losses and change in unrealized losses for the three months ended March 31, 2009 relating to those available-for-sale securities for which the Company utilized significant Level 3 inputs to determine fair value and that were still held by the Company at March 31, 2009 (in thousands):

For the Three Months Ended March 31, 2009 (unaudited)		
Total other-than-temporary loss on impaired securities for the period	$	(268)
Increase in unrealized gains on securities still held at reporting date	$	31

As of March 31, 2009, the Company does not have any liabilities that are measured at fair value on a recurring basis.

Certain assets and liabilities are measured at fair value on a nonrecurring basis; that is, the instruments are not measured at fair value on an ongoing basis but are subject to fair value adjustments only in certain circumstances (for example, when there is evidence of impairment). There were no assets or liabilities measured at fair value on a nonrecurring basis during the three months ended March 31, 2009.

5. INVENTORIES

Inventories are recorded net of reserves of $1.5 million and $1.4 million as of March 31, 2009 and December 31, 2008, respectively. Inventory balances, net of reserves, consist of (in thousands):

	March 31, 2009 (unaudited)		December 31, 2008	
Raw materials and component parts	$	2,787	$	2,719
Work in process		58		40
Finished goods		479		282
Inventory, net	$	3,324	$	3,041

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. The Company determined that it likely would continue to use some portion of the fully reserved component parts in production. The Company used $18,000 and $15,000 of its fully reserved component parts inventory during the first three months of 2009 and 2008, 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 three months of 2009 and 2008, 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 $593,000 as of March 31, 2009, and the Company intends to continue to use this reserved component parts inventory in production when appropriate.

6. PREPAID EXPENSES AND OTHER ASSETS

Prepaid expenses and other assets as of March 31, 2009 and December 31, 2008, respectively, consist of (in thousands):

	March 31, 2009 (unaudited)		December 31, 2008	
Receivable from Food and Drug Administration	$	1,877	$	1,877
Refundable federal income taxes		—		156
Prepaid clinical studies		873		200
Interest receivable		324		368
Prepaid insurance		466		448
Other prepaid expenses and assets		687		695
Total	$	4,227	$	3,744

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 the Company's 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). Certain of the agreements were amended and restated on March 16, 2009. 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 the Deerfield Sub, and $10 million from the sale of the Company's common stock under a securities purchase agreement. Under the FARA, the Deerfield Sub made $3.3 million payments to the Company in April, September and December 2008 and February 2009 and will make two quarterly payments of approximately $3.3 million, thereafter. The Company will pay royalties on the current net sales of MUSE and if approved, on 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.

The agreements also provide 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 before April 3, 2011, or $26 million if exercised after April 3, 2011 but before April 3, 2012 (the purchase prices are subject to other adjustments as defined in the agreement). After April 3, 2011, 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 the Company's 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 or each, a Major Transaction. Under these conditions, the cost of the shares of the Deerfield Sub would be $23 million on or before April 3, 2011 and $26 million from April 3, 2011 through April 3, 2018. The sale of the shares of the 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 machinery and equipment arising out of or relating to MUSE and avanafil are collateral for this transaction. At March 31, 2009, substantially all of the accounts receivable, inventory and machinery and equipment on the Company's condensed consolidated balance sheet relates to MUSE and serves as collateral for this transaction.

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 it 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 the Company. 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 has recorded 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 additional 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 interest rate was revised to 33% at December 31, 2008 based on the actual royalty payments made and the timing of payments and advances in 2008. 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% for the quarters ended March 31, 2009 and 2008, 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):

	March 31, 2009 (unaudited)	December 31, 2008
Deerfield loan	$ 8,653	$ 6,277
Crown Bank N.A. loan	5,009	5,045
Total notes payable	13,662	11,322
Less current portion	(148)	(145)
Total long-term notes payable	$ 13,514	$ 11,177

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

Future minimum principal payments of the long-term notes payable as of March 31, 2009 are as follows (in thousands):

As of March 31, 2009	Deerfield Loan	Crown Bank N.A. Loan	Total
Remainder of 2009	$ —	$ 145	$ 145
2010	—	157	157
2011	8,653	169	8,822
2012	—	181	181
2013	—	197	197
Thereafter	—	4,160	4,160
Total	$ 8,653	$ 5,009	$ 13,662

In the first quarter of 2004, the Company signed an agreement for a secured line of credit with Tanabe Holding America, Inc., a subsidiary of Tanabe Seiyaku Co., Ltd., or Tanabe, allowing it to borrow up to $8.5 million to be used for the development of avanafil. In October 2007, Tanabe and Mitsubishi Pharma Corporation completed their merger and announced their name change to Mitsubishi Tanabe Pharma Corporation, or Mitsubishi Tanabe. On April 24, 2007, in connection with the Company's sale of Evamist to K-V (see Note 11: "Sale of Evamist Product"), the Company paid off the outstanding balance of $6.7 million, including all accrued interest, in order to obtain Mitsubishi Tanabe's release of liens against all assets including the Evamist assets and intellectual property.

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. In October 2007, Tanabe and Mitsubishi Pharma Corporation completed their merger and announced their name change to Mitsubishi Tanabe Pharma Corporation, or Mitsubishi Tanabe. 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. No payments were made under this agreement with Mitsubishi Tanabe in the years ended December 31, 2007 and 2008; however, the Company paid Mitsubishi Tanabe $4 million in January 2009 following the enrollment in December 2008 of the first patient in the first Phase 3 clinical study. The Company expects to make other substantial payments to Mitsubishi Tanabe in accordance with its agreements with Mitsubishi Tanabe 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 $15 million in the aggregate and include payments upon: 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 Mitsubishi 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 Mitsubishi 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 Mitsubishi 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 three months of 2009 and 2008, the Company recorded royalty expenses of $9,000 and $68,000, 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.

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 March 31, 2009, it was considered more likely than not that the Company's deferred tax assets would not be realized.

As of March 31, 2009, the Company believes that the amount of the deferred tax assets recorded on its condensed consolidated balance sheet would not ultimately be recovered. 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 is also eligible to receive certain one-time payments of up to $30 million based on K-V achieving certain annual net sales thresholds for Evamist. In February 2009, K-V and certain of its subsidiaries announced a voluntary recall of most of its prescription products. Subsequent to the recall, K-V announced plans to reduce its workforce by 700 employees. In January 2009, K-V voluntarily suspended the manufacturing and shipping of all of its products. Evamist is not manufactured by K-V and was not subject to the recall. Given the uncertainties with K-V, it is difficult to determine the extent of the adverse impact on Evamist. Although the Company is entitled to additional milestone payments from future sales of Evamist by K-V, at the present time the Company does not anticipate receiving any additional milestones for the sales of 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 Mitsubishi Tanabe's release of liens against all assets including the Evamist assets and intellectual property, the Company repaid the Mitsubishi Tanabe line of credit (see Note 8: "Notes Payable").

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.

As the Company recognized a net loss for the three months ended March 31, 2009 and 2008, all potential common equivalent shares were excluded as they were anti-dilutive. For the three months ended March 31, 2009 and 2008, 5,760,918 and 2,814,600 options outstanding, respectively, 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 its 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. On December 16, 2008, we entered into an amendment to this lease. Under the terms of the amended lease, we will continue to lease the office space for our corporate headquarters for a two year period commencing on August 1, 2009 and expiring on July 31, 2011. The base monthly rent is set at $1.64 per square foot or $23,000 per month. The amended lease allows us one option to extend the term of the lease for one year from the expiration of the lease.

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

Remainder of 2009	$ 397
2010	513
2011	299
	$ 1,209

Manufacturing Agreements

In November 2002, the Company entered into a manufacturing agreement to purchase alprostadil 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.

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 March 31, 2009, its remaining commitment under these agreements totaled $41.3 million. The Company has remaining commitments under various general and administrative services agreements totaling $2 million at March 31, 2009, including $1.3 million related to Leland F. 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 March 31, 2009, its remaining commitment under these agreements totaled $8.3 million. In addition, the Company has entered into marketing promotion and related agreements for its erectile dysfunction product, MUSE. At March 31, 2009, its remaining commitment under these marketing agreements totaled $695,000.

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. On January 23, 2009, the Compensation Committee approved an amendment to the Employment Agreement, or the Amendment, which amends the Employment Agreement. Pursuant to the Amendment, the initial term of the Employment Agreement was increased from two to three years commencing on June 1, 2007 and other relevant dates were also extended to reflect the three year initial term.

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 17: "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.

14. CONCENTRATION OF CUSTOMERS AND SUPPLIERS

During the first three months of 2009 and 2008, sales to significant customers as a percentage of total revenues were as follows:

	2009	2008
Customer A	2%	5%
Customer B	58%	42%
Customer C	11%	19%
Customer D	21%	23%

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 months ended March 31, 2009, the Company spent $7.2 million for services provided by one clinical research organization on the Qnexa Phase 3 studies, which represented 36% of the Company's total research and development expenses for the quarter. Separately, the Company spent another $5.2 million for services provided by another clinical research organization on the avanafil Phase 3 studies, which represented 26% of the Company's total research and development expenses for the quarter. In the three months ended March 31, 2008, the Company spent $17.3 million for services provided by one clinical research organization on the Qnexa Phase 3 studies, which represented 74% of the Company's total research and development expenses for the quarter.

15. INTEREST INCOME, NET

The components of interest income, net were as follows (in thousands):

	Three Months Ended March 31, 2009	Three Months Ended March 31, 2008
Interest income	$ 465	$ 2,121
Realized losses on marketable securities, net	(257)	(12)
Interest income, net	$ 208	$ 2,109

16. EQUITY TRANSACTIONS

On April 3, 2008, the Company entered into several agreements with the Deerfield Affiliates (see Note 7: "Deerfield Financing"). Certain of these agreements were amended and restated on March 16, 2009. 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) which 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 (File Number 333-150647) 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).

On March 9, 2009, the Company filed a Form S-8 (File Number 333-157787) 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.

17. 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 through its wholly owned subsidiary FemPharm Pty Ltd., or Acrux, are parties to the Testosterone Development and Commercialization Agreement dated February 12, 2004, or the Testosterone Agreement. The Testosterone Agreement covers the Company's investigational product candidate, Luramist, which is licensed from Acrux under the Testosterone Agreement. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding certain claims related to Luramist. Acrux's demand sought a reversion of all rights assigned to the Company related to Luramist, monetary damages and the payment of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. The Company asserted counterclaims against Acrux in the arbitration and sought the enforcement of the Company's rights under the Testosterone Agreement. The arbitration hearing concluded on January 23, 2009,and on April 6, 2009 the panel of arbitrators, or the Panel, issued its Interim Arbitration Award finding in favor of the Company that it was in compliance with the Testosterone Agreement and denying all of the relief sought by Acrux in its demand. The Panel found that the Company had used diligent, commercially reasonable efforts to develop Luramist and that the Company has satisfied its obligations to keep Acrux informed on the status of the development efforts. The Panel also ruled in favor of the Company on certain of its counterclaims. The Interim Arbitration Award requires the parties to meet and confer on a number of contractual obligations and to report back to the Panel within 35 days on the results of these efforts. See Note 18: "Subsequent Event".

In January 2009, a former employee filed a U.S. Equal Employment Opportunity Commission Claim. The Notice of Charge of Discrimination was vague as to the nature and scope of the claim, merely indicating that sex discrimination and retaliation under Title VII of the Civil Rights Act is alleged. Additionally, the Company received a letter from a former employee claiming California labor code violations in connection with the former employee's recruitment and wrongful termination. The Company has fully investigated the charges by these former employees and believes that there is no merit to these charges and that it has meritorious defenses to such charges. The Company believes the employees have no claim to additional compensation or benefits. Due to the current economic downturn, employees may be more likely to file employment-related claims, especially those that have received poor performance reviews. Although there may be no merit to such claims, the Company may be required to allocate additional monetary and personnel resources to defend against these types of allegations in the future.

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.

18. SUBSEQUENT EVENT

As mentioned in Note 17: "Legal Matters", the arbitration hearing between the Company and Acrux concluded on January 23, 2009, and on April 6, 2009 the Panel issued its Interim Arbitration Award finding in favor of the Company that it was in compliance with the Testosterone Agreement and denying all of the relief sought by Acrux in its demand. The Interim Arbitration Award requires the parties to meet and confer on a number of contractual obligations and to report back to the Panel within 35 days on the results of these efforts.

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 drug candidates and 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 investigational drug 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 ended March 31, 2009 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 biopharmaceutical company, incorporated in 1991, dedicated to the development and commercialization of therapeutic products for large underserved markets. Our investigational drugs currently under development could serve the obesity, diabetes and sexual health markets. Our current and investigational drug candidates in development encompass patented proprietary formulations and novel delivery systems. To date, through employment of this strategy, we have one FDA approved drug and several investigational drug candidates in late stages of clinical development. 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 our investigational sexual health product candidates each represent a projected market greater than $1 billion annually.

The current investigational drug pipeline includes three late-stage clinical drug 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. Another of our investigational drug candidates, avanafil, is in Phase 3 trials for erectile dysfunction.

All of the pivotal Phase 3 studies for Qnexa for obesity were initiated in the fourth quarter of 2007 and are fully enrolled. The first Phase 3 study, EQUATE (OB-301), was completed in late 2008. The co-primary endpoints for the ongoing 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 utilize our novel once-a-day formulation of Qnexa, which at full strength contains 15 mg phentermine and 92 mg of a proprietary controlled release formulation of topiramate.

Our late-stage investigational product candidate pipeline includes:

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

In April 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, and $10 million from the sale of our common stock under a securities purchase agreement. We pay royalties on the current net sales of MUSE (alprostadil) and if approved, future sales of avanafil, an investigational product candidate, to the Deerfield Affiliates.

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 for $150 million in cash, which has all been received.

In 1997, we launched MUSE 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 drug 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 drug candidates or technologies with competitive advantages from third parties for new and established markets.

It is our objective to become a leader in the development and commercialization of products for large underserved markets. We believe we have strong intellectual property supporting several opportunities in obesity, diabetes and sexual health. Our future growth depends on our ability to further develop and obtain regulatory approval of our investigational drug candidates for indications in which we are studying 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 drug 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 are 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 metered dose transdermal spray, or 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 March 31, 2009, we have incurred a cumulative deficit of $186.6 million and expect to incur operating losses in future years.

Year-to-Date 2009

Year-to-date highlights include:

- **Issuance of Key European Patent for Qnexa –** In January 2009, we announced that the European Patent Office had granted a patent for Qnexa. The European patent, No. 1,187,603, broadly covers Qnexa and its use as a weight loss treatment and extends the intellectual property protection of Qnexa beyond the already issued patents in the United States and abroad.

- **Qnexa Treatment Resulted in Improved Glucose Control in Obese Non-Diabetic Subjects–** In January 2009, we announced additional results from the EQUATE study (OB-301), which found that EQUATE study subjects treated with Qnexa had a significant reduction in HbA1c compared to placebo treated subjects. The EQUATE study was designed as a weight loss trial; however, additional analysis of the results showed a significant control of blood sugar in these non-diabetic subjects treated with Qnexa as compared to the placebo group.

- **Senior Management Promotions –** In January 2009, we announced that Peter Tam had been promoted to chief operating officer (COO). In his capacity as COO, Mr. Tam will continue to have overall responsibility for business development, clinical and preclinical development, regulatory affairs and chemistry, manufacturing and controls. In addition, Charles Bowden, M.D., was promoted to senior director, clinical development. Dr. Bowden has assumed responsibility for the avanafil Phase 3 clinical studies and continues to lead our efforts in experimental medicine.

- **Initiated Second Pivotal Phase 3 Trial of Avanafil for Treatment of Erectile Dysfunction –** In February 2009, we announced that we had initiated the REVIVE-Diabetes (TA-302) study to evaluate avanafil for treatment of ED in men with diabetes, one of the most common causes of erectile dysfunction.

Our Product Pipeline

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

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

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 the United States. 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.

In December 2008, we announced the results from the EQUATE (OB-301) study. The EQUATE study included 756 obese subjects (599 females and 157 males) across 32 centers in the United States. The average baseline body mass index, or BMI, of the study population was 36.3 kg/m(2) and baseline weight was 223 pounds. Subjects treated with full-dose and mid-dose Qnexa lost 9.2% and 8.5% of their starting body weight in 28-weeks, respectively, as compared to 1.7% for those in the placebo group (ITT-LOCF p<0000.1%). On an observed basis, patients on full-dose Qnexa lost 11.6% of their body weight in 28-weeks. The protocol for the EQUATE study was designed to meet current FDA guidelines for combination drug development.

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 CDC 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 global market for diabetes medications was estimated at $24 billion in 2007, according to IMS Health. 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 clinically meaningful reduction of hemoglobin A1c, a measure used to determine treatment efficacy of anti-diabetic agents.

In December 2008, we announced the results of our DM-230 diabetes study, a 56-week, Phase 2 clinical trial in 130 type 2 diabetics conducted at 10 sites in the United States. Subjects treated with Qnexa had a reduction in hemoglobin A1c of 1.6%, from 8.8% to 7.2%, as compared to 1.1% from 8.5% to 7.4% in the placebo group (ITT LOCF $p=0.0381$) at 56 weeks. Subjects treated with Qnexa for 56-weeks also had a reduction in body weight of 9.4%.

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. We believe that by combining these compounds, 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 controlled release topiramate and phentermine. 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. FDA draft guidelines for obesity products set forth a primary efficacy benchmark in Phase 3 trials of at least 35% of patients achieving 5% or more weight loss. 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. The FDA and foreign authorities require obesity studies to be conducted for at least one year. Although the results for both of our Phase 2 studies and our first Phase 3 obesity trial met these current guidelines for efficacy, there can be no assurance that these results can be replicated in a one-year Phase 3 trial.

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 protocols (OB-301 and OB-303) of Qnexa for the treatment of obesity and weight-related co-morbidities. The key elements of the SPA and suggestions from the FDA were also incorporated into the OB-302 protocol. 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 obesity development program also includes a six-month Phase 3 pivotal factorial-design study, known as EQUATE (OB-301). The EQUATE study included 756 obese subjects (599 females and 157 males) across 32 centers in the United States. The average baseline BMI of the study population was 36.3 kg/m2 and baseline weight was 223 pounds. The proportion of patients losing 5% or more of their initial body weight was 66% for full-dose, 62% for mid-dose and 15% for placebo ($p<0.0001$). The proportion of patients losing 10% or more of their initial body weight was 41% for full-dose, 39% for mid-dose and 7% for the placebo group ($p<0.0001$).

The EQUATE study met the primary endpoint by demonstrating superior weight loss with both the full-dose and mid-dose of Qnexa, as compared to the individual components and placebo. Subjects treated with full-dose and mid-dose Qnexa had an average weight loss of 9.2% and 8.5% respectively, as compared to weight loss of 1.7% reported in the placebo group (ITT LOCF $p<0.0001$). Average weight loss was 19.8 pounds and 18.2 pounds in the treatment arms as compared to 3.3 pounds in the placebo group. Qnexa was well-tolerated, with no drug-related serious adverse events in the study.

The most common drug-related adverse events reported for the full-dose, mid-dose and placebo group were paresthesia (tingling of the extremities) (23%, 16%, 3%), dry mouth (18%, 13%, 0%), altered taste (15%, 8%, 0%), headache (16%, 15%, 13%) and constipation (15%, 7%, 8%). Reported drug-related adverse events for depression and altered mood were minimal (1.9%, 0.9% and 1.8%, respectively). Moreover, individual depression assessments for each subject, as measured by PHQ-9, demonstrated statistically significant improvements ($p<0.05$) from baseline for both Qnexa treatment groups. Overall average completion rate for the Qnexa treatment group was 70%.

Subjects in the EQUATE study had a 4-week dose titration period followed by 24 weeks of treatment. The study was a randomized, double-blind, placebo-controlled, 7-arm, prospective trial with subjects randomized to receive once-a-day treatment with mid-dose Qnexa (7.5 mg phentermine/46 mg topiramate CR), full-dose Qnexa (15 mg phentermine/92 mg topiramate CR), the respective phentermine and topiramate constituents, or placebo. Subjects were asked to follow a hypocaloric diet representing a 500-calorie/day deficit and were advised to implement a simple lifestyle modification program.

The EQUATE study was designed as a weight loss trial; however, additional analysis of the results showed a significant control of blood sugar in these non-diabetic subjects treated with Qnexa as compared to the placebo group. Subjects treated with Qnexa had a significant improvement in glycemic control as measured by a reduction in hemoglobin A1c (HbA1c) compared to placebo. The overall placebo subtracted reduction in HbA1c was 0.11% and 0.10% for Qnexa full and mid-dose, respectively, over the 28-week treatment period ($p < 0.0001$). Baseline HbA1c levels were 5.48% and 5.42% for the full-dose and mid-dose groups.

In November 2007, we initiated two Phase 3 double-blind, placebo-controlled, multi-center studies comparing Qnexa to placebo over a 56-week treatment period. All Phase 3 studies are utilizing our once-a-day formulation of Qnexa, which at full dose contains 15 mg phentermine and 92 mg of a proprietary controlled release formulation of topiramate. The studies are designed to prospectively demonstrate the safety and efficacy of Qnexa in obese and overweight patients with different baseline characteristics. The first year-long 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 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. Top-line results from the EQUIP and CONQUER studies are expected in the third quarter of 2009.

We have initiated a one-year extension study for subjects who complete the CONQUER study. The extension study is known as SEQUEL (OB-305). Subjects will continue in a blinded fashion in their respective treatment groups. This extension study is not required by the FDA nor does it need to be completed prior to submission of an NDA. We expect to enroll up to 1,000 subjects in this study. The purpose of this study is to provide long-term safety and efficacy data for commercial purposes.

Safety and tolerability of Qnexa will be determined in the Phase 3 studies that include approximately 4,500 subjects by assessment of serious and non-serious adverse events, physical exam, findings and clinical laboratory data. In addition to these standard methods, there are specialized tools for cognitive function, mood and suicidality assessments.

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.

Our first patent covering Qnexa was issued on June 6, 2006. In January 2009, we announced that the European Patent Office granted a patent for Qnexa. The European patent, No. 1,187,603, broadly covers Qnexa and its use as a weight loss treatment. The patent extends the intellectual property protection of Qnexa beyond the already issued patents in the United States and abroad. In addition, Qnexa is the subject of multiple U.S. and international patent applications.

Qnexa for Diabetes

In December 2008, we announced the results of the DM-230 study, a one-year study in type 2 diabetics. The study met its primary endpoint of demonstrating glycemic control as measured by a reduction of hemoglobin A1c of 1.6% from 8.8% to 7.2% for subjects treated with Qnexa, as compared to 1.1% from 8.5% to 7.4% in the placebo group (ITT LOCF $p=0.0381$) at 56 weeks. Subjects in the study were actively managed according to American Diabetes Association, or ADA, standards of care with respect to diabetes medications and lifestyle. For subjects treated with placebo, significant increases in the number and doses of concurrent anti-diabetic medications were required to bring about the observed reduction in HbA1c. By contrast, concurrent anti-diabetic medications were actually reduced over the course of the trial in subjects treated with Qnexa ($p<0.05$).

Fasting plasma glucose levels were reduced in subjects treated with Qnexa from 176 mg/dL to 133 mg/dL, as compared to a decrease from 171 mg/dL to 145 mg/dL for the placebo group ($p=0.02$). Over 56 weeks, subjects treated with Qnexa also lost 9.4% of their baseline body weight, or 20.5 pounds, as compared to 2.7%, or 6.1 pounds, for the placebo group ($p<0.0001$). Subjects treated with Qnexa had reductions in blood pressure, triglycerides and waist circumference. Both treatment groups had a study completion rate greater than 90%.

The most common drug-related adverse events reported over the year for the treatment and placebo groups, respectively, were tingling (19%, 0%), constipation (13%, 4%) and nausea (12%, 6%). Patients on antidepressants such as SSRI's or SNRI's were allowed to participate in the studies. Subjects were monitored for depression and suicidality using the PHQ-9 questionnaire, a validated mental health assessment tool agreed to by the FDA for use in our studies. Subjects treated with Qnexa demonstrated greater improvements in PHQ-9 scores from baseline to the end of the study than the placebo group.

Despite a mean baseline HbA1c level of 8.8%, 53% of the subjects treated with Qnexa were able to achieve the ADA recommended goal of 7% or lower, versus 40% of the subjects in the placebo arm ($p<0.05$). The incidence of hypoglycemia in the treatment and placebo arms were similar (12% and 9%, respectively). Qnexa was well-tolerated, with no treatment-related serious adverse events.

The DM-230 study enrolled 130 subjects, who completed OB-202, at 10 study sites to continue in a blinded fashion as previously randomized for an additional 28 weeks. The results of the DM-230 study included assessments from the start of the OB-202 study through the end of the DM-230 study in this population, for a total treatment period of 56 weeks.

Male Sexual Health

Erectile dysfunction, or ED, is defined as the inability to attain or maintain an erection sufficient for intercourse. ED 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 2008 of PDE5 inhibitor products for ED were in excess of $3.7 billion, including approximately $1.9 billion in sales of Viagra, approximately $1.5 billion in sales of Cialis and approximately $300 million in estimated 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. 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 have exclusive worldwide development and commercialization rights for avanafil with the exception of certain Asian markets.

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.

In December 2008, we initiated the first of several pivotal Phase 3 studies of avanafil. The first study, REVIVE (TA-301), is a randomized, double-blind, placebo-controlled, efficacy and safety study of avanafil in men with a history of ED. In April 2009, we completed enrollment in this study. Subjects will undergo a four-week run-in period followed by 12 weeks of treatment. Subjects will be randomized to placebo or one of three dose levels of active drug. The primary endpoints of the study will be improvement in erectile function as measured by the Sexual Encounter Profile and improvements in the International Index of Erectile Function score, or IIEF.

The REVIVE study (TA-301) is being conducted pursuant to an SPA agreement with the FDA. TA-301 has enrolled over 600 patients at approximately 40 sites in the United States. Subjects are instructed to attempt sexual intercourse 30 minutes after taking avanafil, with no restrictions on food or alcohol consumption. TA-301 will study three doses of avanafil: 50mg, 100 mg and 200mg.

The Phase 3 program will include two additional studies. It is expected that REVIVE-Diabetes (TA-302) will enroll 300 subjects with ED caused by diabetes; REVIVE-RP (TA-303) will enroll 375 subjects with ED who have undergone a radical prostatectomy. REVIVE-Diabetes and REVIVE-RP have commenced enrollment. Subjects will undergo a four-week run-in period followed by 12 weeks of treatment. Subjects will be randomized to placebo or one of three dose levels of active drug. The primary endpoints of the study will be improvement in erectile function as measured by the Sexual Encounter Profile and improvements in the IIEF score. Subjects are instructed to attempt sexual intercourse 30 minutes after taking avanafil, with no restrictions on food or alcohol consumption. TA-302 and TA-303 will study two doses of avanafil: 100 mg and 200mg.

The Phase 3 program will also include an open-label safety study, TA-314. Enrollment in TA-314 has begun. The open label study will follow subjects for up to one year with the objective of providing data on at least 300 subjects for six months and 100 subjects for 12 months.

VIVUS has entered into a $30 million funding collaboration with Deerfield to provide funding for the Phase 3 studies of avanafil.

Female Sexual Health

We believe that the market for the treatment of sexual disorders in women is large and underserved. A paper published in 1999 in the *Journal of the American Medical Association* noted that 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.

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 applied transdermally 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 January 2008, we successfully completed and reached agreement with the FDA regarding the SPA for the Phase 3 efficacy trial for Luramist. We plan to conduct two identically designed efficacy trials. 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.

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 14 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, upon the closing, we received an upfront payment of $10 million. 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 are also eligible to 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 Mitsubishi Tanabe's blanket release of liens against our assets including the Evamist assets and intellectual property, we repaid the Mitsubishi 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.

In February 2009, K-V and certain of its subsidiaries announced a voluntary recall of most of its prescription products. Subsequent to the recall, K-V announced plans to reduce its workforce by 700 employees. In January 2009, K-V voluntarily suspended the manufacturing and shipping of all of its products. Evamist is not manufactured by K-V and was not subject to the recall. Given the uncertainties with K-V, it is difficult to determine the extent of the adverse impact on Evamist. Although we are entitled to additional milestone payments from future sales of Evamist by K-V, at the present time we do not anticipate receiving any additional milestones for the sales of Evamist.

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). Certain of the agreements were amended and restated on March 16, 2009. 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 Funding and Royalty Agreement, or 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 Sub made $3.3 million payments to us in April, September and December 2008 and February 2009 and will make two 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, on 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, to manufacture, promote and sell MUSE, and to 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, each as described in greater detail below. 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, the Company, the Deerfield Affiliates and the Deerfield Sub entered into the Option and Put Agreement, dated April 3, 2008, and an Amended and Restated Option and Put Agreement dated March 16, 2009, 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 the 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 the 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, less $2 million we paid on closing, if the Option is exercised on or prior to the third anniversary of the execution of the OPA; or
- $28 million, less $2 million we paid on closing, 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 the Deerfield Sub at the date of the closing of the resulting sale of the common stock of the Deerfield Sub; (ii) accrued and unpaid royalties; and *minus* (i) the option premium of $2 million that was paid at the closing of the transaction (referred to as the Option Premium); (ii) accrued but unpaid taxes; (iii) unpaid Funding Payments; (iv) loans payable by the Deerfield Sub; and (v) any other outstanding liabilities of the 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, or April 3, 2011, 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, or April 3, 2011, and we have provided the Deerfield Affiliates a Major Transaction Notice; or

- $17 million, in all other cases.

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 the Deerfield Sub at the date of the closing of the resulting sale of the common stock of the Deerfield Sub; (ii) accrued and unpaid royalties; and *minus* (i) accrued but unpaid taxes; (ii) unpaid Funding Payments; (iii) loans payable by the Deerfield Sub, and (iv) any other outstanding liabilities of the 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 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 April 3, 2008 if, immediately prior to such issuance, the market capitalization of the Company is less than $300 million.

In connection with the FARA, the Deerfield Sub and the Company have entered into a Royalty Security Agreement, whereby we have granted the 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 over that granted to the 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 available-for-sale securities, 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.

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 and has a 24-month shelf-life. As of March 31, 2009, the shipments of MUSE in the United States made in 2009, 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.

  At March 31, 2009, we continued to use an estimated product returns rate of 6.5%. We have used this rate since December 31, 2007, based on our product returns experience. Actual product returns can fluctuate between years due to both the timing of expiration and timing of when customers apply the credit memos that have been issued for returned product. The product returns reserve at March 31, 2009, covering the estimated returns exposure for product shipped in 2009, 2008, 2007 and a portion of 2006, was $2.8 million. This product returns reserve calculation is based upon the most recent information available, and we believe is reasonable and adequate to cover the estimated future credit memos to be issued for the return of prior sales of MUSE. Quarterly, we will continue to monitor the product returns experience and make adjustments to the product returns reserve, as appropriate.

- 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, including those with 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 which we began receiving in 2007. 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. 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 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 SEC'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, 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 are 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, 2008 was $83.7 million and for the three months ended March 31, 2009 was $20.9 million. Such revenue in future quarters is expected to be recognized as follows (in thousands):

Quarter ending	License revenue
June 30, 2009	$ 10,465

We are also eligible to 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.

In February 2009, K-V and certain of its subsidiaries announced a voluntary recall of most of its prescription products. Subsequent to the recall, K-V announced plans to reduce its workforce by 700 employees. In January 2009, K-V voluntarily suspended the manufacturing and shipping of all of its products. Evamist is not manufactured by K-V and was not subject to the recall. Given the uncertainties with K-V, it is difficult to determine the extent of the adverse impact on Evamist. Although we are entitled to additional milestone payments from future sales of Evamist by K-V, at the present time we do not anticipate receiving any additional milestones for the sales of Evamist.

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 and include advertising for clinical trials and patient recruitment costs. These costs are recorded as a component of R&D expenses and are expensed as incurred. 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 condensed consolidated 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 March 31, 2009, it was considered more likely than not that the Company's deferred tax assets would not be realized.

As of March 31, 2009, 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.

Inventories

Inventories are valued at the lower of cost or market. 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. As of March 31, 2009, the remaining inventory reserve balance is $1.5 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 three months of 2009 and 2008, 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 invested 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 accounts 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 capital preservation and liquidity 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. Also, if the banking system or the financial markets do not improve, continue to deteriorate or remain volatile, our investment portfolio may be impacted and the values and liquidity of our investments could be adversely affected.

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. These fair values are obtained primarily from multiple third-party pricing services. We may or may not hold 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 may 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 sheet at March 31, 2009.

Securities are carried at fair value, with the unrealized gains and losses, net of taxes, reported as a component of stockholders' 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, in which case such securities are written down to fair value and the loss is charged to other-than-temporary loss on impaired securities. We evaluate our investment securities for other-than-temporary declines based on quantitative and qualitative factors. Any realized gains or losses on the sale of marketable securities are determined on a specific identification method, and such gains and losses are reflected as a component of interest income.

Financial Accounting Standards Board, or FASB, Statement of Financial Accounting Standards, or SFAS, No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and Staff Accounting Bulletin, or 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. A significant judgment in the valuation of investments is the determination of when an other-than-temporary decline in value has occurred. We follow a consistent and systematic process for recognizing impairments on securities that sustain other-than-temporary declines in value. We have established a policy for the impairment review process. The decision to impair a security incorporates both quantitative criteria and qualitative information. The impairment review process considers a number of factors including, but not limited to: (i) the length of time and the extent to which the fair value has been less than book value, (ii) the financial condition and near term prospects of the issuer, (iii) our intent and ability to retain impaired investments for a period of time sufficient to allow for any anticipated recovery in value, (iv) whether the debtor is current on interest and principal payments and (v) general market conditions and industry or sector specific factors. For securities that are deemed to be other-than-temporarily impaired, the security is adjusted to fair value and the resulting losses are recognized in other-than-temporary loss on impaired securities in the condensed consolidated statements of operations. The new cost basis of the impaired securities is not increased for future recoveries in fair value.

During our quarterly impairment assessment, we determined that a decline in value of certain securities was other-than-temporary. Accordingly, we recorded other-than-temporary impairment adjustments of $444,000 in the three months ended March 31, 2009. We 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). Other-than-temporary impairment losses recognized in 2009 included impairments on investments for which we determined that the impairment was other-than-temporary due to credit downgrades and/or our intent and ability to hold the investment to maturity. These securities covered a number of industries. If market, industry, and/or investee conditions deteriorate, we may incur further impairments. In addition, due to the current lack of a readily available market for certain of our available-for-sale securities totaling $631,000, and the continued uncertainty in the capital markets, we expect to recover the carrying values of these securities beyond the next 12 months. Consequently, we have classified those available-for-sale securities as non-current in the condensed consolidated balance sheets.

In December 2007, our enhanced money market fund investment, Columbia Strategic Cash Portfolio Fund, or Columbia fund, ceased accepting cash redemption requests and changed to a floating net asset value. In light of the restricted liquidity, we elected to receive a pro-rata allocation of the underlying securities in a separately managed account. At March 31, 2009, the market value of securities received in-kind from the Columbia fund investment included in available-for-sale securities was $9.3 million.

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. We record legal fees and costs as an expense when incurred.

Share-Based Payments

We follow the fair value method of accounting for share-based compensation arrangements in accordance with 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 $1.3 million and $1.4 million of share-based compensation expense for the quarters ended March 31, 2009 and 2008, 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.

Fair Value

On January 1, 2008, we adopted SFAS No. 157 *Fair Value Measurements* and effective October 10, 2008, we adopted FSP No. SFAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active,* except as it applies to the nonfinancial assets and nonfinancial liabilities subject to FSP 157-2. Adoption of the provisions of this standard did not have a material effect on our financial position.

Financial Instruments Measured at Fair Value. Our cash and cash equivalents and 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 cash flow amounts to a single present value 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).

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. 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.

These types of instruments primarily consist of financial instruments whose value is based on quoted market prices such as cash, money market funds and U.S. Treasury securities that are actively traded. Management judgment was required to determine our policy that defines the levels at which sufficient volume and frequency of transactions is met for a market to be considered active.

- 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.

The types of instruments valued based on other observable inputs include debt securities of U.S. government agencies, corporate bonds, mortgage-backed and asset-backed products. 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.

These types of instruments include certain corporate bonds, mortgage-backed securities and asset-backed securities. Level 3 is comprised of unobservable inputs that are supported by little or no market activity. These instruments 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 may still include some observable inputs such as yield spreads derived from markets with limited activity. 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 March 31, 2009, these securities were valued primarily using valuation models that incorporate transaction details such as contractual terms, maturity, timing and amount of future cash inflows, as well as assumptions, including but not limited to, about prepayment speeds, credit spreads, default rates and benchmark yields and 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.

Fair Value Measurements

As of March 31, 2009, our cash and cash equivalents and available-for-sale securities measured at fair value on a recurring basis totaled $165.8 million. Of these, approximately $151.8 million were classified as Level 1, $12 million were classified as Level 2, and approximately $2 million as Level 3.

Approximately 92% of our cash and cash equivalents and available-for-sale securities are cash, money market instruments and U.S. Treasury securities and these are classified as Level 1. The valuation techniques used to measure the fair values of these financial instruments were derived from quoted market prices, as substantially all of these instruments have maturity dates, if any, within one year from the date of purchase and active markets for these instruments exists.

Approximately 7% of the balance of our cash and cash equivalents and available-for-sale securities that are measured at fair value on a recurring basis and classified as Level 2 were classified as such due to the usage of observable market prices for identical securities that are traded in less active markets. When observable market prices for identical securities are not available, we price our marketable debt instruments using: quoted market prices for similar instruments, or pricing models, such as a discounted cash flow model, with all significant inputs derived from or corroborated with observable market data. Securities classified as Level 2 generally include debt securities of U.S. government agencies, corporate bonds, mortgage-backed securities and asset-backed securities.

When values are determined using inputs that are both unobservable and significant to the values of the instruments being measured, we classify those instruments as Level 3 under the SFAS No. 157 hierarchy. As of March 31, 2009, our investment securities classified as Level 3 totaled $2 million or 1% of cash, cash equivalents and available-for-sale securities. For the three months ended March 31, 2009, we experienced $268,000 in impairment losses related to the Level 3 assets in our portfolio.

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). Certain of these agreements were amended and restated on March 16, 2009. 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 Funding and Royalty Agreement, or 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, September, and December 2008 and February 2009 and will make two quarterly payments of approximately $3.3 million, thereafter. We have agreed to pay royalties on the current net sales of MUSE and if approved, on 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 October 2008, the FASB issued FASB Staff Position, or FSP, SFAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*. FSP SFAS 157-3 clarifies the application of SFAS No. 157 in a market that is not active and addresses application issues such as the use of internal assumptions when relevant observable data does not exist, the use of observable market information when the market is not active and the use of market quotes when assessing the relevance of observable and unobservable data. FSP SFAS 157-3 is effective for all periods presented in accordance with SFAS No. 157. The guidance in FSP SFAS 157-3 is effective immediately and did not have a significant impact on our condensed consolidated financial position or results of operations upon adoption. See Note 4: "Cash, Cash Equivalents and Available-for-Sale Securities" to the notes to condensed consolidated financial statements in this Form 10-Q for information and related disclosures regarding our fair value measurements.

In February 2008, the FASB issued FSP SFAS 157-2, which delays the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value on a recurring basis (items that are remeasured at least annually). The FSP deferred the effective date of SFAS 157 for non-financial assets and non-financial liabilities until our fiscal year beginning on January 1, 2009. We do not expect the adoption of SFAS 157 for non-financial assets and non-financial liabilities to have a material effect on our condensed consolidated financial statements.

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. On January 1, 2009, we adopted this Statement, which did not 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. On January 1, 2009, we adopted this Statement, which did not 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.

In April 2009, the FASB issued FSP FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. This FSP amends SFAS No. 107, *Disclosures About Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. This FSP also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in summarized financial information at interim reporting periods. This FSP is effective for interim reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The FSP does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, this FSP requires comparative disclosures only for periods ending after initial adoption. We are currently evaluating this FSP and we do not expect the changes associated with adoption of this FSP will have a material effect on the determination or reporting of our financial results.

In April 2009, the FASB issued FSP FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*. This FSP amends the other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. This FSP does not amend existing recognition and measurement guidance related to other-than-temporary impairments of equity securities. This FSP modifies the requirements for recognizing other-than-temporarily impaired debt securities and revises the existing impairment model for such securities, by modifying the current *intent and ability* indicator in determining whether a debt security is other-than-temporarily impaired. This FSP is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The FSP does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, this FSP requires comparative disclosures only for periods ending after initial adoption. We are currently evaluating this FSP and we do not expect the changes associated with adoption of this FSP will have a material effect on the determination or reporting of our financial results.

In April 2009, the FASB issued FSP FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*. This FSP provides additional guidance for estimating fair value in accordance with SFAS No. 157, *Fair Value Measurements*, when the volume and level of activity for the asset or liability have significantly decreased. This FSP also includes guidance on identifying circumstances that indicate a transaction is not orderly. FSP 157-4 provides guidance on how to determine the fair value of assets and liabilities under SFAS 157 in the current economic environment and reemphasizes that the objective of a fair value measurement remains an exit price. If we were to conclude that there has been a significant decrease in the volume and level of activity of the asset or liability in relation to *normal* market activities, quoted market values may not be representative of fair value and we may conclude that a change in valuation technique or the use of multiple valuation techniques may be appropriate. This FSP is effective for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The FSP does not require disclosures for earlier periods presented for comparative purposes at initial adoption. In periods after initial adoption, this FSP requires comparative disclosures only for periods ending after initial adoption. We are currently evaluating this FSP and we do not expect the changes associated with adoption of this FSP will have a material effect on the determination or reporting of our financial results.

RESULTS OF OPERATIONS

Executive Overview

For the three months ended March 31, 2009, we reported a net loss of $6.8 million, or $0.10 net loss per share, as compared to a net loss of $7.1 million, or $0.12 net loss per share, during the same period in 2008. The lower net loss in the first quarter of 2009 as compared to the first quarter of 2008 is primarily due to reduced operating expenses, a decrease in losses on other-than-temporarily impaired securities, partially offset by lower U.S. and international revenue, a decrease in interest income and an increase in interest expense. The decrease in operating expenses was primarily attributable to decreased spending related to our Phase 3 clinical trials of Qnexa for the treatment of obesity in the first quarter of 2009 as compared to the first quarter of 2008.

On April 3, 2008, we entered into several agreements with Deerfield Management Company, L.P., or Deerfield, a healthcare investment fund, and its affiliates. Certain of these agreements were amended and restated on March 16, 2009. 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, September and December 2008 and February 2009 and will make two 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 are 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.

The revenue related to the transaction recognized in the first quarter of 2009 was $20.9 million and the revenue in future quarters is expected to be recognized as follows (in thousands):

Quarter ending	License revenue
June 30, 2009	$ 10,465

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 March 31, 2009	Three Months Ended March 31, 2008	(Decrease)	% Change
	(In thousands, except percentages)			
United States product, net	$ 893	$ 1,088	$ (195)	(18)%
International product	293	554	(261)	(47)%
License and other revenue	21,046	21,046	0	0%
Total revenues	$ 22,232	$ 22,688	$ (456)	(2)%

Product revenues for the quarters ended March 31, 2009 and 2008 were $1.2 million and $1.6 million, respectively. U.S. product revenues in the quarter ended March 31, 2009 decreased as compared to the same period in 2008. While the U.S. units shipped and the price of MUSE increased in the first quarter of 2009, revenues decreased partially due to an increase in the sales allowance for pricing discounts for certain government customers of $136,000. The decrease in international revenue in the quarter ended March 31, 2009 as compared to the same period in 2008 was partially due to a reduction in transfer prices resulting from the difference in currency exchange rates. We anticipate that these exchange rate differences and the resulting lower transfer prices are likely to continue. Also contributing to the decrease in both U.S. and international product revenues in the first quarter 2009 as compared with the same period of 2008 were sales allowances of $212,000 and $208,000, respectively, for certain production lots of the 125 mg and 250 mg strength MUSE shipped that do not meet certain specifications applied toward the end of the 24 month shelf life. This out-of-specification condition appears to arise in the last six months of the 24 month shelf life. This condition does not pose any safety risk to the patient. We have recorded these sales allowances based upon the best estimate at this time of the quantity of 125 mg and 250 mg MUSE that may be on hand at the wholesale level. This matter remains under investigation and revisions to our estimates will be charged to income in the period in which the information that gives rise to the revision becomes known. The increase in MUSE domestic shipments 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 our largest wholesaler customer will continue its historical pattern of making purchases in the fourth quarter that exceed expected quarterly demand. If our largest wholesaler customer does not repeat this pattern of purchasing quantities of MUSE that exceed quarterly demands, revenues from the sale of MUSE in 2009 may be lower as compared to 2008.

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 March 31, 2009	Three Months Ended March 31, 2008	(Decrease)	% Change
	(In thousands, except percentages)			
Cost of goods sold and manufacturing	$ 2,603	$ 2,787	$ (184)	(7)%

Cost of goods sold and manufacturing, or cost of goods sold, in the first quarter of 2009 decreased $184,000, or 7%, to $2.6 million, as compared to $2.8 million for the first quarter of 2008. Cost of goods sold decreased in the three months ended March 31, 2009 as compared to the same period in 2008 primarily due to the disposal of inventory due to the non-conformance of certain raw materials in 2008.

We anticipate cost of goods sold for the year 2009 will be similar to costs incurred in 2008.

Research and development. (Unaudited)

	Three Months Ended March 31, 2009	Three Months Ended March 31, 2008	(Decrease)	% Change
	(In thousands, except percentages)			
Research and development	$ 20,069	$ 23,371	$ (3,302)	(14)%

Research and development expenses in the first quarter of 2009 decreased $3.3 million, or 14%, to $20.1 million, as compared to $23.4 million for the first quarter of 2008. In the first quarter of 2009, this decrease in spending was primarily due to lower Qnexa for obesity spending of $8.3 million and other net project spending decreases of $515,000, partially offset by increased spending for avanafil of $5.3 million and a net increase in non-project related spending of $205,000 (primarily due to increases in compensation and related expense of $412,000 due to an increase in headcount partially offset by a decrease in non-cash stock based compensation expense of $191,000), as compared to the first quarter of 2008. In the three months ended March 31, 2009, we spent $7.2 million for services provided by one clinical research organization on the Qnexa Phase 3 studies, which represented 36% of our research and development expenses for the quarter. Separately, we spent another $5.2 million for services provided by another clinical research organization on the avanafil Phase 3 studies, which represented 26% of our research and development expenses for the first quarter of 2009.

We anticipate that our research and development expenses in 2009 will be similar to costs incurred in 2008, as we continue to advance the clinical program for Qnexa for the treatment of obesity, avanafil for erectile dysfunction and our other investigational products. The current remaining contractual obligation for payments to our primary contract research organization, or CRO, for the Phase 3 Qnexa trials totals $18.1 million and for payments to our primary CRO for the Phase 3 avanafil trials totals $13.4 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 at least 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 March 31,			%
	2009	2008	Increase	Change
	(In thousands, except percentages)			
Selling, general and administrative	$ 5,411	$ 4,252	$ 1,159	27%

Selling, general and administrative expenses in the three months ended March 31, 2009 of $5.4 million increased $1.2 million, or 27% as compared to the three months ended March 31, 2008. In the quarter ended March 31, 2009, this increase is primarily due to an incremental increase of $234,000 in investor relations expense, $732,000 in corporate legal fees and other net increases in selling, general and administrative expenses totaling $193,000, as compared to the quarter ended March 31, 2008.

We anticipate that our selling, general and administrative expenses in 2009 will increase slightly compared to those in 2008 due to higher legal expenses relating to the Acrux arbitration matter.

Interest income and expense.

Interest income for the quarter ended March 31, 2009 was $208,000, as compared to $2.1 million for the quarter ended March 31, 2008. The decrease in interest income in the quarter ended March 31, 2009 as compared to the same period last year is primarily due to lower investment yields in the three months ended March 31, 2009 as compared to the same period in 2008.

Interest expense for the quarter ended March 31, 2009 was $716,000 as compared to $122,000 during the same period last year. The net increase in interest expense in the three months ended March 31, 2009 as compared to the same period in 2008 is primarily due to interest expense on the Deerfield financing in 2009.

The other-than-temporary loss on impaired securities was $444,000 in the three months ended March 31, 2009 as compared to $1.4 million during the same period in 2008. The $444,000 other-than-temporary loss primarily represents unrealized impairment losses recorded on securities that are classified as available-for-sale securities on our condensed consolidated balance sheet as of March 31, 2009. The majority of the other-than-temporary losses on impaired securities were recorded on securities obtained in late 2007 through the redemption-in-kind distribution from the Bank of America Columbia Strategic Cash Portfolio Fund. 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 $165.8 million at March 31, 2009, as compared to $189.2 million at December 31, 2008. The decrease in cash, cash equivalents and available-for-sale securities of $23.4 million is the net result of cash used for operating and investing activities partially offset by cash provided by financing activities for the first three months of 2009. Included in these amounts are $3.3 million in cash receipts from the Deerfield financing, and $185,000 from stock option exercises.

Since inception, we have financed operations primarily from the issuance of equity securities. Through March 31, 2009, we raised $300.1 million from financing activities, received $150 million from the sale of Evamist and had an accumulated deficit of $186.6 million at March 31, 2009.

Available-for-sale securities. We focus on capital preservation and liquidity 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.

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 capital preservation and on liquidity 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 March 31, 2009, we had $42.7 million in cash and cash equivalents and $123.1 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 realized or unrealized losses in the value of our portfolio which would have an adverse effect on our results of operations, liquidity and financial condition. Also, if the banking system or the financial markets do not improve, continue to deteriorate or remain volatile, our investment portfolio may be impacted and the values and liquidity of our investments could be adversely affected.

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 three months ended March 31, 2009, we recorded unrealized charges for other-than-temporary impairment of securities of $444,000. 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.

Investment securities are exposed to various risks, such as interest rate, market and credit. Due to the level of risk associated with certain investment securities and the level of uncertainty related to changes in the value of investment securities, it is possible that changes in these risk factors in the near term could have an adverse material impact on our results of operations or shareholders' equity.

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 March 31, 2009 was $912,000, as compared to $4.2 million at December 31, 2008. The 79% decrease in the accounts receivable balance at March 31, 2009 is primarily due to the collection of the accounts receivable outstanding at December 31, 2008. Currently, we do not have any significant concerns related to accounts receivable or collections.

Liabilities. Total liabilities were $55.6 million at March 31, 2009, or $20.8 million lower than at December 31, 2008. The change in total liabilities includes a $21 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.

We have entered into a manufacturing agreement with a supplier to purchase alprostadil. As of March 31, 2009, our remaining commitment under this agreement is to purchase a minimum of $1.5 million of product from 2009 through 2011. Should our inventory of alprostadil exceed our future production needs, it may be necessary to write-off additional excess inventory.

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 $25.2 million of cash and $13.3 million of cash during the three months ended March 31, 2009 and 2008, respectively. During the first three months of 2009, our net operating loss of $6.8 million was offset by a $444,000 other-than-temporary loss on impaired securities, $1.3 million in non-cash stock based compensation expense, a $781,000 increase in accrued research and clinical expenses primarily due to the Qnexa for obesity development effort, and a $3.2 million reduction in our accounts receivable, due to the collection of monies owed to us. These positive cash flows to our net operating loss were in turn offset by the recognition of $21 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 and a $2.8 million decrease in accounts payable due to the timing of payments.

Investing Activities. Our investing activities used and provided $744,000 and $29.1 million in cash during the three months ended March 31, 2009 and 2008, 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 $2.5 million and $85,000 during the three months ended March 31, 2009 and 2008, respectively. In the first three months of 2009, the cash provided by financing activities included $3.3 million in cash receipts from the Deerfield financing and $185,000 in proceeds from the exercise of stock options and partially offset by $993,000 in principal payments under our notes payable.

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% for the first three months of 2009 and 2008, 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. Certain of the agreements with Deerfield were amended and restated on March 16, 2009. 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 Sub made $3.3 million payments to us in April, September and December 2008 and February 2009 and will make two 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, 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.

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 through a purchase and sale of all the shares of the Deerfield Sub. If we exercise our right to purchase the Deerfield Sub, the net price will be $23 million if exercised before April 3, 2011 or $26 million if exercised after April 3, 2011 but before April 3, 2012 (the purchase price is subject to other adjustments, as defined in the agreement). After April 3, 2011, 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 the Deerfield Sub would be $23 million on or before April 3, 2011 and $26 million from April 3, 2011 through April 3, 2018. The sale of the shares of the 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) which 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 and approval by the FDA 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.

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 costs involved in establishing a commercial operation and in launching a product without a partner;
- 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 state of the economy and financing environment;
- the regulatory approval environment and regulatory hurdles for safety assessment for new products;

- the health care reimbursement system or the impact of healthcare reform, if any, imposed by the U.S. federal government;
- 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, to fund operating expenses, to pursue regulatory approvals for our investigational product candidates, to finance 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 or new manufacturing and marketing capabilities in the future, or to launch a product. In particular, we expect to make other substantial payments to Acrux and Mitsubishi 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 markets at any time. The sale of additional equity securities would result in additional dilution to our stockholders. We may also seek additional funding through strategic alliances, acquisitions of companies with cash balances 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 March 31, 2009, 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. This table includes our enforceable and legally binding obligations and future commitments, as well as obligations related to all contracts that we are likely to continue, regardless of the fact that they were cancelable as of March 31, 2009. These do not include milestones and assumes 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**	**2009 (9 months)**	**2010-2012**	**2013-2014**	**Thereafter**
			(in thousands)		
Operating leases	$ 1,209	$ 397	$ 812	$ —	$ —
Manufacturing and other agreements	12,570	9,712	2,825	10	23
Clinical trials	41,295	37,238	4,057	—	—
Notes payable	13,662	145	9,160	409	3,948
Interest payable	9,855	2,504	4,726	639	1,986
Total contractual obligations	$ 78,591	$ 49,996	$ 21,580	$ 1,058	$ 5,957

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. This 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. On December 16, 2008, we entered into an amendment to this lease. Under the terms of the amended lease, we will continue to lease the office space for our corporate headquarters for a two year period commencing on August 1, 2009 and expiring on July 31, 2011. The base monthly rent is set at $1.64 per square foot or $23,000 per month. The amended lease allows us one option to extend the term of the lease for one year from the expiration of the lease.

Manufacturing and Other Agreements

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 alprostadil from a supplier beginning in 2003 and ending in 2008. In May 2007, we amended the terms of this agreement and our remaining commitment is to purchase a minimum total of $1.5 million of product from 2009 through 2011.

Other Agreements

We have remaining commitments under various general and administrative services agreements totaling $2 million at March 31, 2009, including $1.3 million related to Leland F. 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, testing and manufacturing including animal studies and, at March 31, 2009, our remaining commitment under these agreements totaled $8.3 million. In addition, we have entered into marketing promotion and related agreements for our erectile dysfunction product, MUSE. At March 31, 2009, our remaining commitment under the MUSE agreements totaled $695,000.

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. On January 23, 2009, the Compensation Committee approved an amendment to the Employment Agreement, or the Amendment, which amends the Employment Agreement. Pursuant to the Amendment, the initial term of the Employment Agreement was increased from two to three years commencing on June 1, 2007 and other relevant dates were also extended to reflect the three year initial term.

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 March 31, 2009, our remaining commitment under these agreements totaled $41.3 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 mortgage loan from Crown. The land and buildings, among other assets, located at our principal MUSE 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% for the three months ended March 31, 2009 and 2008, respectively. As of March 31, 2009, we have a principal balance of $5 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 2% at March 31, 2009 (the fourth year of the loan term). If prepayment 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). Certain of the agreements were amended and restated on March 16, 2009. 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 Funding and Royalty Agreement, or 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 Sub made $3.3 million payments to us in April, September and December 2008 and February 2009 and will make two 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, on 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, to manufacture, promote and sell MUSE, and to 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, each as described in greater detail below. 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, the Company, the Deerfield Affiliates and the Deerfield Sub entered into the Option and Put Agreement, dated April 3, 2008, and an Amended and Restated Option and Put Agreement dated March 16, 2009, 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 the 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 the 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, less $2 million we paid on closing, if the Option is exercised on or prior to the third anniversary of the execution of the OPA; or
- $28 million, less $2 million we paid on closing, 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 the Deerfield Sub at the date of the closing of the resulting sale of the common stock of the Deerfield Sub; (ii) accrued and unpaid royalties; and *minus* (i) the option premium of $2 million that was paid at the closing of the transaction (referred to as the Option Premium); (ii) accrued but unpaid taxes; (iii) unpaid Funding Payments; (iv) loans payable by the Deerfield Sub, and (v) any other outstanding liabilities of the 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, or April 3, 2011, 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, or April 3, 2011, and we have provided the Deerfield Affiliates a Major Transaction Notice; or
- $17 million, in all other cases.

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 the Deerfield Sub at the date of the closing of the resulting sale of the common stock of the Deerfield Sub; (ii) accrued and unpaid royalties; and *minus* (i) accrued but unpaid taxes; (ii) unpaid Funding Payments; (iii) loans payable by the Deerfield Sub, and (iv) any other outstanding liabilities of the 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 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 April 3, 2008 if, immediately prior to such issuance, the market capitalization of the Company is less than $300 million.

In connection with the FARA, the Deerfield Sub and the Company have entered into a Royalty Security Agreement, whereby we have granted the 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 over that granted to the 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. The above Contractual Obligations table includes estimated interest payable on the principal owing at March 31, 2009 from the Deerfield Financing based upon a 33% imputed effective interest rate whereas actual quarterly royalty payments are based upon a percentage of net MUSE sales at a rate substantially lower than the imputed effective interest rate used to calculate interest expense.

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.

Mitsubishi Tanabe

In January 2001, we entered into an exclusive development, license and supply agreement with Tanabe Seiyaku Co., Ltd., or Tanabe, now Mitsubishi Tanabe, and hereinafter referred to as Mitsubishi 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, Mitsubishi Tanabe agreed to grant an exclusive license to us for products containing avanafil outside of Japan, North Korea, South Korea, China, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Vietnam and the Philippines. We agreed to grant Mitsubishi Tanabe an exclusive, royalty-free license within those countries for oral products that we develop containing avanafil. In addition, we agreed to grant Mitsubishi Tanabe an exclusive option to obtain an exclusive, royalty-bearing license within those countries for non-oral products that we develop containing avanafil. Mitsubishi 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 Mitsubishi 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 noted above. We paid Mitsubishi 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 Mitsubishi Tanabe in the years ended December 31, 2007 and 2008; however, we paid Mitsubishi Tanabe $4 million in January 2009 following the enrollment in December 2008 of the first patient in the first Phase 3 clinical studies. We expect to make other substantial payments to Mitsubishi Tanabe in accordance with our agreements with Mitsubishi 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 $15 million in the aggregate and include payments upon: 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 Mitsubishi 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 Mitsubishi 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 Mitsubishi 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 notes to condensed consolidated financial statements included in this Form 10-Q for additional information concerning the terms of this agreement.

In November 2006, we were notified of certain claims by Acrux regarding the Luramist agreements. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding certain claims related to Luramist. Acrux's demand sought a reversion of all rights assigned to us related to Luramist, monetary damages and the payment of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. We asserted counterclaims against Acrux in the arbitration and sought the enforcement of our rights under the Testosterone Agreement. The arbitration hearing concluded on January 23, 2009, and on April 6, 2009 the panel of arbitrators, or the Panel, issued its Interim Arbitration Award finding in favor of VIVUS that we were in compliance with the Testosterone Agreement and denying all of the relief sought by Acrux in its demand. The Panel found that we had used diligent, commercially reasonable efforts to develop Luramist and that we had satisfied our obligations to keep Acrux informed on the status of the development efforts. The Panel also ruled in favor of VIVUS on certain of its counterclaims. The Interim Arbitration Award requires the parties to meet and confer on a number of contractual obligations and to report back to the Panel within 35 days on the results of these efforts.

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.

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 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.

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 March 31, 2009 by approximately $376,000. 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.

We have investments in U.S. Treasury securities and debt securities of U.S. government agencies, 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 million loan payable to Crown Bank, N.A. as of March 31, 2009. 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 7.5% for the first three months of 2009 and 2008, respectively.

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.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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 through its wholly owned subsidiary FemPharm Pty Ltd., or Acrux, are parties to the Testosterone Development and Commercialization Agreement dated February 12, 2004, or the Testosterone Agreement. The Testosterone Agreement covers the Company's investigational product candidate, Luramist, which is licensed from Acrux under the Testosterone Agreement. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding certain claims related to Luramist. Acrux's demand sought a reversion of all rights assigned to the Company related to Luramist, monetary damages and the payment of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. The Company asserted counterclaims against Acrux in the arbitration and sought the enforcement of the Company's rights under the Testosterone Agreement. The arbitration hearing concluded on January 23, 2009, and on April 6, 2009 the panel of arbitrators, or the Panel, issued its Interim Arbitration Award finding in favor of the Company that it was in compliance with the Testosterone Agreement and denying all of the relief sought by Acrux in its demand. The Panel found that the Company had used diligent, commercially reasonable efforts to develop Luramist and that the Company has satisfied its obligations to keep Acrux informed on the status of the development efforts. The Panel also ruled in favor of the Company on certain of its counterclaims. The Interim Arbitration Award requires the parties to meet and confer on a number of contractual obligations and to report back to the Panel within 35 days on the results of these efforts.

In January 2009, a former employee filed a U.S. Equal Employment Opportunity Commission Claim. The Notice of Charge of Discrimination was vague as to the nature and scope of the claim, merely indicating that sex discrimination and retaliation under Title VII of the Civil Rights Act is alleged. Additionally, the Company received a letter from a former employee claiming California labor code violations in connection with the former employee's recruitment and wrongful termination. The Company has fully investigated the charges by these former employees and believes that there is no merit to these charges and that it has meritorious defenses to such charges. The Company believes the employees have no claim to additional compensation or benefits. Due to the current economic downturn, employees may be more likely to file employment-related claims. Although there may be no merit to such claims, the Company may be required to allocate additional monetary and personnel resources to defend against these types of allegations in the future.

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.

ITEM 1A. RISK FACTORS

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 VIVUS. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

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.

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 dosing 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, avanafil and Luramist, have not successfully completed all of the large, pivotal Phase 3 trials for efficacy and safety that are required for approval by the FDA and other worldwide regulatory authorities. Recently, we completed a 28-week Phase 3 study of Qnexa and its components in 756 patients. 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, dosage, 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 treatment 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 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. Earlier studies with Qnexa were completed using a twice-a-day dose. 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 are using the once-a-day formulation in the Phase 3 studies of Qnexa. Our first completed Phase 3 study used the once-a-day formulation and was for 28 weeks in 756 obese patients. 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 first Phase 3 obesity study. The FDA has also asked us to study the effects of a lower dose of Qnexa, which we are doing 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 been demonstrated in clinical trials for any of our current investigational product candidates. If any of our investigational product candidates fail 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.

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 with substantial evidence 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 and approval by the FDA 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;
- poor 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
- inability 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 and the EQUATE study which contained two phentermine arms. 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.

Adverse side effects associated with topiramate, one of two ingredients 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 first completed Phase 3 obesity study, tingling was experienced in 23% of the patients on the full-dose of Qnexa. In the Phase 2 diabetes study, paresthesia was experienced by 17% of the patients. 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 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 issued an alert on the use of antiepileptic drugs and a potential risk of increased suicidal ideation. 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. In December 2008, the FDA asked the manufacturers of the antiepileptic drugs included in the analysis to add warnings about suicidality to the labels and to issue a medication guide covering the results of the meta analysis. In April 2009, the FDA approved these new labels. We anticipate that the label for Qnexa, if approved, will contain the similar suicidality warnings to those contained in the topiramate label.

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 who become pregnant during the study period are required to immediately discontinue study medication. We are unable to predict the effect or impact of the use of Qnexa on study subjects who become pregnant or their fetuses.

Subjects in our trials will experience side effects. Serious adverse events will be reported to the FDA and study investigators as required in accordance with current guidelines and standards. Serious adverse events or adverse events that occur in small numbers may be not disclosed to the public until such time the various documents submitted to the FDA as part of the approval process are made public. We are unable to determine what adverse events, if any, will fall into this category. We are also unable to determine if the subsequent disclosure of adverse events, severe or otherwise will have an adverse effect on our stock price.

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

Topiramate and phentermine are each approved for sale by the FDA and have been on the market for many years. Adverse events and side effects observed in pre-clinical and post-marketing studies are included in the full prescribing information or 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, paresthesia and various drug interactions. The label for ADIPEX, a popular branded form of phentermine, contains warnings and precautions including recommendation against coadministration of phentermine with other drugs for weight loss. Adverse side effects include, among other things, 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 warnings and precautions for both of these products are updated often.

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, physicians, analysts, investors, the media or the public in general 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 with individual drugs contained in the Qnexa formulation and immediate competition.

Each of the approved drugs that are combined to produce our investigational product candidate, Qnexa, will likely 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 Qnexa’s 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 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.

We may choose or be required by regulatory authorities to restrict distribution of Qnexa to specialty pharmacies after physicians register to ensure a safe and secure launch. Our success in distributing our product candidate in this manner could be limited which could have an adverse effect on our business, financial condition and results of operations and cash flow.

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 are 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 more effective than each of the components. As a result, we will be required to include in our clinical trial protocols 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 was designed to meet the combination guidelines set by the FDA. The EQUATE study contained separate component arms as well as the combination. We believe the results of the EQUATE study meet FDA guidelines for combination therapy studies; however, there can be no assurance that we have satisfied the combination requirements or that further testing of the combination will not be required. The EQUATE study also contained a mid-dose of Qnexa containing 46 mg of topiramate CR and 7.5 mg of phentermine. The mid-dose is included in the OB-303 study. We may file for approval for the mid-dose in addition to the full-dose. We have not conducted any additional testing on the mid-dose. Further, the number of subjects on the mid-dose in the OB-303 may not be sufficient for approval. We have no assurance that the mid-dose of Qnexa will be approved as monotherapy or that additional pre-clinical and clinical testing may not be needed prior to approval.

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 Seiyaku Co., Ltd., or Tanabe, in 2001. In October 2007, Tanabe and Mitsubishi Pharma Corporation completed their merger and announced their name change to Mitsubishi Tanabe Pharma Corporation, or Mitsubishi Tanabe. The rights to Evamist were sublicensed to K-V. 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. The monetary and disruption costs of any disputes involving our collaborative agreements could be significant despite rulings in our favor.

The Company and Acrux Limited through its wholly owned subsidiary FemPharm Pty Ltd., or Acrux, are parties to the Testosterone Development and Commercialization Agreement dated February 12, 2004, or the Testosterone Agreement. The Testosterone Agreement covers our investigational product candidate, Luramist, which is licensed from Acrux under the Testosterone Agreement. On November 5, 2007, Acrux made a demand for arbitration under the Testosterone Agreement regarding certain claims related to Luramist. Acrux's demand sought a reversion of all rights assigned to us related to Luramist, monetary damages and the payment of a milestone payment for Luramist under the Testosterone Agreement and declaratory relief. We asserted counterclaims against Acrux in the arbitration and sought the enforcement of our rights under the Testosterone Agreement. The arbitration hearing concluded on January 23, 2009, and on April 6, 2009 the panel of arbitrators, or the Panel, issued its Interim Arbitration Award finding in favor of the Company that we were in compliance with the Testosterone Agreement and denying all of the relief sought by Acrux in its demand. The Panel found that we had used diligent, commercially reasonable efforts to develop Luramist and that we had satisfied our obligations to keep Acrux informed on the status of the development efforts. The Panel also ruled in favor of the Company on certain of its counterclaims. The Interim Arbitration Award requires the parties to meet and confer on a number of contractual obligations and to report back to the Panel within 35 days on the results of these efforts. The monetary and disruption costs of this arbitration were significant despite the favorable rulings by the Panel.

While we may be entitled to future milestone payments under existing contractual arrangements, we may not receive these payments.

Certain of our contractual arrangements include future milestone payments to us based upon the other party achieving defined sales targets. Meeting those milestone targets is dependent on the performance of the other party to the contractual arrangement and we have little, or no, control over those outcomes. We have no assurance any of those milestone targets will be achieved and that the milestones will be paid to us.

For example, on March 30, 2007, we entered into a definitive agreement with K-V to transfer the assets and grant a sublicense of our rights under our licensing agreement with Acrux related to Evamist, a metered dose transdermal spray for the treatment of menopause symptoms, to K-V. Under the terms of this agreement, we are also eligible to receive certain one-time payments of up to $30 million based on K-V achieving certain annual net sales thresholds for Evamist. In February 2009, K-V and certain of its subsidiaries announced a voluntary recall of most of its prescription products. Subsequent to the recall, K-V announced plans to reduce its workforce by 700 employees. In January 2009, K-V voluntarily suspended the manufacturing and shipping of all of its products. Evamist is not manufactured by K-V and was not subject to the recall. Given the uncertainties with K-V, it is difficult to determine the extent of the adverse impact on Evamist. Although we are entitled to additional milestone payments from future sales of Evamist by K-V, at the present time we do not anticipate receiving any additional milestones for the sales of Evamist.

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 Mitsubishi Tanabe. There can be no guarantee that the merger of Tanabe and Mitsubishi will not have an adverse material effect on our agreement with Mitsubishi 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;
- our collaborators may be required to disclose our confidential information or may fail to protect our confidential information;
- we may be required to relinquish important rights such as marketing and distribution rights;
- business combinations or significant changes in a collaborator’s business strategy may adversely affect a collaborator’s willingness or ability to complete its obligations under any arrangement;
- legal disputes or disagreements may occur with our collaborative partners;
- 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. The FDA has since published a guidance document in December 2008 for the evaluation of cardiovascular risk in new antidiabetic therapies specifically for the treatment of Type II diabetes. In general, the FDA recommends that sponsors should compare the incidence of important cardiovascular events occurring with the investigational agent to the incidence of the same type of events with the control group to estimate the relative risk of the investigational agent. This may be accomplished by either conducting an integrated analysis (meta-analysis) of the Phase 2 and Phase 3 studies or conduct a single, large, long-term cardiovascular safety 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 likely be subject to this recommendation. If we are required to complete a long-term cardiovascular study for Qnexa prior to an NDA submission, the ultimate approval may be delayed for several years and the overall cost of the program will significantly 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. Although the active ingredients in Qnexa have been previously approved by FDA at higher doses for other indications, it is a centrally acting drug that may increase the risk of psychiatric side effects such as depression and/or suicidal ideation.

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 a 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.

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 and how we may distribute our products. 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 pre-defined 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. CROs and their vendors or suppliers may also face changes in regulatory requirements from governmental agencies in the U.S. and other countries. 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 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 replacement third parties or enter into favorable agreements with these third parties, 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.

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 is limited. 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 would delay our Qnexa clinical studies, which could have a material adverse impact on our development plan, market price of our common stock and financial condition.

We rely on third parties to maintain appropriate levels of confidentiality of the data compiled during clinical trials.

We seek to maintain the confidential nature of our confidential information through contractual provisions in our agreements with third parties, including our agreements with clinical research organizations, or CROs, that manage our clinical studies for our investigational product candidates. These CROs may fail to comply with their obligations of confidentiality or may be required as a matter of law to disclose our confidential information. As the success of our clinical studies depends in large part on our confidential information remaining confidential prior to, during and after a clinical study, any disclosure could have a material adverse effect on the outcome of a clinical study, our business, financial condition and results of operations.

For example, the CRO managing several of our Phase three clinical studies for Qnexa is a party to a patent infringement suit in which the claimant accuses the CRO of infringing a U.S. patent through the CRO's alleged use of certain electronic data capture applications for data collection and data management in clinical trials. We are informed that the applications at issue have been used by the CRO in the clinical studies performed on behalf of the Company. The parties to the suit are currently involved in discovery and the claimant has requested documents and information that qualifies as confidential information under various agreements between us and the CRO. The CRO has informed us that it intends to take steps to ensure that our confidential information is disclosed in a limited and controlled manner, if at all, in order to protect and maintain its confidential nature; however, there can be no assurance that this information will remain confidential. Should the information not remain confidential we could be harmed which could have a material adverse effect on our business, financial condition or results of operations.

Risks Relating to our Operations

If we, or our suppliers, fail to comply with FDA and other regulatory agency 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 such 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.

Another example of non-conformance came to light during the first quarter 2009, when we, as part of our routine testing, identified that certain lots of the 125 mg and 250 mg strength MUSE product had exceeded the specified limit of allowable impurities. The identified product appears to be out of compliance with the impurity specification in the 18th-24th month of its shelf life. All MUSE products have a 24 month shelf life. In 2008, sales of the 125 mg and 250 mg strength MUSE represented 11% of our worldwide sales. Upon identifying this non-conformance, we promptly notified the FDA. The occurrence of known impurities to some level is typical within most pharmaceutical products. Our preliminary investigation concerning this MUSE impurity issue suggests that the elevation in impurities may have been caused during the routine sterilization process. The current investigation is continuing and other lots of commercialized product may also be identified as containing levels of impurity that exceed the product’s specifications. Although we believe that this impurity poses no safety risk to the patients, it is possible that we may recall some of the commercialized lots of product as part of our commitment to maintaining cGMP and compliance to FDA regulations. We do not believe that there are significant quantities of the product with identified impurities remaining at the wholesale distributors. However, there can be no assurance that a product recall will not occur in this instance or will not occur in the future from similar or other variations of the manufacturing process. Also, there can be no assurance that inherent and future variations in the sterilization process will not produce product that will exceed the product’s impurity specification or that would have some other effect which would still render the product to not be within its full range of specification over the full course of its shelf life. Should a recall be necessary, there may be periods when the 125 mg and 250 mg strength MUSE product are not fully available to the commercial market and these strengths may go into a back order status. In addition, the FDA and/or international regulatory agencies may require us to perform extensive investigations and/or extensive process revalidations in relationship to the resolution of this issue. Should such extensive investigations be necessary, a product recall be made, or a product shortage and back order occur, there could be a material adverse impact 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 container were within the VIVUS held inventory, were separated from our other inventory and were subsequently destroyed. 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 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 commercial 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 and distribution channels. 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, as well as 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 product labeling 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, we are not able to anticipate if one of our larger wholesalers will continue their historical pattern of making purchases in the fourth quarter that exceed expected quarterly demands. If that wholesaler does not repeat this pattern of purchasing quantities of MUSE that exceed quarterly demands, revenues from the sale of MUSE in 2009 may be lower as compared to 2008.

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 or our investigational product candidates less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience. Mergers, acquisitions, joint ventures and similar events may also significantly change the competition.

Current approved 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 product candidates in Phase 3 clinical trials being developed by Arena Pharmaceuticals, Inc., Novo Nordisk A/S, Takeda Pharmaceutical Company and Orexigen Therapeutics, Inc., and approximately 20 product candidates in Phase 2 clinical trials by companies including Amylin Pharmaceuticals, Inc., Neurosearch A/S 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 halted 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 has also halted all human trials of the Acomplia obesity medicine after health authorities in a few countries requested local tests be stopped.

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 Corporation in the United States.

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., or NexMed, announced that the NDA filed for its ED product, Vitaros®, a topically applied alprostadil cream, was accepted for review by the FDA. In February 2009, NexMed announced that they had sold the U.S. rights to Vitaros to Warner Chilcott Company, Inc. (a subsidiary of Warner Chilcott, Ltd., NASDAQ:WCRX), or Warner. Under the reported terms of the agreement, NexMed received an initial, up-front payment of $2.5 million and is eligible to receive an additional payment of $2.5 million upon Warner’s receipt of FDA approval of the NDA. If the NDA for the NexMed product is approved and Warner 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.

Two companies are developing products that could compete with our investigational product candidates for the treatment of FSD. The Proctor & Gamble Company has been developing Intrinsa, a testosterone patch for the treatment of HSDD, but announced in December 2008 that they will halt research and consider divestiture of their four key pharmaceutical brands, including Intrinsa. BioSante Pharmaceuticals, Inc. is developing forms of testosterone gels for HSDD. 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 supplier fails to supply us with the active pharmaceutical ingredients, or APIs, 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 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. Currently, we only have a manufacturing agreement with Chinoin 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.

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 supply 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. Although both companies are approved for the sterilization of MUSE, E- Beam is not currently an operational facility. If E-Beam is unable to become operational or interruptions in MUSE sterilization services occur for any reason, including a decision by E-Beam or Beam One to discontinue providing these 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 alprostadil and an interruption to this supply could harm our business.

We rely on a single manufacturing company, Chinoin Pharmaceutical and Chemical Works Private Co., Ltd., in Hungary, or Chinoin, for our supply of alprostadil. We currently have a written manufacturing agreement with Chinoin to supply alprostadil through 2011. There is no assurance that we will be able to re-establish a manufacturing agreement with NeraPharm, s.r.o., in the Czech Republic, or NeraPharm, an alternative supplier from whom we previously purchased alprostadil, or that we will be able to identify and qualify additional sources of alprostadil. We are required to receive FDA approval for new suppliers before using a new supply source. Until we secure a new manufacturing agreement with NeraPharm or qualify additional sources of alprostadil, we are entirely dependent upon Chinoin. If interruptions in this supply occur for any reason, including a decision by Chinoin to discontinue manufacturing, labor disputes or a failure of Chinoin 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 alprostadil could have a material adverse effect on our business, financial condition or 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, Flint Hills Resources. 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. There can be no assurance that we will be able to obtain components from Medegen or to identify and qualify additional sources of 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 prior to using supplies from a new vendor. 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, a failure of Medegen to follow regulations or the inability of Medegen to secure a new source of resin, 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.

We have been notified by Medegen that the Flint Hills Resources facility in Texas has discontinued manufacturing the resin required for MUSE plastic components in early 2009. The Flint Hills Resources facility in Texas has been the single source used by Medegen for the MUSE plastic components. Medegen has some inventory of resin from the Flint Hills Texas facility. We secured plastic components from Medegen during the first quarter of 2009 to support projected MUSE production requirements through the second quarter of 2010. Medegen has identified a new source of resin and is in the process of qualifying the vendor. Medegen has not manufactured two of the plastic components since 1998 and there is no assurance the manufacturing molds will pass inspection and be approved for future use. The inability to utilize these molds and the inability of Medegen to secure an alternative resin supplier 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 laminated foil components for MUSE and an interruption to this supply source could harm our business.

We rely on a single lamination company, Glenroy, Inc., or Glenroy, for our supply of laminated foil. In turn, Glenroy obtains its supply of resin, a key ingredient of the laminated foil, from a single source, Flint Hills Resources in Texas. Orders to Glenroy are made on a periodic basis with purchase orders. We do not have a written agreement with Glenroy for the supply of the laminated foil. If we are unable to obtain foil from Glenroy for any reason, or if we are unable to identify and qualify additional sources of foil, or additional foil produced using a new resin, we could experience interruptions in supply, which would harm our business. We are required to receive FDA approval for new suppliers prior to using supplies from a new vendor. Until we secure and qualify additional sources of laminated foil, we are entirely dependent upon Glenroy. If interruptions in this supply occur for any reason, including a decision by Glenroy to discontinue manufacturing, labor disputes, a failure of Glenroy to follow regulations or the inability of Gilroy to secure an alternative resin supplier, the manufacture and marketing of MUSE and other potential products could be delayed or prevented. An extended interruption in the supply of laminated foil could have a material adverse effect on our business, financial condition or results of operations.

We have been notified by Glenroy that the Flint Hills Resources facility located in Texas will discontinue manufacturing the resin required for laminated foil in early 2009. The Flint Hills Resources Texas facility has been the single source used by Glenroy for the MUSE laminated foil. We secured laminated foil from Glenroy during the first quarter of 2009 to support projected MUSE production requirements through the second quarter of 2010. Glenroy has identified a new source of resin and is in the process of qualifying the vendor. Our inability to secure a qualified source for additional laminated foil and/or Glenroy's inability to secure the necessary resin would have a material adverse effect on our business, financial condition and results of operations.

Currently there is a global shortage of Acetonitrile, a solvent which is required in the testing and verification of MUSE, and an interruption to this supply could harm our business.

We have been notified by several of our laboratory supply vendors of a global shortage of Acetonitrile, a solvent which is required in the testing and verification of MUSE. We have secured an adequate supply of Acetonitrile to support projected manufacturing needs through the first quarter of 2010. Our inability to secure additional Acetonitrile would have a material adverse effect on our business, financial condition and results of operations.

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.

Allegations of discrimination, regardless of merit, could negatively affect our operations by causing us to allocate additional monetary and personnel resources to these issues.

In January 2009, a former employee filed a U.S. Equal Employment Opportunity Commission Claim. The Notice of Charge of Discrimination was vague as to the nature and scope of the claim, merely indicating that sex discrimination and retaliation under Title VII of the Civil Rights Act is alleged. Additionally, we received a letter from a former employee claiming California labor code violations in connection with the former employee's recruitment and wrongful termination. We have fully investigated the charges by these former employees and we believe that there is no merit to these charges and that we have meritorious defenses to such charges. We believe the employees have no claim to additional compensation or benefits. Due to the current economic downturn, employees may be more likely to file employment-related claims. Although there may be no merit to such claims, we may be required to allocate additional monetary and personnel resources to defend against these types of allegations in the future.

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.

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.

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 expired 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 or any other indication, 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.

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, accidents, 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 this patent extends into 2019. In January 2009, the European Patent Office granted European patent No. 1,187,603 which broadly covers Qnexa and its use as a weight loss treatment. The patent extends the intellectual property protection of Qnexa beyond the already issued patents in the United States and abroad. 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, CROs, 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.

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 collaborations, sublicenses and strategic alliances and the related costs;
- the costs involved in establishing a commercial operation and in launching a product without a partner;
- 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 state of the economy and financing environment;
- the level of resources devoted to sales and marketing capabilities;
- the regulatory approval environment and regulatory hurdles for safety assessment for new products;
- the health care reimbursement system or the impact of healthcare reform, if any, imposed by the new administration; 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 through 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 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 $186.6 million as of March 31, 2009 and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $186.6 million for the period from our inception through March 31, 2009, and we anticipate losses in future years due to continued 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, 2008, we had approximately $86.2 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 of approximately $1.9 million 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, 2007 and 2008 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:

- results within the clinical trial programs for Qnexa and avanafil;
- 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;
- 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 relative to 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.

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 significant obligations and uncertainty of compliance 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.

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 March 31, 2009, we had $42.7 million in cash and cash equivalents and $123.1 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 the continuing economic turmoil that has affected various sectors of the financial markets and caused credit and liquidity issues. An investment in money market mutual funds is not insured or guaranteed by the Federal Deposit Insurance Corporation or 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, Columbia, we took a redemption-in-kind distribution 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 distribution 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 distribution 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 distribution 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 has been and may continue to be negatively affected.

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.

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 $123.1 million and represented 68% of our total condensed consolidated assets at March 31, 2009. These securities 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 quarter ended March 31, 2009, we recorded charges for other-than-temporary impairment of securities of $444,000. 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

Simultaneously with the sale of securities to funds affiliated with Deerfield or the Deerfield Affiliates, on April 15, 2008, we entered into the Funding and Royalty Agreement, or FARA, an Option and Put Agreement, or the OPA, and a Security Agreement with the Deerfield Sub, a newly incorporated subsidiary of Deerfield. The FARA and OPA were amended on March 16, 2009. We also entered into a Security Agreement with the shareholders of the Deerfield Sub. Under the terms of the FARA, the Deerfield Sub made $3.3 million payments to us in April, September and December 2008 and February 2009 and will make two 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 the 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 the Deerfield Sub, thus ending any further royalty payments. The OPA allows for the purchase of the shares of the 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 all the shares of the 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 ,or each, a Major Transaction. Under these conditions, the cost of the shares of the 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 the 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 the Deerfield Sub. As security for the payment under the forced purchase of shares of the Deerfield Sub to us, we have pledged certain unencumbered MUSE and avanafil assets to Deerfield Affiliates.

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 the Deerfield Sub or if Deerfield Affiliates does not force us to purchase the shares of the 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 the 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. Under the OPA, the shareholders of the Deerfield Sub have agreed to indemnify us for certain liabilities related to the operations of the Deerfield Sub, if any. Should we incur any such liabilities and the shareholders of the Deerfield Sub fail to pay for such liabilities as part of the indemnity, we would have to reallocate our resources to paying such liabilities and incur further expenses to enforce our right to indemnification under the OPA.

Under the OPA, we only have four years to repurchase the shares of the 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 the 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.

We entered into a Security Agreement with the 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.

Table of Contents

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(4)	Specimen Common Stock Certificate of the Registrant.
4.2(5)	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 May 11, 2009, 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 May 11, 2009, 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 filed with the Commission on March 28, 2007.

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

(5) Incorporated by reference to Exhibit 4.1 filed with the Registrant's Registration Statement on Form 8-A filed with the Commission on March 28, 2007.

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: May 11, 2009	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

VIVUS, INC.

INDEX TO EXHIBITS

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Exhibit 31.1

CERTIFICATION

I, Leland F. Wilson, 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: May 11, 2009

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

Exhibit 31.2

CERTIFICATION

I, Timothy E. Morris, 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: May 11, 2009

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 March 31, 2009 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: May 11, 2009

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 March 31, 2009 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: May 11, 2009

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