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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2007

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 0-23490

VIVUS, INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

Delaware	**94-3136179**
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(IRS EMPLOYER IDENTIFICATION NUMBER)
1172 Castro Street 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 x No o

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

Large accelerated filer o Accelerated filer x Non-accelerated filer o

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

At October 25, 2007, 58,658,748 shares of common stock, par value $.001 per share, were outstanding.

VIVUS, INC.

Quarterly Report on Form 10-Q

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PART I: FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

VIVUS, INC.

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

	SEPTEMBER 30 2007 (UNAUDITED)	DECEMBER 31 2006*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 161,208	$ 44,628
Available-for-sale securities	11,378	14,243
Accounts receivable, (net of allowance for doubtful accounts of $17 and $67 at September 30, 2007 and December 31, 2006, respectively)	1,738	4,359
Inventories, net	3,262	3,327
Prepaid expenses and other assets	4,074	2,408
Total current assets	181,660	68,965
Property, plant and equipment, net	7,619	8,549
Restricted cash	700	700
Available for-sale securities, net of current	16,444	—
Total assets	$ 206,423	$ 78,214
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,431	$ 2,102
Accrued product returns	1,971	2,473
Accrued research and clinical expenses	1,757	460
Accrued chargeback reserve	494	1,531
Accrued employee compensation and benefits	1,143	1,490
Income taxes payable	3,508	1,245
Deferred revenue-short term	84,315	594
Accrued and other liabilities	1,387	1,506
Total current liabilities	100,006	11,401
Notes payable-long term	5,092	11,488
Deferred revenue-long term	54,164	2,185
Total liabilities	159,262	25,074
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding at September 30, 2007 and December 31, 2006	—	—
Common stock; $.001 par value; 200,000 shares authorized; 58,653 shares issued and outstanding at September 30, 2007 and 58,144 at December 31, 2006	59	58
Additional paid-in capital	227,283	221,744
Accumulated other comprehensive income (loss)	12	(11)
Accumulated deficit	(180,193)	(168,651)
Total stockholders' equity	47,161	53,140

Total liabilities and stockholders' equity	$ 206,423	$ 78,214

* Derived from audited consolidated financial statements filed in the Company's 2006 Annual Report on Form 10-K.

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

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

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	SEPTEMBER 30 2007 (UNAUDITED)	SEPTEMBER 30 2006 (UNAUDITED)	SEPTEMBER 30 2007 (UNAUDITED)	SEPTEMBER 30 2006 (UNAUDITED)
Revenue:				
United States product, net	$ 4,075	$ 3,348	$ 7,572	$ 6,948
International product	944	567	3,003	1,643
License and other revenue	14,069	116	14,300	347
Total revenue	19,088	4,031	24,875	8,938
Operating expenses:				
Cost of goods sold and manufacturing	2,736	2,627	8,498	8,542
Research and development	8,644	4,301	15,610	11,162
Selling, general and administrative	3,691	3,510	11,988	10,678
Total operating expenses	15,071	10,438	36,096	30,382
Income (loss) from operations	4,017	(6,407)	(11,221)	(21,444)
Interest income (expense):				
Interest income	1,811	398	3,276	1,087
Interest expense	(125)	(145)	(409)	(448)
Total interest income (expense)	1,686	253	2,867	639
Income (loss) before provision for income taxes	5,703	(6,154)	(8,354)	(20,805)
Provision for income taxes	(4,382)	(6)	(4,394)	(18)
Net income (loss)	$ 1,321	$ (6,160)	$ (12,748)	$ (20,823)
Other comprehensive income (loss):				
Unrealized gain (loss) on securities	20	(4)	23	26
Comprehensive income (loss)	$ 1,341	$ (6,164)	$ (12,725)	$ (20,797)
Net income (loss) per share:				
Basic and diluted	$ 0.02	$ (0.13)	$ (0.22)	$ (0.45)
Shares used in per share computation:				
Basic	58,627	48,399	58,449	46,619
Diluted	59,492	48,399	58,449	46,619

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	NINE MONTHS ENDED SEPTEMBER 30	
	2007 (UNAUDITED)	2006 (UNAUDITED)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (12,748)	$ (20,823)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:		
Provision for doubtful accounts	(50)	(114)
Provision for excess inventory	(3)	763
Depreciation	807	808
Share-based compensation expense	2,755	1,599
Excess tax benefits related to share-based compensation expense	(904)	—
(Gain) loss on disposal of property and equipment	(17)	22
Sale of Evamist assets	559	—
Changes in assets and liabilities:		

Accounts receivable	2,671	5,347
Inventories	(142)	(304)
Prepaid expenses and other assets	(1,666)	(952)
Accounts payable	3,329	(688)
Accrued product returns	(502)	(905)
Accrued research, clinical and licensing fees	1,297	(3,020)
Accrued chargeback reserve	(1,037)	(1,149)
Accrued employee compensation and benefits	(347)	(240)
Deferred revenue	135,700	1,653
Income taxes payable	4,373	6
Accrued and other liabilities	(112)	(207)
Net cash provided by (used for) operating activities	133,963	(18,204)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(228)	(425)
Increase in restricted cash	—	(700)
Proceeds from sale of property and equipment	19	—
Investment purchases	(39,024)	(14,282)
Proceeds from sale/maturity of securities	25,468	11,630
Net cash used for investing activities	(13,765)	(3,777)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Borrowing under note agreements	379	6,469
Principal payments under note agreement	(6,782)	(66)
Exercise of common stock options	1,732	30
Excess tax benefits related to share-based compensation expense	904	—
Sale of common stock through employee stock purchase plan	149	167
Proceeds from issuance of common stock	—	12,026
Net cash (used for) provided by financing activities	(3,618)	18,626
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS	116,580	(3,355)
CASH AND CASH EQUIVALENTS:		
Beginning of period	44,628	22,236
End of period	$ 161,208	$ 18,881
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Reclassification of income taxes payable to accumulated deficit	$ 1,206	—

See accompanying notes to unaudited condensed consolidated financial statements.

VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2007

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America. Accordingly, they do not include all of the information and footnotes required by United States generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the quarter and nine-month period ended September 30, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007. The unaudited financial statements should be read in conjunction with the audited financial statements and notes thereto included in our annual report on Form 10-K for the year ended December 31, 2006, as filed on March 14, 2007 with the Securities and Exchange Commission. 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 ("Meda") to market and distribute MUSE internationally in some Member States of the European Union. In Canada, the Company has entered into a license and supply agreement with Paladin Labs, Inc. ("Paladin") for the marketing and distribution of MUSE. Sales to Meda, who supplies MUSE in the European marketplace, for 2006, 2005 and 2004 were 91.7%, 93.4% and 96.7% 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 recorded $1.5 million of unearned revenue related to an upfront payment in accordance with the international supply agreement signed with Meda in September 2002. In January 2006, the Company received a milestone payment from Meda of $2.0 million. The milestone payment provides Meda with the right to continue to sell and distribute MUSE in its European territories. These amounts are being recognized as income ratably over the term of the supply agreement. Through September 30, 2007, $1.3 million has been recognized as revenue.

License and Other Revenue

The Company recognizes license revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 104, Revenue Recognition, and Emerging Issues Task Force ("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

On May 15, 2007, the Company closed its transaction with K-V Pharmaceutical Company ("K-V") for the sale of its 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 U.S. Food and Drug Administration ("FDA") for marketing. The sale transaction contained multiple deliverables, including: the delivery at closing of the Evamist assets, a grant of a sublicense of our rights under a license 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 ("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 $10.0 million upon the closing and received an additional $140.0 million milestone payment in August 2007 upon FDA Approval.

Upon FDA Approval, the two remaining deliverables are the transition services to be performed under the Transition Services Agreement ("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, $150.0 million, will be recognized as revenue

on a pro-rata basis over the term of the last deliverable, which in this case is the license to improvements which expires on May 15, 2009. As a result, the initial $10.0 million paid at closing and the $140.0 million paid upon FDA Approval have been recorded as deferred revenue and will be recognized as revenue together with the future billings, if any, under the TSA, ratably over the remaining 21.5-month term of the license to improvements, from August 1, 2007 to May 15, 2009. Through September 30, 2007, $14.0 million has been recognized as revenue.

The Company may also receive milestone payments of up to $30.0 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.

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 retrospective transition method.

Total estimated share-based compensation expense, related to all of the Company's share-based awards, recognized for the quarters and nine months ended September 30, 2007 and 2006 was comprised as follows (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Cost of goods sold and manufacturing expense	$ 150	$ 87	$ 419	$ 273
Research and development	231	173	685	479
Selling, general and administrative	529	287	1,651	847
Share-based compensation expense before taxes	910	547	2,755	1,599
Related income tax benefits	—	—	—	—
Share-based compensation expense, net of taxes	$ 910	$ 547	$ 2,755	$ 1,599
Basic and diluted per common share	$ 0.02	$ 0.01	$ 0.05	$ 0.03

At September 30, 2007, a total of 5,588,605 stock options and restricted stock units were outstanding under our stock option plans. Stock-based compensation expense recognized for the quarters and nine months ended September 30, 2007 and 2006 included compensation expense for stock options granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123. Included in stock-based compensation expense was $855,000 and $508,000 related to stock options, $41,000 and $37,000 related to the employee stock purchase plan, and $14,000 and $2,000 related to restricted stock units, net of the estimated forfeitures for the third quarters of 2007 and 2006, respectively. For the nine months ended September 30, 2007 and 2006, included in stock-based compensation expense was $2.6 million and $1.5 million related to stock options, $103,000 and $121,000 related to the employee stock purchase plan, and $43,000 and $2,000 related to restricted stock units, net of the estimated forfeitures, respectively.

As of September 30, 2007, unrecognized estimated compensation expense totaled $3.2 million related to non-vested stock options, $20,000 related to the employee stock purchase plan, and $68,000 related to restricted stock units. The weighted average remaining requisite service period of the non-vested options was 1.3 years, of the employee stock purchase plan was 1.5 months, and of the restricted stock units was 4.0 years.

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

	Nine Months Ended September 30, 2007	
	Shares	Weighted Average Exercise Price
Outstanding at January 1, 2007	4,550,152	$ 4.21
Granted	1,669,063	$ 4.28
Exercised	(459,503)	$ 3.77
Cancelled	(233,607)	$ 5.18
Outstanding at September 30, 2007	5,526,105	$ 4.23
Options exercisable at September 30, 2007	3,245,174	
Weighted average fair value of options granted		$ 2.78

A summary of restricted stock units award activity under the 2001 Plan as of September 30, 2007 and changes during the nine month period then ended are presented below:

	Nine Months Ended September 30, 2007			
	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Restricted stock units outstanding January 1, 2007	62,500	$ 2.04	4.7	$ 255,000
Granted	—	—	—	—
Vested	—	—	—	—
Forfeited	—	—	—	—
Restricted stock units outstanding, September 30, 2007	62,500	$ 2.04	4.0	$ 255,000

At September 30, 2007, stock options were outstanding and exercisable as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding at	Weighted-Average Remaining	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price

	September 30, 2007	Contractual Life		September 30, 2007	
$2.00 - $3.88	1,952,748	5.84 years	$ 3.28	1,309,793	$ 3.23
$3.90 - $4.25	2,252,860	8.28 years	$ 4.18	765,625	$ 4.08
$4.41 - $8.08	1,320,497	4.87 years	$ 5.70	1,169,756	$ 5.77
$2.00 - $8.08	5,526,105	6.60 years	$ 4.23	3,245,174	$ 4.34

The aggregate intrinsic value of outstanding options as of September 30, 2007 was $5.2 million, of which $3.1 million related to exercisable options.

At September 30, 2007, 1,478,624 options remain available for grant. 1,000,000 of these shares were registered on a Form S-8 filed with the SEC on April 25, 2007. In the nine months ended September 30, 2007, in accordance with the terms of the 2001 Plan, the Company transferred a net total of 42,388 expired plan shares to the 2001 Plan. Options under these plans generally vest over four years, and all options expire after ten years.

As of September 30, 2007, 1,081,956 shares have been issued to employees and there are 318,044 available for issuance under the Stock Purchase Plan.

Valuation Assumptions

The fair value of stock options granted in the nine months ended September 30, 2007 and 2006 was estimated using a Black-Scholes Model with the following weighted average assumptions:

	Non-Director Stock Options Nine Months Ended September 30,		Director Stock Options Nine Months Ended September 30,		ESPP Nine Months Ended September 30,	
	2007	2006	2007	2006	2007	2006
Expected life (in years)	6.25	6.25	5.19	5.19	0.50	0.50
Volatility	68.02%	76.71%	63.24%	68.55%	44.48%	64.84%
Risk-free interest rate	4.59%	4.90%	4.62%	4.98%	4.91%	5.02%
Dividend yield	—	—	—	—	—	—

Expected Term: VIVUS' expected term represents the period that our stock-based awards are expected to be outstanding based on the simplified method provided in Staff Accounting Bulletin No. 107 ("SAB 107"), which averages an award's weighted average vesting period and expected term for "plain vanilla" share options. Under SAB 107, options are considered to be "plain vanilla" if they have the following basic characteristics: granted "at-the-money"; exerciseability is conditioned upon service through the vesting date; termination of service prior to vesting results in forfeiture; limited exercise period following termination of service; and options are non-transferable and non-hedgeable. Options granted to our Board of Directors generally become fully vested after eight months, while those granted to our employees become fully vested after four years. As a result of this and other differences identified between these two groups, we have valued their options using separate assumptions.

Expected Volatility: The Company estimated volatility using the historical share price performance over the expected term of the option. The Company also considered other factors such as its planned clinical trials and other company activities that may affect the volatility of VIVUS' stock in the future but determined that at this time, the historical volatility was more indicative of expected future stock price volatility.

Expected Dividend: The Black-Scholes Model requires a single expected dividend yield as an input. The Company does not anticipate paying any dividends in the near future.

Risk-Free Interest Rate: The Company bases the risk-free interest rate used in the Black-Scholes Model on the implied yield available on U.S. Treasury zero-coupon issues with an equivalent remaining term, in effect during the period of the grant.

Estimated Pre-vesting Forfeitures: The Company develops pre-vesting forfeiture assumptions based on an analysis of historical data.

4. CASH AND CASH EQUIVALENTS AND MARKETABLE SECURITIES

The Company considers highly liquid investments with maturities from the date of purchase of three months or less to be cash equivalents. All cash equivalents are in money market funds and commercial paper. The fair value of the funds approximated their cost.

Available-for-sale securities represent investments in debt securities that are stated at fair value. We restrict our cash 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 or better.

The difference between amortized cost (cost adjusted for amortization of premiums and accretion of discounts which are recognized as adjustments to interest income) and fair value, representing unrealized holding gains or losses, are recorded in "accumulated other comprehensive income (loss)," a separate component of stockholders' equity until realized.

Our policy is to record investments in debt securities as available-for-sale because the sale of such securities may be required prior to maturity. Any gains and losses on the sale of debt securities are determined on a specific identification basis and are included in interest and other income in the accompanying consolidated statements of operations. Available-for-sale securities with original maturities beyond one year from the balance sheet date are classified as non-current.

5. INVENTORIES

Inventories are recorded net of reserves of $1.6 million and $4.4 million as of September 30, 2007 and December 31, 2006, respectively. In the second quarter of 2007, the Company disposed of $2.4 million of fully reserved alprostadil which had no impact on cost of goods sold. Inventory balances, net of reserves, consist of (in thousands):

	SEPTEMBER 30, 2007 (unaudited)	DECEMBER 31, 2006
Raw materials and component parts	$ 2,370	$ 2,793
Work in process	104	66
Finished goods	788	468
Inventory, net	$ 3,262	$ 3,327

As noted above, the Company has significant reserves against the carrying value of its inventory of raw material and certain component parts. When the Company establishes reserves, it establishes a new, lower cost basis for the inventory for accounting purposes. The reserves relate primarily to inventory that the Company previously estimated would not be used. In the first quarter of 2005, the Company determined that it likely would continue to use some portion of the fully reserved component parts inventory in production. The Company used $75,000 and $52,000 of its fully reserved component parts inventory during the first nine months of 2007 and 2006, respectively. The fully reserved inventory is charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. The original cost of the fully reserved inventory related to component parts is $745,000 as of the end of the first nine months of 2007, and we intend to continue to use this reserved component parts inventory in production when appropriate.

6. PREPAID EXPENSES AND OTHER ASSETS

Prepaid expenses and other assets includes a receivable of $1.3 million for a FDA refund of the Company's application fee paid in September 2006 for the New Drug Application ("NDA") for Evamist and a refund of the fiscal year 2007 product and establishment fees for its marketed product, MUSE, which was paid to the FDA in October 2006. The Company is due a refund pursuant to Section 736(d)(1)(C) of the Federal Food, Drug and Cosmetic Act ("FDC Act") on the basis that the fees paid by the Company exceed the anticipated present and future costs incurred by the FDA in the reviewing of human drug applications for VIVUS, Inc.

7. NOTES PAYABLE

Tanabe Line of Credit

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, an investigational erectile dysfunction compound. There were no financial covenants associated with this secured line of credit. On April 24, 2007, in connection with the Company's sale of Evamist to K-V (see Note 10: "Sale of Evamist Product"), the Company paid off the outstanding balance of $6.7 million, including all accrued interest. All the assets of the Company, except the land and buildings, served as collateral for this line of credit. On May 1, 2007, Tanabe signed a Termination and Release acknowledging payment in full of the principal and interest due under the line of credit and releasing the lien on the Company's assets, and thereby terminating the line of credit. In September 2007, Tanabe Seiyaku Co., Ltd., following its merger with Mitsubishi Pharma Corporation, announced its name change to Mitsubishi Tanabe Pharma Corporation.

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 (the "Agreements") with Crown Bank N. A. ("Crown") secured by the land and buildings used in the manufacturing of MUSE, among other assets, located at 735 Airport Road and 745 Airport Road in Lakewood, New Jersey (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 9.25% and 8.25% for the first nine months of 2007 and 2006, respectively. The Agreements contain prepayment penalties, and a requirement to maintain a depository account at Crown with a minimum collected balance of $100,000 which, if not maintained, will result in an automatic increase in the interest rate on the note of one-half (0.5%) percent. The Facility, assignment of rents and leases on the Facility, and a $700,000 Certificate of Deposit held by Crown, classified as restricted cash, serve as collateral for these Agreements.

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

	September 30, 2007 (unaudited)	December 31, 2006
Tanabe line of credit	$ —	$ 6,324
Crown Bank N.A. loan	5,202	5,281
Total notes payable	5,202	11,605
Less current portion	(110)	(117)
Total long-term notes payable	$ 5,092	$ 11,488

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 September 30, 2007 are as follows (in thousands):

Year ending December 31,	Crown Bank N.A. Loan
2007 (remainder of)	$ 27
2008	113
2009	125
2010	137
2011	151
Thereafter	4,649
Total	$ 5,202

8. AGREEMENTS

In 2001, VIVUS entered into a Development, Licensing and Supply Agreement with Tanabe for the development of avanafil, an oral PDE5 inhibitor product candidate for the treatment of erectile dysfunction. Under the terms of the 2001 Development, Licensing and Supply Agreement with Tanabe, the Company paid a $2.0 million license fee obligation to Tanabe in the year ended December 31, 2006, which was previously accrued in the year ended December 31, 2004. The Company expects to make other substantial payments to Tanabe in accordance with its agreements with them. These payments are based on certain development, regulatory and sales milestones. In addition, VIVUS is required to make royalty payments on any future product sales.

In February 2004, the Company entered into exclusive licensing agreements with Acrux Limited ("Acrux") and a subsidiary of Acrux under which it agreed to develop and, if approved, commercialize Testosterone MDTS ("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 $2.0 million, up to $3.3 million for the achievement of certain clinical development milestones, up to $3.0 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 $1.0 million, up to $1.0 million for the achievement of certain clinical development milestones, up to $3.0 million for achieving product approval milestones, and royalties on net sales in the United States following approval and commercialization. The Company made a $1.0 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 $3.0 million product approval milestone became due and was paid to Acrux in August 2007. Per the terms of the Asset Purchase Agreement with K-V for the sale of Evamist, K-V paid $1.5 million of this $3.0 million obligation. Although the Company has sublicensed its rights under the Acrux Agreement related to Evamist to K-V, the Company will continue to have certain obligations under this license in the event that K-V does not satisfy the requirements under the sublicense agreement. See Note 10: "Sale of Evamist Product" below for additional information concerning the terms of this agreement and Note 17: "Legal Matters" for further information regarding Acrux.

The Company has entered into several agreements to license patented technologies that are essential to the development and production of the Company's transurethral product for the treatment of erectile dysfunction. In connection with these agreements, the Company is obligated to pay royalties on product sales of MUSE (4% of United States and Canadian product sales and 3% of sales elsewhere in the world). In the first nine months of 2007 and 2006, the Company recorded royalty expenses, in thousands, of $482 and $291, respectively, as a 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, we have collected $3.6 million in milestone payments from our current international distributors.

9. INCOME TAXES

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

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

The Company assesses the likelihood that it will be able to recover its deferred tax assets. The Company considers all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that the Company will recover its deferred tax assets, the Company will increase its provision for taxes by recording a valuation allowance against the deferred tax assets that the Company estimates will not ultimately be recoverable. As a result of the Company's analysis of all available evidence, both positive and negative, as of September 30, 2007, it was not considered more likely than not that the Company's deferred tax assets would be realized with the exception of certain net operating loss and tax credit carryforwards used to offset the effect of the Evamist taxable gain.

The provision for income taxes in the amount of $4.4 million for the three months ended September 30, 2007 relates to the U.S. alternative minimum tax ("AMT") and certain state income taxes. The utilization of tax loss carryforwards is limited in the calculation of AMT and as a result, a federal tax charge was recorded in the three months ended September 30, 2007. The current AMT liability is available as a credit against future tax obligations upon the full utilization or expiration of the Company's net operating loss carryforward. The provision for income taxes for the three months ended September 30, 2007 was prepared on a discrete quarterly basis, as a yearly effective tax rate was not considered a reliable estimate for the current quarter provision. This provision reflects tax recognition of the entire $150.0 million in non-refundable payments the Company received from K-V Pharmaceutical Company ("K-V") in the second and third quarters of fiscal 2007 for the sale of Evamist (see Note 10: "Sale of Evamist Product").

For Federal and State income tax reporting purposes, respective net operating loss, or NOL, carryforwards of approximately $4.0 million and $0 are available to reduce future taxable income, if any. During the nine months ended September 30, 2007, we realized excess tax benefits due to stock option exercises which totaled $904,000 that have been accounted for as a credit to additional paid in capital and through a reduction in income taxes payable. For Federal and State income tax reporting purposes, respective credit carryforwards of approximately $5.2 million and $1.7 million are available to reduce future

taxable income, if any. These carryforwards, except for the California Research and Development Credit, expire on various dates through 2026. The California research and development credits do not expire. 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 a significant change in ownership interest.

As of September 30, 2007, the Company believed that the amount of the deferred tax assets recorded on its 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 cannot recover its deferred tax assets.

Effective January 1, 2007, the Company adopted Financial Accounting Standards Interpretation, or FIN, No. 48, *Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109*. FIN No. 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a company's income tax return, and also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN No. 48 utilizes a two-step approach for evaluating uncertain tax positions accounted for in accordance with SFAS No. 109, *Accounting for Income Taxes* ("SFAS No. 109"). Step one, Recognition, requires a company to determine if the weight of available evidence indicates that a tax position is more likely than not to be sustained upon audit, including resolution of related appeals or litigation processes, if any. Step two, Measurement, is based on the largest amount of benefit, which is more likely than not to be realized on ultimate settlement.

Upon adoption of FIN No. 48, the Company recognized a cumulative effect adjustment of $1.2 million, decreasing its income tax liability for unrecognized tax benefits, and decreasing the January 1, 2007 accumulated deficit balance. At January 1, 2007, after the foregoing decrease in the tax liability, the Company did not have any unrecognized tax benefits, nor does it expect any material change in its unrecognized tax benefits over the next twelve months.

The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of its provision for income taxes. As of January 1, 2007, the Company had no accrual for payment of interest and penalties related to unrecognized tax benefits, nor were any amounts for interest or penalties recognized during the nine months ended September 30, 2007.

Although the Company files U.S. federal, various state, and foreign tax returns, the Company's only major tax jurisdictions are the United States, California and New Jersey. Tax years 1991 to 2006 remain subject to examination by the appropriate governmental agencies due to tax loss carryovers from those years.

10. 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 agreement with Acrux related to Evamist, a metered dose transdermal spray for the treatment of menopause symptoms, to K-V (the "Transaction"). 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 $10.0 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 $140.0 million.

The Company may also receive certain one-time payments of up to $30.0 million based on K-V achieving certain annual net sales thresholds for Evamist. In addition, per the terms of the Transaction, K-V reimbursed VIVUS for $1.5 million of the $3.0 million milestone payment paid by VIVUS to Acrux upon FDA Approval of the NDA. In connection with the Transaction, in order to obtain Tanabe's release of liens against all assets including the Evamist assets and intellectual property, the Company repaid the Tanabe line of credit (see Note 7: "Notes Payable").

11. NET INCOME (LOSS) PER SHARE

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net income (loss)	$ 1,321	$ (6,160)	$ (12,748)	$ (20,823)
Basic weighted-average shares outstanding	58,627	48,399	58,449	46,619
Dilutive effect of:				
Options to purchase common stock	865	—	—	—
Diluted weighted-average shares outstanding	59,492	48,399	58,449	46,619
Net income (loss) per share:				
Basic	$ 0.02	$ (0.13)	$ (0.22)	$ (0.45)
Diluted	$ 0.02	$ (0.13)	$ (0.22)	$ (0.45)

For the three months ended September 30, 2007, 865,349 options outstanding were not included in the computation of diluted net income per share for the Company because the effect would be anti-dilutive. As the Company recognized a net loss for the three months ended September 30, 2006, and the nine months ended September 30, 2007 and 2006, all potential common equivalent shares were excluded for these periods as they were anti-dilutive. For the three months ended September 30, 2006, 4,097,852 options outstanding were not included in the computation of diluted net loss per share for the Company because the effect would be anti-dilutive. For the nine months ended September 30, 2007, and 2006, respectively, 2,953,372 and 4,038,095 options outstanding were not included in the computation of diluted net loss per share for the Company because the effect would be anti-dilutive.

12. COMMITMENTS AND CONTINGENCIES

Lease Commitments

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

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

2007 (remainder)	$	139
2008		555
2009		324
	$	1,018

Manufacturing Agreements

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

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

Other Agreements

The Company has entered into various agreements with clinical consultants and clinical research organizations to perform clinical studies on its behalf and, at September 30, 2007, its remaining commitment under these agreements totaled $57.5 million. The Company has remaining commitments under various general and administrative services agreements totaling $422,000 at September 30, 2007. The Company has also entered into various agreements with research consultants and other contractors to perform regulatory services, drug research, testing and manufacturing including animal studies and, at September 30, 2007, its remaining commitment under these agreements totaled $4.1 million. In addition, the Company has entered into marketing promotion agreements for its erectile dysfunction product, MUSE. At September 30, 2007, its remaining commitment under the MUSE agreements totaled $558,000.

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 certain of our clinical research organizations and investigator sites. 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 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. See Note 17: "Legal Matters" for further information regarding Acrux.

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, VIVUS has 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.

13. CONCENTRATION OF CUSTOMERS AND SUPPLIERS

During the first nine months of 2007 and 2006, sales to significant customers as a percentage of total revenues were as follows:

	2007	2006
Customer A	47%	55%
Customer B	14%	6%

Customer C	12%	14%
Customer D	22%	15%

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 September 30, 2007, the Company's sole-source manufacturer of Qnexa Phase 3 clinical supplies represented 28% of the Company's total research and development expenses.

14. RESEARCH AND DEVELOPMENT

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

15. EQUITY TRANSACTIONS

On May 10, 2006, the Company sold $12.0 million of its common stock in a registered direct offering. Under the terms of the financing, the Company sold 3,669,725 shares of VIVUS common stock at a price of $3.27 per share to two institutional investors. On May 11, 2006, the Company filed a prospectus supplement with the Securities and Exchange Commission ("SEC") relating to this registered direct offering under the existing shelf Registration Statement (File Number 333-12159) and supplement thereto.

On July 14, 2006, VIVUS, Inc. filed with the SEC a shelf Registration Statement on Form S-3. The shelf Registration Statement (File Number 333-135793) was declared effective by the SEC on August 16, 2006, providing the Company with the ability to offer and sell up to an aggregate of $80.0 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. This shelf Registration Statement (File Number 333-135793) replaces shelf Registration Statement (File Number 333-12159).

On November 17, 2006, the Company raised $33.6 million in a registered direct offering of VIVUS common stock pursuant to this shelf Registration Statement. Under the terms of this financing, the Company sold and issued a total of 6,750,000 shares of its common stock at a price of $3.50 per share in an initial closing and an additional 2,850,000 shares at $3.50 per share in a second closing on December 8, 2006. All of the shares of common stock were offered pursuant to the effective shelf Registration Statement on Form S-3 filed with the SEC on July 14, 2006.

16. RELATED PARTY TRANSACTIONS

Mario M. Rosati, one of our directors, is also a member of Wilson Sonsini Goodrich & Rosati, Professional Corporation, which has served as our outside corporate counsel since our formation and has received compensation at normal commercial rates for these services. In the first nine months of 2007 and 2006, we paid $699,000 and $458,000, respectively, to Wilson Sonsini Goodrich & Rosati.

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 received notice from a former employee seeking payment due to their termination in 2005 and in the third quarter of 2006, the Company concluded this matter without a material impact on its financial position.

On November 14, 2006, the Company received a letter from Manatt, Phelps & Phillips LLP ("Manatt") on behalf of Acrux DDS Pty Ltd., FemPharm PTY Ltd., and Acrux Limited (collectively "Acrux") notifying the Company of an alleged dispute under the Testosterone ("Luramist") and Estradiol ("Evamist") Development Agreements (the "Acrux Agreements") between the Company and Acrux. Since that time the Company and Acrux have corresponded regarding the alleged dispute. The claims relating to Evamist have not progressed further, but, to date, such claims have not been formally withdrawn. Per the terms of the Company's Asset Purchase Agreement with K-V, the license with Acrux related to Evamist is sublicensed to K-V. Although the Company has sublicensed its rights under the Acrux Agreement related to Evamist to K-V, it will continue to have certain obligations under this license in the event that K-V does not satisfy the requirements under the sublicense agreement. The Company believes that it has a meritorious defense to the claims made by Acrux in connection with the alleged dispute; however, in the event that Acrux should prevail in this matter relating to Evamist it could have a material adverse effect on the Company's business, financial condition and results of operations, including the possible payment of liquidated damages up to the amount paid by K-V for Evamist.

On November 5, 2007, the Company's legal counsel received a demand for arbitration under the Acrux Agreements regarding Luramist. Acrux's demand seeks a reversion of all rights assigned to the Company regarding Luramist, monetary damages, a portion of a milestone payment for Luramist under the Acrux Agreements and declaratory relief. The Company believes that it is in compliance with all material aspects of the Acrux Agreements including those related to Luramist and that it currently does not owe damages or any milestone payment under the Acrux Agreements. If the Company is unable to resolve these Luramist related claims with Acrux, the Company intends to seek to enforce its rights under the Acrux Agreements in arbitration. Development and commercialization of Luramist continues. The Company believes that it has a meritorious defense to the claims made by Acrux in connection with the alleged dispute; however, in the event that Acrux should prevail in this matter relating to Luramist, it could have a material adverse effect on the Company's business, financial condition and results of operations.

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. STOCKHOLDER RIGHTS PLAN

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

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

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

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

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

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

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the quarter and nine months ended September 30, 2007 are not necessarily indicative of the results that may be expected for the full fiscal year or any future period.

BUSINESS OVERVIEW

VIVUS, Inc. is a pharmaceutical company dedicated to the development and commercialization of therapeutic products for large underserved markets of obesity and sexual health using patented proprietary formulations and novel delivery systems and by seeking new indications for previously approved pharmaceutical products. To date, through employment of this strategy we have one commercial product and several development-stage products that address these markets. In these sectors patients seek more effective treatment options with fewer side effects. With respect to obesity, analysts estimate that this potential market could exceed $5 billion annually. The indications targeted by VIVUS' sexual health products each represent a projected market greater than $1 billion annually.

In 1997, we launched MUSE (alprostadil) in the United States and, together with our partners, internationally. We market MUSE as a prescription product for the treatment of erectile dysfunction. We are currently advancing three late-stage clinical products, each addressing specific components of the obesity and sexual health markets. Two of these investigational products are being prepared to enter Phase 3 clinical trials, and for one product we have initiated a Phase 3 study under a Special Protocol Assessment (SPA) with the FDA.

On November 8, 2007, we initiated the first of two pivotal Phase 3 studies of Qnexa in obese patients. The EQUIP study (OB-302) will enroll morbidly obese patients with Body Mass Index ("BMI") that equals or exceeds 35. The co-primary endpoints for these studies will evaluate the differences between treatments from baseline to the end of the treatment period, in mean percent weight loss and in the percentage of subjects achieving weight loss of 5% or more. All Phase 3 studies will utilize our novel once-a-day formulation of Qnexa, which at full strength, contains 15 mg phentermine immediate release and 92 mg topiramate controlled release. Pharmacokinetic-Pharmacodynamic (PK/PD) studies have confirmed that the once-a-day formulation is comparable to the twice-a-day formulation used in the Phase 2 study.

Our late-stage investigational product pipeline includes:

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

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

On March 30, 2007, we announced that we had entered into a definitive agreement with K-V to transfer certain of our assets and grant a sublicense under our exclusive rights to certain patents and know-how related to Evamist pursuant to our

Estradiol Development and Commercialization Agreement with FemPharm Pty Ltd. and Acrux DDS Pty Ltd. (together, "Acrux"), dated February 12, 2004, as amended (the "Acrux Agreement") to K-V (the "Transaction").

On May 15, 2007, the Transaction closed. Under the terms of the Transaction, we received an upfront payment of $10.0 million upon the closing. On August 1, 2007, we transferred and assigned the Evamist FDA submissions, and all files related thereto to K-V and on August 8, 2007, we received a $140.0 million milestone payment from K-V. K-V also paid $1.5 million of the $3.0 million product approval milestone payment due to Acrux upon approval of Evamist. In connection with the Transaction, in order to obtain Tanabe's release of liens against the Evamist assets and intellectual property, we repaid the Tanabe line of credit. We are also eligible to receive certain one-time milestone payments from K-V totaling to $30.0 million based on achieving certain annual net sales thresholds for Evamist.

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 product candidates in our pipeline;
- establishing strategic relationships with marketing partners to maximize sales potential for our products that require significant commercial support;
- licensing complementary clinical stage products or technologies with competitive advantages from third parties for new and established markets; and
- Licensing or selling our late-stage product candidates to third parties.

It is our objective to become a leader in the development and commercialization of products that help to treat obesity and restore sexual health in women and men. We believe that we have strong intellectual property supporting several opportunities in obesity treatment and sexual health. Our future growth will come from further development and regulatory approval of our product candidates as well as in-licensing and product line extensions.

We have funded operations primarily through private and public offerings of our common stock and through product sales of MUSE. We expect to generate future net losses due to increases in operating expenses as product candidates are advanced through the various stages of clinical development. In connection with the sale of Evamist, we received $150.0 million. The sale of Evamist was a unique transaction. As discussed in Note 10: "Sale of Evamist Product", an initial $10.0 million was paid at closing and $140.0 million was paid upon FDA approval of Evamist. These payments are non-refundable and have been recorded as deferred revenue and will be recognized as license and other revenue ratably over a 21.5-month period, from August 1, 2007 to May 15, 2009, which is the remaining term of a license to improvements to the MDTS applicator. As compared to revenues from product sales, license and other revenue will be significant on a quarterly basis until all of the revenue from the sale of Evamist is recognized, currently expected to be May 2009. Since the $150.0 million has been received and we have no related contingencies, the future recognition of revenue and the corresponding reduction of deferred revenue related to the Evamist sale will have no impact on our cash flows from operations in future periods through May 2009. As of September 30, 2007, we have incurred a cumulative deficit of $180.2 million and expect to incur operating losses in future years.

Year-to-Date 2007

Highlights year to date include:

- **Sale of Evamist Rights to K-V Pharmaceutical Company** — In March 2007, we executed an Asset Purchase Agreement to transfer our assets and grant a sublicense of our rights under the Acrux Agreement related to Evamist to K-V and in May 2007 we closed the transaction. At the closing, we received a cash payment of $10.0 million. On July 27, 2007, we received FDA approval for Evamist and on August 8, 2007, we received the additional $140.0 million milestone payment from K-V.
- **Appointment of Vice President and Chief Accounting Officer** — In February 2007, we promoted Lee B. Perry to the position of Vice President and Chief Accounting Officer. His responsibilities will include oversight of the Company's accounting operations and systems, external reporting, financial planning and analysis, cost accounting, internal controls,

taxation and risk management. Mr. Perry has over 30 years of experience in corporate finance and operations and public accounting. For the past twenty years he has held senior financial positions in life sciences and manufacturing industries.

- **Formation of Qnexa Scientific Advisory Board** — In order to help guide the upcoming Qnexa Phase 3 clinical trials, the Qnexa Scientific Advisory Board (the "Qnexa SAB") was formed in mid-June. The Qnexa SAB consists of six leading figures in the areas of obesity, trial design, psychology and diabetes.
- **Completed End of Phase 2 Meeting with the FDA for Qnexa** — In June 2007, we announced that the FDA reviewed Qnexa's current data package and clinical development plan and provided input on our overall plans for a Phase 3 clinical development program and the plan to apply for an SPA to support the registration of Qnexa in the United States as a treatment for obesity.

- **Initiated Phase 2 diabetes study with Qnexa** — In June 2007, we announced that we have initiated a 28-week Phase 2 study with Qnexa in obese patients with type 2 diabetes.

- **Completed Proprietary Formulation Development of Qnexa** — In June 2007, we completed the formulation development of a proprietary formulation of Qnexa as a once-a-day pill to be used in our Phase 3 program for the treatment of obesity

- **Completed SPA Process for Qnexa Phase 3 Studies** — In November 2007, we announced that we had successfully concluded communications with the FDA under the SPA process regarding key elements of the pivotal Phase 3 clinical trials of Qnexa for the treatment of obesity and weight-related co-morbidities.

- **Initiated Pivotal Phase 3 Trial in Obese Patients and Announced Qnexa Dose** — In November, 2007, we initiated the first of two pivotal Phase 3 studies of Qnexa, the EQUIP study.

Our Product Pipeline

We currently have three research and development programs targeting obesity and sexual health:

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

Obesity

In 2004, the U.S. Centers for Disease Control and Prevention (the "CDC") ranked obesity as the number one health threat in America. Obesity is a chronic condition that affects millions of people and often requires long-term or invasive treatment to promote and sustain weight loss. Obesity is the second leading cause of preventable death in the United States. The American Obesity Association estimates that approximately 127 million, or 64.5 percent, of adults in the U.S. are overweight, and an estimated 60 million, or 30.5 percent, 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 U.S. are attributable to obesity. The total direct and indirect costs attributed to overweight and obesity amounted to $117 billion in 2000. Additionally, Americans spend more than $30 billion annually on weight-loss products and services.

Qnexa

Qnexa is our proprietary oral investigational product candidate for the treatment of obesity, incorporating low doses of active ingredients from two previously approved products, topiramate and phentermine. By combining each of these compounds, we believe Qnexa can simultaneously address excessive appetite and high threshold for satiety, or the feeling of being full, the two main mechanisms that impact eating behavior. Qnexa is a once-a-day pill containing a proprietary formulation of controlled release topirmate and phentermine, which will be evaluated in our Phase 3 program for the treatment of obesity.

Previously, we reported results from a Phase 2 double blind, randomized, and placebo-controlled clinical trial conducted at Duke University, 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 body mass index (BMI) of 38.6. (A BMI of > 30.0 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 (QoL), 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 significant weight loss. These results suggest that the component of phentermine increases the tolerability of topiramate, which was the scientific rationale for combining these two agents at low doses for the treatment of obesity and related co-morbidities.

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

The primary efficacy endpoint for Phase 3 weight loss trials as recommended by the FDA is an assessment of the mean percent reduction in baseline body weight and the proportion of subjects who lose 5% or more of their baseline body weight compared to placebo over a one-year period. Recently issued FDA draft guidelines for obesity products set forth a primary efficacy benchmark in Phase 3 trials of at least 35% of patients achieving 5% weight loss. The weight loss in patients taking the obesity product should also be twice the weight loss of the placebo group. In our Phase 2 trial after 24 weeks, 82% of patients lost 5% of their baseline weight as compared to 14% in the placebo group. In Europe, The Committee for Medicinal Products for Human Use ("CHMP") of the

European Medicines Agency ("EMEA") has recommended that demonstration of significant weight loss of at least 10% of baseline weight is considered to be a valid primary endpoint for anti-obesity drugs. In the Phase 2 study after 24 weeks, 50% of the patients on Qnexa lost 10% of their baseline weight as compared to 8% of the patients in the placebo group. The FDA and the Medicines and Healthcare products Regulatory Agency, the regulatory authority in the United Kingdom, require obesity studies to be conducted for at least one year. While the results from our single center Phase 2 trial for six months of treatment meet these guidelines, there can be no assurance that these results can be replicated in a multi-center, one-year, Phase 3 trial, or with a once-a-day controlled release formulation of the product. We completed the development of our once-a-day controlled release formulation of Qnexa prior to the initiation of our Phase 3 clinical trials.

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

Also in June 2007, we announced that the FDA reviewed Qnexa's current data package and clinical development plan and accepted our overall plans for a Phase 3 clinical development program and the plan to apply for an SPA to support the registration of Qnexa in the United States as a treatment for obesity.

In November 2007, we announced that we had successfully concluded communications with the FDA under the SPA process regarding key elements of the pivotal Phase 3 clinical trials of Qnexa for the treatment of obesity and weight-related co-morbidities. We have reached agreement with the FDA on study design features that will be employed throughout the entire Phase 3 program including the co-primary endpoints of the study, scope and size of the patient population, specific safety assessments, inclusion/exclusion criteria, duration of the trials and the statistical method for analyzing the co-primary study endpoints.

The Phase 3 Qnexa program will include two pivotal, double blind, placebo-controlled, multi-center studies in distinct populations that will compare Qnexa to placebo during a 56-week treatment period. The studies are designed to proactively demonstrate the safety of Qnexa. The first study, known as EQUIP (OB-302), will enroll morbidly obese adult subjects with a body mass index ("BMI") of 35 or greater with controlled co-morbidities. The second trial, known as CONQUER (OB-303), will enroll 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.

On November 8, 2007, we initiated the first of these two pivotal Phase 3 studies of Qnexa, the EQUIP study. All Phase 3 studies will utilize our novel once-a-day formulation of Qnexa, which at full strength, contains 15 mg phentermine immediate release and 92 mg topiramate controlled release. Pharmacokinetic-Pharmacodynamic (PK/PD) studies have confirmed that the once-a-day formulation is comparable to the twice-a-day formulation used in the Phase 2 study.

The Phase 3 program will also include a six-month confirmatory factorial study, known as EQUATE (OB-301), in obese subjects with BMI's from 30 to 45. This trial will evaluate two dose levels of Qnexa, compared to both placebo and the individual constituents of the combination. The primary endpoints will be similar to those evaluated in the pivotal studies.

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

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

Female Sexual Health

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

Testosterone MDTS

Hypoactive Sexual Desire Disorder

Hypoactive Sexual Desire Disorder ("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, we noted that there were over 1.4 million units prescribed by OB/GYNs for Androgel®, an approved testosterone treatment for hypogonadism in males, in 2006. 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 transdermally applied testosterone has the ability to improve sexual desire 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 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 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 for obtaining marketing approval for this indication. 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. Based on the outcome of this meeting, we plan to submit the Phase 3 program to the FDA in the fourth quarter of 2007 with the objective to complete the SPA process with the FDA.

Male Sexual Health

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

The worldwide sales in 2006 of PDE5 inhibitor products for ED were in excess of $3.0 billion, including approximately $1.7 billion in sales of Viagra, approximately $971 million in sales of Cialis and approximately $313 million in sales of Levitra. Based on the aging baby boomer population and the desire to maintain an active sexual lifestyle, we believe the market for PDE5 inhibitors will continue to grow.

Avanafil

Our Clinical Candidate

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

Pre-clinical and clinical data suggests 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, multicenter, 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 ("GTN") in subjects pretreated with placebo, avanafil, and sildenafil citrate (Viagra). Results revealed that avanafil had less impact on blood pressure and heart rate than Viagra. The clinical significance of this data is unknown.

An End-of-Phase 2 meeting with the FDA for avanafil took place in November 2005. We discussed the Phase 2 results and the proposed protocol for the Phase 3 trials. Based on feedback from the FDA at this meeting, we anticipate completing several non-clinical studies prior to the initiation of Phase 3. In December 2006, we filed an SPA for a Phase 3 clinical trial to the FDA. We have received a response to our SPA and we accepted the FDA's recommendations. We consider this protocol in line with all FDA feedback for SPA and the SPA process for avanafil has been completed.

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 12 million units of MUSE have been sold since we introduced MUSE to the market.

In May 2005, results were reported from a 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

In June 2007, we announced that we have initiated a 28-week Phase 2 study with Qnexa in obese patients with type 2 diabetes. The randomized, double-blind, parallel-designed study will measure the effects of this combination on associated metabolic, cardiovascular, and anthropometric risk factors as well as changes in absolute weight, percent of baseline body weight lost, and a change in waist circumference. Subjects will also have a BMI between 27 and 42. Patients on antidepressants and common psychiatric medications such as SSRI's or SNRI's are allowed to participate in the study. The trial has enrolled 210 patients in ten centers nationwide and results from this study are expected by mid-2008.

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 Acrux Agreement related to Evamist to K-V (the "Transaction"). The closing of the Transaction occurred on May 15, 2007. Under the terms of the Transaction, we received an upfront payment of $10.0 million upon the closing. On July 27, 2007, we received FDA approval of the NDA for Evamist. On August 1, 2007, we transferred and assigned the Evamist FDA submissions, and all files related thereto to K-V and on August 8, 2007, K-V paid us the additional $140.0 million milestone payment due upon FDA approval of the Evamist NDA. We may also receive certain one-time payments of up to $30.0 million based on achieving certain annual net sales thresholds for Evamist. In connection with the Transaction, in order to obtain Tanabe's blanket release of liens against our assets including the Evamist assets and intellectual property, we repaid the Tanabe line of credit.

In May 2006, we announced positive results from the pivotal Phase 3 clinical trial of Evamist. The study showed a statistically significant reduction in the number and severity of moderate and severe hot flashes. We submitted the NDA for Evamist to the FDA in the third quarter of 2006 and made a $1.0 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 $3.0 million product approval milestone became due and was paid to Acrux in August 2007. Per the terms of the Transaction, K-V paid $1.5 million of this $3.0 million milestone.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

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, other rebates, 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. As of September 30, 2007, the shipments of MUSE in the United States made in 2007, 2006, 2005 and a portion of the shipments in 2004 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 return reserve by utilizing historical information and data obtained from external sources, along with the shelf life of the product. 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.

- Government Chargebacks: Government chargebacks are contractual commitments by us to provide MUSE to Federal government organizations including the Veterans Administration at specified prices. Government chargeback allowances are recorded at the time of sale and accrued as a reserve. In estimating the government chargeback reserve, we analyze actual chargeback amounts and apply chargeback rates to estimates of the quantity of units subject to chargeback. We routinely reassess the chargeback estimates and adjust the reserves accordingly.

- Other Rebates: We estimate amounts payable by us for Medicare Part D rebates, and other rebate programs, primarily with managed care organizations, for the reimbursement of portions of the prescriptions filled that are covered by these programs. Rebate allowances are estimated and reserved at the time of sale. We estimate this reserve by utilizing historical information, contractual and statutory requirements, estimated quantities sold to these organizations and estimated customer inventory levels. Effective January 1, 2007, MUSE no longer qualifies for Medicare Part D.

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

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

On May 15, 2007, we closed our transaction with K-V Pharmaceutical Company ("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 ("FDA Approval"), and on August 1, 2007, we transferred and assigned the Evamist FDA submissions, and all files related thereto to K-V.

We received an upfront payment of $10.0 million in May 2007 upon the closing and received an additional $140.0 million milestone payment in August 2007 upon FDA Approval. These payments are non-refundable.

We evaluated this multiple deliverable arrangement under EITF Issue 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 ("TSA") and a license to improvements to the MDTS applicator ("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 Issue 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 $10.0 million paid at closing and the $140.0 million paid upon FDA Approval have been recorded as deferred revenue and will be recognized as license revenue, together with the future billings under the TSA, if any, ratably over the remaining 21.5-month term of the Improvement License, from August 1, 2007 to May 15, 2009. The revenue related to the transaction recognized in the third quarter of 2007 is $14.0 million and such revenue in future quarters is expected to be recognized as follows (in thousands):

Quarter ending	License revenue
December 31, 2007	$ 20,930
March 31, 2008	$ 20,930
June 30, 2008	$ 20,930
September 30, 2008	$ 20,930
December 31, 2008	$ 20,930
March 31, 2009	$ 20,930
June 30, 2009	$ 10,465

We may also receive milestone payments of up to $30.0 million based upon sales of Evamist through the term of the agreements. Revenue associated with these performance milestones will be recognized when they are earned and collectiblity is reasonably assured.

Research and Development Expenses

Research and development ("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 on-going clinical trial costs. Clinical trial costs represent costs incurred by clinical research organizations, or CROs, and clinical sites. These costs are recorded as a component of R&D expenses. Under our agreements, progress payments are typically

made to investigators, clinical sites and CROs. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

Accounts Receivable and Allowance for Doubtful Accounts

We extend credit to our customers for product sales resulting in accounts receivable. For qualified customers, we grant payment terms of 2%, net 30 days. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. The accounts receivable are reported on the balance sheet, net of the allowance for doubtful accounts.

Income Taxes

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

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

We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that we will recover our deferred tax assets, we will increase our provision for taxes by recording a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable. As a result of our analysis of all available evidence, both positive and negative, as of September 30, 2007, it was not considered more likely than not that our deferred tax assets would be realized with the exception of certain net operating loss and tax credit carryforwards used to offset the effect of the Evamist taxable gain.

The provision for income taxes in the amount of $4.4 million for the three months ended September 30, 2007 relates to the U.S. alternative minimum tax ("AMT") and state income taxes. The utilization of tax loss carryforwards is limited in the calculation of AMT and as a result, a federal tax charge was recorded in the three months ended September 30, 2007. The current AMT liability is available as a credit against future tax obligations upon the full utilization or expiration of the Company's net operating loss carryforward. The provision for income taxes for the three months ended September 30, 2007 was prepared on a discrete quarterly basis, as a yearly effective tax rate was not considered a reliable estimate for the current quarter provision. This provision reflects tax recognition of the entire $150.0 million in non-refundable payments we received from K-V in the second and third quarters of fiscal 2007 for the sale of Evamist (see Note 10: "Sale of Evamist Product").

As of September 30, 2007, we believed that the amount of the deferred tax assets recorded on our 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 cannot recover our deferred tax assets.

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

of accumulated deficit on the adoption date. As a result of the implementation of FIN No. 48, we recognized a decrease of approximately $1.2 million in our income tax liability, which resulted in a decrease of $1.2 million in accumulated deficit. See Note 9: "Income Taxes" to the unaudited notes to condensed consolidated financial statements included in this Form 10-Q for a discussion of the impact of adopting FIN No. 48 on January 1, 2007.

Inventories

We record inventory reserves for estimated obsolescence, unmarketable or excess inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. In 2006, we recorded a $764,000 inventory write-down related to the purchase of alprostadil, considered to be in excess of projected production needs. During the quarter ended September 30, 1998, we established significant reserves against our inventory to align with new estimates of expected future demand for MUSE. In the second quarter of 2007, we disposed of $2.4 million of fully reserved alprostadil which had no impact on cost of goods sold. As of September 30, 2007, the remaining inventory reserve balance is $1.6 million relating to raw materials and components. In the first quarter of 2005, we determined that we likely would continue to use some portion of the fully reserved component parts inventory in production. When we record inventory reserves, we establish a new, lower cost basis for the inventory for accounting purposes. Accordingly, to the extent that this fully reserved inventory was used in production in the first nine months of 2007 and 2006, it was charged to cost of goods sold at a zero basis, which had a favorable impact on cost of goods sold.

Available-for-Sale Securities

Available-for-sale securities represent investments in debt securities that are stated at fair value. We restrict our cash 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 difference between amortized cost (cost adjusted for amortization of premiums and accretion of discounts which are recognized as adjustments to interest income) and fair value, representing unrealized holding gains or losses, are recorded in "accumulated other comprehensive income (loss)," a separate component of stockholders' equity until realized.

Our policy is to record investments in debt securities as available-for-sale because the sale of such securities may be required prior to maturity. Any gains and losses on the sale of debt securities are determined on a specific identification basis and are included in interest and other income in the accompanying consolidated statements of operations. Available-for-sale securities with original maturities beyond one year from the balance sheet date are classified as non-current.

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.

Share-Based Payments

We follow the fair value method of accounting for share-based compensation arrangements in accordance with the Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("SFAS") 123R, *Share-Based Payment*. 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 ("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 during each offering period and the percentage of the purchase discount.

We recorded $910,000 and $2.8 million of share-based compensation expense for the quarter and nine months ended September 30, 2007, respectively, and $547,000 and $1.6 million of share-based compensation expense for the quarter and nine months ended September 30, 2006, 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. We calculated the estimated life of stock options granted using a "simplified" method, which is based on the average of the vesting term and the term of the option, as a result of guidance from the SEC, as contained in Staff Accounting Bulletin No. 107 permitting the initial use of this method. We determine expected volatility using the historical method, which is based on the daily historical trading data of our common stock over the expected term of the option. Management selected the historical method primarily because we have not identified a more reliable or appropriate method to predict future volatility. For more information about SFAS 123R, see Note 3: "Share-Based Compensation" to the unaudited notes to condensed consolidated financial statements included in this Form 10-Q.

Recent Accounting Pronouncements

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.* 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. Management is currently evaluating the impact of adopting this Statement.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements.* SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP) and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We are currently evaluating the effect, if any, that the adoption of SFAS 157 will have on our financial position and 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*, 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. We are currently evaluating the effect, if any, that the adoption of EITF 07-03 will have on our financial position and results of operations.

RESULTS OF OPERATIONS

Executive Overview

For the three months ended September 30, 2007, we reported net income of $1.3 million, or $0.02 net income per share, as compared to a net loss of $6.2 million, or $0.13 net loss per share, during the same period in 2006. The net income in the third quarter of 2007 as compared to the net loss in the third quarter of 2006 is primarily due to the amortization of the deferred license revenue earned due to the sale of Evamist to K-V in May 2007. The increase in revenue was partially offset by an increase in operating expenses in the third quarter of 2007 as compared to the same period in 2006.

In connection with the sale of Evamist, we received $150.0 million. The sale of Evamist was a unique transaction. As discussed in Note 10: "Sale of Evamist Product", an initial $10.0 million was paid at closing and $140.0 million was paid upon FDA approval of Evamist. These payments are non-refundable and have been recorded as deferred revenue and will be recognized as license and other revenue ratably over a 21.5-month period, from August 1, 2007 to May 15, 2009, which is the remaining term of a license to improvements to the MDTS applicator. As compared to revenues from product sales, license and other revenue will be significant on a quarterly basis until all of the revenue from the sale of Evamist is recognized, currently expected to be May 2009. Since the $150.0 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 third quarter of 2007 is $14.0 million and the revenue in future quarters is expected to be recognized as follows (in thousands):

Quarter ending	License revenue
December 31, 2007	$ 20,930
March 31, 2008	$ 20,930
June 30, 2008	$ 20,930
September 30, 2008	$ 20,930
December 31, 2008	$ 20,930
March 31, 2009	$ 20,930
June 30, 2009	$ 10,465

With the exception of income generated from the revenue recognition of the $150.0 million received from K-V, we may have continued losses in future years, depending on the timing of our research and development expenditures, because we expect MUSE sales to remain steady and we plan to continue to invest in clinical development of our current research and development product candidates to bring those potential products to market.

Revenue.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	2007 vs.	2007	2006	2007 vs.

			2006			2006
			(In thousands, except percentages)			
United States product, net	$ 4,075	$ 3,348	22%	7,572	$ 6,948	9%
International product	944	567	66%	3,003	1,643	83%
Other revenue	14,069	116	12,028%	14,300	347	4,021%
Total revenues	$ 19,088	$ 4,031	374%	$ 24,875	$ 8,938	178%

Product revenues for the quarters ended September 30, 2007 and September 30, 2006, were $5.0 million and $3.9 million, respectively. In the nine months ended September 30, 2007 and September 30, 2006, product revenues totaled $10.6 million and $8.6 million, respectively.

The increase in U.S. product revenues in both the three and nine months ended September 30, 2007 as compared to the same periods in 2006 is primarily due to increases in domestic shipments of MUSE and a price increase in 2007. In addition, in the third quarters of 2007 and 2006, revenue increased due to adjustments to our sales allowances of $519,000 and $238,000, respectively. The increase in international revenue in both the three and nine months ended September 30, 2007 as compared to the same periods in 2006 was due to the timing of orders from our international partners. 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.

Domestic demand for MUSE at the retail and government level remains consistent with prior periods, averaging approximately 200,000 units per quarter. Similar to prior years, wholesalers made purchases in the fourth quarter of 2006 that were greater than the current demand. Based on the fourth quarter demand for MUSE, we estimate purchases made by wholesalers in the fourth quarter of 2006 represent approximately 3 to 4 months of excess demand.

Although the demand for MUSE has stabilized, given the loss of coverage under Medicare Part D and the volatility seen in the domestic credit markets, we are not able to anticipate if wholesalers will continue their historical pattern of making purchases in the fourth quarter that exceed expected quarterly demands. If wholesalers do not repeat this pattern of purchasing quantities of MUSE that exceed quarterly demands, revenues from the sale of MUSE in 2007 may be lower as compared to 2006.

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 Acrux Agreement related to Evamist to K-V (the “Transaction”). 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 $10.0 million was paid at closing and $140.0 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.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	2007 vs. 2006	2007	2006	2007 vs. 2006
	(In thousands, except percentages)					
Cost of goods sold and manufacturing	$ 2,736	$ 2,627	4%	$ 8,498	$ 8,542	(1)%

Cost of goods sold and manufacturing (“cost of goods sold”) in the third quarter of 2007 increased $109,000, or 4%, to $2.7 million, as compared to $2.6 million for the third quarter of 2006, and in the nine months ended September 30, 2007 remained constant at $8.5 million as compared to the same period last year.

Cost of goods sold increased in the three months ended September 30, 2007 as compared to the same period of 2006 primarily due to increased stock-based compensation charges of $63,000 in the quarter ended September 30, 2007 as compared to the same period last year. In the nine months ended September 30, 2006, cost of goods sold were higher due to a $764,000 inventory write-down taken in the first quarter of 2006 related to the purchase of alprostadil considered to be in excess of projected production needs offset by increases to cost of goods sold due to increased international shipments of MUSE in the nine months ended September 30, 2007 as compared to the same period of 2006.

We anticipate cost of goods sold and manufacturing in 2007 will be similar to costs incurred in 2006.

Research and development.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	2007 vs. 2006	2007	2006	2007 vs. 2006
	(In thousands, except percentages)					
Research and development	$ 8,644	$ 4,301	101%	$ 15,610	$ 11,162	40%

Research and development expenses in the third quarter of 2007 increased $4.3 million, or 101%, to $8.6 million, as compared to $4.3 million for the third quarter of 2006. In the third quarter of 2007, increased Qnexa spending of $4.9 million and non-project related spending of $117,000 were partially offset by decreases in other clinical trial and project activity of $704,000 (primarily a $478,000 decrease in ALISTA project related spending, due to the completion of clinical trial activities in 2006), as compared to the third quarter of 2006. In the three months ended September 30, 2007, we spent $2.4 million on Qnexa Phase 3 clinical supplies and formulation work performed by our sole-source manufacturer which represented 28% of our total research and development expenses.

In the nine months ended September 30, 2007 research and development expenses increased $4.4 million, or 40%, to $15.6 million, as compared to $11.2 million in the same period last year. This increase was primarily the result of a $3.9 million net increase in project related spending (including increased spending of $7.1 million for Qnexa partially offset by decreased spending of $1.7 million for Evamist and $1.5 million for ALISTA) and a net increase of $538,000 in non-project related spending (primarily due to increases of $209,000 in stock compensation expense and $160,000 in patent related legal fees) in the nine months ended September 30, 2007 as compared to the nine months ended September 30, 2006. Evamist and ALISTA clinical trial activities ended in 2006 and consequently, aside from the $1.5 million milestone payment made to Acrux in August 2007 for the approval of Evamist, there was little spending on these projects in 2007.

We anticipate that our research and development expenses will continue to increase significantly in 2007, as we continue to advance the clinical program for Qnexa for the treatment of obesity and our other programs. 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. If we are successful in obtaining FDA regulatory approval for any new product candidates being developed through our research and development efforts, we do not expect to recognize revenue from sales of any such new products, if any, for several years.

We filed an NDA for Evamist with the FDA in the third quarter of 2006 and in October 2006 made a $1.0 million clinical development milestone payment to Acrux under the terms of our licensing agreement related to this filing, which was expensed in the third quarter of 2006. On July 27, 2007, the FDA approved the NDA for Evamist. K-V paid $1.5 million of the $3.0 million product approval milestone payment made to Acrux in August 2007 for the approval of the NDA for Evamist.

Selling, general and administrative.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	2007 vs. 2006	2007	2006	2007 vs. 2006
	(In thousands, except percentages)					
Selling, general and administrative	$ 3,691	$ 3,510	5%	$ 11,988	$ 10,678	12%

Selling, general and administrative expenses in the three months ended September 30, 2007 of $3.7 million increased $181,000, or 5% as compared to the three months ended September 30, 2006. In the quarter ended September 30, 2007, this increase is primarily due to $241,000 in additional stock compensation expense and a net increase of $140,000 in other selling, general and administrative expenses, partially offset by decreases in corporate legal expense of $114,000 and MUSE related marketing expenses of $86,000, as compared to the quarter ended September 30, 2006.

In the nine months ended September 30, 2007 selling, general and administrative expenses increased $1.3 million, or 12% to $12.0 million as compared to the same period in 2006. In the nine months ended September 30, 2007, the increase is primarily due to an incremental increase in corporate general and administrative expenses of $1.1 million (primarily attributable to increased stock compensation expense of $804,000) and MUSE related sales and marketing expenses of $249,000, as compared to the nine months ended September 30, 2006.

Interest income and expense.

Interest income for the quarter ended September 30, 2007 was $1.8 million, as compared to $398,000 for the quarter ended September 30, 2006, and $3.3 million for the nine months ended September 30, 2007, as compared to $1.1 million for the nine months ended September 30, 2006. The increase in interest income is primarily due to the increase in our average investment cash balance (due to the receipt of the $140.0 million payment from K-V in August 2007) from the three and nine months ended September 30, 2006 as compared to the same periods in 2007.

Interest expense for the quarter ended September 30, 2007 was $125,000 as compared to $145,000 during the same period last year and $409,000 in the nine months ended September 30, 2007 as compared to $448,000 during the same period last year. On April 24, 2007, in connection with the sale of Evamist to K-V, we paid off the $6.7 million outstanding balance on the Tanabe line of credit, including all accrued interest and terminated the line of credit.

Provision for income taxes.

Provision for income taxes for the quarter ended September 30, 2007 was $4.4 million, as compared to $6,000 for the quarter ended September 30, 2006, and $4.4 million for the nine months ended September 30, 2007, as compared to $18,000 for the nine months ended September 30, 2006. The provision for income taxes in the amount of $4.4 million for the three and nine months ended September 30, 2007 relates to the U.S. AMT and state income taxes, while the provision for the three and nine months ended September 30, 2006 relates to state income taxes. The utilization of tax loss carryforwards is limited in the calculation of AMT and as a result, a federal tax charge was recorded in the three months ended September 30, 2007. This provision reflects tax recognition of the entire $150.0 million in non-refundable payments we received from K-V in the third quarter of fiscal 2007 for the sale of Evamist.

LIQUIDITY AND CAPITAL RESOURCES

Cash. Unrestricted cash, cash equivalents and available-for-sale securities totaled $189.0 million at September 30, 2007, as compared to $58.9 million at December 31, 2006. The increase in cash, cash equivalents and available-for-sale securities of $130.1 million is the net result of the $150.0 million received from the K-V transaction, cash provided by operating activities, partially offset by cash used for investing and financing activities for the first nine months of 2007. Included in these amounts are cash receipts from the collection of amounts owed at December 31, 2006 from customers as measured by a decrease of $2.7 million in accounts receivable, and $1.7 million from exercises of stock options, offset by the $6.7 million payoff of the Tanabe loan.

Since inception, we have financed operations primarily from the issuance of equity securities. Through September 30, 2007, we raised $227.3 million from financing activities, received $150.0 million from the sale of Evamist and had an accumulated deficit of $180.2 million at September 30, 2007.

Available-for-sale securities. We focus on liquidity and capital preservation in our investments in available-for-sale securities. We restrict our cash 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 or better.

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

Accounts Receivable. Accounts receivable (net of allowance for doubtful accounts) at September 30, 2007 was $1.7 million, as compared to $4.4 million at December 31, 2006. The 60% decrease in the accounts receivable balance at September 30, 2007 is primarily due to the collection of accounts receivable outstanding at December 31, 2006. Currently, we do not have any significant concerns related to accounts receivable or collections.

Liabilities. Total liabilities were $159.3 million at September 30, 2007, $134.2 million higher than at December 31, 2006. The change in total liabilities includes a $136.0 million net increase in deferred revenue due to $150.0 million in deferred license revenue received from K-V on the sale of Evamist (offset by the recognition of $14.0 million of this deferred license revenue during the nine months ended September 30, 2007), a $3.3 million increase in accounts payable due to the timing of payments for goods and services supporting the development effort for Qnexa, a $2.3 million increase in income taxes payable (includes an increase of $3.5 million in federal and state taxes related to the Evamist license revenue, partially offset by a $1.2 million decrease, as a result of the implementation of FIN No. 48), and a reduction in notes payable, primarily due to the $6.7 million payoff of the Tanabe loan in the second quarter of 2007. The deferred revenue balance primarily results from the K-V transaction and the related amortization over time of the revenue based on the receipt of the cash. Deferred revenue is a non-cash liability and does not represent any future obligations on our part.

We have entered into manufacturing agreements with suppliers to purchase raw materials. As of September 30, 2007, our remaining commitment under these agreements is to purchase a minimum of $3.1 million of product from 2006 through 2011. In the first quarter of 2006, we recorded a $764,000 inventory write-down related to the purchase of alprostadil considered to be in excess of projected production needs. Should our inventory of raw materials 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 $3.0 million, up to $4.3 million for the achievement of certain clinical development milestones, up to $6.0 million for achieving product approval milestones, and royalties on net sales in the United States upon commercialization of each product. We made a $1.0 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 $3.0 million product approval milestone payment for the approval of this NDA in August 2007. Per 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 provided $134.0 million of cash (mainly from the receipt of the $150.0 million in cash received from K-V in the second and third quarters of 2007) and used $18.2 million of cash during the nine months ended September 30, 2007 and 2006, respectively. During the first nine months of 2007, our net operating loss of $12.7 million was offset by the deferral of $136.0 million of license revenue due to the receipt of $150.0 million from K-V for the sale of Evamist, a $3.3 million increase in accounts payable due to the timing of payments, a $2.7 million reduction in our accounts receivable, due to the collection of monies owed to us, $2.8 million in non-cash stock-based compensation expense, and a $3.5 million increase in income taxes payable related to the Evamist license revenue. In addition, the increase in prepaid and other assets increased our use of operating cash by $1.7 million in the nine months ended September 30, 2007. During the first nine months of 2006, our net operating loss of $20.8 million was partially offset by a $5.3 million reduction in our accounts receivable due to the collection of monies owed to us, which in turn was offset by use of cash to pay accrued research, clinical and licensing fees of $3.0 million.

Investing Activities. Our investing activities used $13.8 million and $3.8 million in cash during the nine months ended September 30, 2007 and 2006, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities. In addition, during the first quarter of 2006, we provided Crown Bank with a $700,000 Certificate of Deposit as security for the loan agreement we entered into with them on January 4, 2006.

Financing Activities. Financing activities used $3.6 million and provided $18.6 million during the nine months ended September 30, 2007 and 2006, respectively. In the first nine months of 2007, the cash used by financing activities was primarily due to the $6.7 million payoff of the Tanabe loan in the second quarter of 2007, partially offset by $1.7 million in proceeds from the exercise of stock options. In the first nine months of 2006, the cash provided by financing activities is primarily due to the $12.0 million net proceeds from the registered direct sale of 3,669,725 shares of common stock on May 10, 2006 at a price of $3.27 per share, and the $5.3 million net proceeds from the Crown Bank loan we entered into on January 4, 2006.

In the first quarter of 2004, we signed an agreement for a line of credit with Tanabe Holding America, Inc., a subsidiary of Tanabe Seiyaku Co., Ltd., or Tanabe, allowing us to borrow up to $8.5 million to be used for the development of avanafil. The secured line of credit could be drawn upon quarterly and each quarterly borrowing had a 48-month term and bore interest at the annual rate of 2%. On April 24, 2007, in connection with the sale of Evamist to K-V, we paid off the $6.7 million outstanding balance on the Tanabe line of credit, including all accrued interest and terminated the line of credit. All of the assets of the Company, except the land and buildings, served as collateral for this line of credit. On May 1, 2007, Tanabe signed a Termination and Release acknowledging payment in full of the principal and interest due under the line of credit and releasing the lien on the Company's assets.

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. ("Crown"). The land and buildings, among other assets, located at our principal manufacturing facility and a $700,000 Certificate of Deposit held by Crown serve as collateral for these Agreements. The loan is payable over a 10-year term. The interest rate is adjusted annually to a fixed rate for the year equal to the prime rate plus 1%, with a floor of 7.5%. Principal and interest are payable monthly based upon a 20-year amortization schedule and are adjusted annually at the time of the interest rate reset. All remaining principal is due on February 1, 2016. The interest rate was 9.25% and 8.25% for the first nine months of 2007 and 2006, respectively.

On December 22, 2004, we filed a shelf registration statement (File Number 333-12159) on Form S-3 with the SEC, which allows us to offer and sell up to an aggregate of $50.0 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 February 22, 2005, we filed a prospectus supplement with the SEC relating to an underwritten public offering of 7,500,000 shares of common stock under the existing shelf registration statement and supplement thereto. On March 15, 2005, we sold 6,250,000 shares of our common stock at a price of $3.40 per share, providing us with net proceeds of $19.6 million.

On May 10, 2006, we sold $12.0 million of our common stock in a registered direct offering. Under the terms of the financing, we sold 3,669,725 shares of VIVUS common stock at a price of $3.27 per share to two institutional investors. On May 11, 2006, we filed a prospectus supplement with the SEC relating to this registered direct offering under the existing shelf Registration Statement on Form S-3 and supplement thereto.

On July 14, 2006, VIVUS, Inc. filed with the SEC a shelf Registration Statement on Form S-3. The shelf Registration Statement (File Number 333-135793) was declared effective by the SEC on August 16, 2006, providing us with the ability to offer and sell up to an aggregate of $80.0 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. This shelf Registration Statement (File Number 333-135793) replaces shelf Registration Statement (File Number 333-12159).

On November 17, 2006, we raised $33.6 million in a registered direct offering of our common stock pursuant to this shelf Registration Statement. Under the terms of this financing, we sold and issued a total of 6,750,000 shares of our common stock at a price of $3.50 per share in an initial closing and an additional 2,850,000 shares in a second closing on December 8, 2006. All of the shares of Common Stock were offered pursuant to an effective Registration Statement on Form S-3 filed with the SEC on July 14, 2006.

The funding necessary to execute our business strategies is subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate. It is also important to note that if a clinical 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 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 product candidate. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical studies, including, among others, the following:

- we or the FDA may suspend trials;
- we may discover that a 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 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 research and development projects are difficult to estimate and are subject to considerable variation. Our inability to complete our research and development projects 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 product candidates;
- the costs involved in filing and pursuing patent applications and enforcing patent claims;
- the establishment of collaborations, sublicenses and strategic alliances;
- the cost of manufacturing and commercialization activities and arrangements;
- the results of operations;
- demand for MUSE;

- the cost, timing and outcome of regulatory reviews;
- the rate of technological advances;
- ongoing determinations of the potential commercial success of our products under development;
- the level of resources devoted to sales and marketing capabilities; and
- the activities of competitors.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs through 2008. However, we anticipate that we may require additional funding to continue our research and product development programs, to conduct preclinical studies and trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending our patent claims, if any, and we may require additional funding to establish additional manufacturing and marketing capabilities in the future. In particular, we expect to make other substantial payments to Acrux and Tanabe, in accordance with our agreements with them in connection with the licensing of certain compounds. These payments are based on certain development, regulatory and sales milestones. In addition, we are required to make royalty payments on any future product sales. Similar to the transaction with Evamist we may consider divesting 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 whenever conditions are favorable. The sale of additional equity securities would result in additional dilution to our stockholders. We may also seek additional funding through strategic alliances and other financing mechanisms. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. If adequate funds are not available, we may be required to curtail significantly one or more of our research or development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies or 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 product candidates at any time. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit.

Contractual Obligations

The following table summarizes our contractual obligations at September 30, 2007 and the effect such obligations are expected to have on our liquidity and cash flow in future fiscal years. These do not include milestones or future interest expense and assume non-termination of agreements. These obligations, commitments and supporting arrangements represent payments based on current operating forecasts, which are subject to change:

	Payments Due by Period				
Contractual obligations	**Total**	**2007 (3 months)**	**2008-2010**	**2011-2012**	**Thereafter**
			(in thousands)		
Operating leases	$ 1,018	$ 139	$ 879	—	—
Manufacturing and other purchases	8,092	5,247	2,080	$ 765	—
Clinical trials	57,481	7,943	49,538	—	—
Notes payable	5,202	27	375	315	$ 4,485
Total contractual obligations	$ 71,793	$ 13,356	$ 52,872	$ 1,080	$ 4,485

Operating Leases

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

Manufacturing and Other Purchases

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

Manufacturing Agreements

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

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

Other Agreements

We have remaining commitments under various general and administrative services agreements totaling $422,000 at September 30, 2007. 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 September 30, 2007, our remaining commitment under these agreements totaled $4.1 million. In addition, we have entered into marketing promotion agreements for MUSE. At September 30, 2007, our remaining commitment under the MUSE agreements totaled $558,000.

Clinical Trials

We have entered into various agreements with clinical consultants, investigators and clinical research organizations to perform clinical trial management and clinical studies on our behalf and, at September 30, 2007, our remaining commitment under these agreements totaled $57.5 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

On January 4, 2006, we obtained a $5.4 million loan from Crown. The land and buildings, among other assets, located at our principal manufacturing facility and a $700,000 Certificate of Deposit held by Crown serve as collateral for these Agreements. The loan is payable over a 10-year term. The interest rate is adjusted annually to a fixed rate for the year equal to the prime rate plus 1%, with a floor of 7.5%. Principal and interest are payable monthly based upon a 20-year amortization schedule and are adjusted annually at the time of the interest rate reset. All remaining principal is due on February 1, 2016. The interest rate was 9.25% and 8.25% for the first nine months of 2007 and 2006, respectively. As of September 30, 2007, we have a principal balance of $5.2 million remaining on the Crown loan.

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, we have not included these potential future obligations in the above table.

Tanabe

In January 2001, we entered into an exclusive development, license and supply agreement with Tanabe for the development and commercialization of avanafil, a PDE5 inhibitor compound for the oral and local treatment of male and

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

We have paid upfront licensing fees of $5.0 million to Tanabe and have agreed to make additional payments upon the completion of certain development, regulatory and sales milestones. During the first quarter of 2004, we initiated a Phase 2 clinical trial with avanafil, which meets one of the clinical development milestone criteria above. We paid Tanabe $2.0 million in connection with this milestone in 2006. We have further agreed to pay royalties on net sales of products containing avanafil. No payments have been made under this agreement with Tanabe in the first nine months of 2007.

Acrux

In February 2004, we entered into exclusive licensing agreements with Acrux Limited (“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 $3.0 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 $6.0 million for achieving product approval milestones, and royalties on net sales in the United States following approval and commercialization of each product. We have paid $4.8 million in clinical development milestones payments to date, including the $1.0 million milestone payment we made to Acrux in October 2006 related to the submission of an NDA to the FDA for Evamist and the $3.0 million product approval milestone payment for approval of this NDA, which was paid in August 2007. Per 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 Acrux Agreement related to Evamist to K-V and K-V paid $1.5 million of this $3.0 million obligation. Although we have sublicensed our rights under the Acrux Agreement related to Evamist to K-V, we will continue to have certain obligations under this license in the event that K-V does not satisfy the requirements under the sublicense agreement. See Note 10: “Sale of Evamist Product” to the unaudited notes to condensed consolidated financial statements included in this Form 10-Q for additional information concerning the terms of this agreement and Note 17: “Legal Matters” for further information regarding Acrux.

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, we provide indemnifications of varying scope to customers against claims of intellectual property infringement made by third parties arising from the use of our products and to certain of our clinical research organizations and investigators sites. Historically, costs related to these

indemnification provisions have not been significant and we are unable to estimate the maximum potential impact of these indemnification provisions on our future results of operations.

Pursuant to the terms of the K-V transaction for the sale of Evamist, we made certain representations and warranties concerning our rights and assets related to Evamist and our authority to enter into and consummate the transaction. We also made certain covenants 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.

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.

Interest Rate Risk

We are exposed to interest rate risk on our short-term investments. 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 highly liquid and high quality government and other debt securities. To minimize our exposure due to adverse shifts in interest rates, we invest in short-term securities and ensure that the maximum weighted average of our maturity of our investments does not exceed 18 months. If a 10% change in interest rates were to have occurred on September 30, 2007, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Due to the short holding period of our investments, we have concluded that we do not have a material financial market risk exposure.

We are also exposed to interest rate risk on the $5.2 million loan payable to Crown Bank, N.A. as of September 30, 2007. 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 9.25% and 8.25% for the first nine months of 2007 and 2006, 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 Securities and Exchange Commission's rules and forms, 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, VIVUS receives and makes inquiries regarding patent infringement and other legal matters.

On November 14, 2006,we received a letter from Manatt, Phelps & Phillips LLP ("Manatt") on behalf of Acrux DDS Pty Ltd., FemPharm PTY Ltd., and Acrux Limited (collectively "Acrux") notifying us of an alleged dispute under the Testosterone ("Luramist") and Estradiol ("Evamist") Development Agreements (the "Acrux Agreements") between VIVUS and Acrux. Since that time VIVUS and Acrux have corresponded regarding the alleged dispute. The claims relating to Evamist have not progressed further, but, to date, such claims have not been formally withdrawn. Per the terms of our Asset Purchase Agreement with K-V, the license with Acrux related to Evamist is sublicensed to K-V. Although we have sublicensed our rights under the Acrux Agreement related to Evamist to K-V, we will continue to have certain obligations under this license in the event that K-V does not satisfy the requirements under the sublicense agreement. We believe that we have a meritorious defense to the claims made by Acrux in connection with the alleged dispute; however, in the event that Acrux should prevail in this matter relating to Evamist it could have a material adverse effect on our business, financial condition and results of operations, including the possible payment of liquidated damages up to the amount paid by K-V for Evamist.

On November 5, 2007, our legal counsel received a demand for arbitration under the Acrux Agreements regarding Luramist. Acrux's demand seeks a reversion of all rights assigned to VIVUS regarding Luramist, monetary damages, a portion of a milestone payment for Luramist under the Acrux Agreements and declaratory relief. We believe that we are in compliance with all material aspects of the Acrux Agreements including those related to Luramist and that we currently do not owe damages or any milestone payment under the Acrux Agreements. If we are unable to resolve these Luramist related claims with Acrux, we intend to seek to enforce our rights under the Acrux Agreements in arbitration. Development and commercialization of Luramist continues. We believe that we have a meritorious defense to the claims made by Acrux in connection with the alleged dispute; however, in the event that Acrux should prevail in this matter relating to Luramist, it could have a material adverse effect on our business, financial condition and results of operations.

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

ITEM 1A. RISK FACTORS AFFECTING OPERATIONS AND FUTURE RESULTS

Set forth below and elsewhere in this Form 10-Q and in other documents we file with the Securities and Exchange Commission (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. Product candidates that may appear to be promising at all stages of development may not reach the market for a number of reasons. 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 3 clinical trials in support of various indications, we do not have any experience in managing Phase 3 clinical trials for obesity. 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.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current 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 a product candidate in the general population, but rather to test initial safety, to study pharmacokinetics and pharmacodynamics, to study efficacy in a selected disease population, and to understand the product candidate's side effects at various doses and schedules. Success in pre-clinical studies or completed clinical trials does not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. Favorable results in early studies or trials may not be repeated in later studies or trials, and 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 product candidates, Qnexa, Luramist and avanafil, have not completed the large, pivotal Phase 3 trials for efficacy and safety that are required for approval by the United States Food and Drug Administration ("FDA") and other worldwide regulatory authorities. Pre-clinical data and the limited clinical results that we have obtained for these investigational products 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 clinical trials also may not predict the ability of these investigational products to achieve or sustain the desired effects in the intended population or to do so safely. We may also decide to not conduct additional Phase 2 studies prior to the initiation of pivotal Phase 3 studies. In addition, we may elect to enter into pivotal Phase 3 studies with a new formulation, delivery system or choose to study different populations than had been used or studied in previous clinical trials.

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

We will be required to demonstrate through larger-scale clinical trials that these 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 product candidates proceeding through clinical trials. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our product candidates. If any of our investigational products fails to demonstrate sufficient safety and efficacy in any clinical trial, we will experience potentially significant delays in, or decide to abandon development of, that 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 pre-clinical studies and/or clinical trials indicate that our proposed products are not safe or effective for human use, our business will suffer.

Unfavorable results from ongoing pre-clinical studies 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.

Once a clinical trial has begun, it may be delayed, suspended or terminated due to a number of factors, including:

- ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;
- failure to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated enrollment or retention rate of patients in clinical trials;

- serious adverse events or side effects experienced by participants; or
- insufficient supply or deficient quality of drug candidates or other materials necessary for the conduct of our clinical trials.

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

If the results of current and future clinical testing indicate that our proposed products are not safe or effective for human use, our business will suffer.

All of the 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 product candidates, we must demonstrate through pre-clinical testing and/or clinical trials that our product candidates are safe and effective in humans. Conducting clinical trials is a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. Our ability to complete clinical trials may be delayed by many factors, including, but not limited to:

- inability to manufacture sufficient quantities of compounds for use in clinical trials;
- failure to receive approval by the FDA of our clinical trial protocols;
- changes in clinical trial protocols made by us or imposed by the FDA;
- the effectiveness of our product candidates;
- slower than expected rate of and higher than expected cost of patient recruitment;
- inability to adequately follow patients after treatment;
- unforeseen safety issues;
- government or regulatory delays; or
- our ability to raise the necessary cash to start or complete the trials.

One of the active ingredients in Qnexa, phentermine, had previously been used in combination with fenfluramine and dexfenfluramine. Phentermine is the most commonly prescribed anti-obesity product. As phentermine is an older drug, no new efficacy trials have been conducted with the exception of several trials on the combination of phentermine and fenfluramine in the early and mid 1990s. The combination of fenfluramine or PONDIMIN (“fen”) and phentermine (“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. The fen-phen combination was successful and in 1996, 6.6 million prescriptions of fen-phen were written in the U.S. Dexfen-phen refers to the combination of dexfenfluramine or Redux (“dexfen”) and phentermine. Dexfenfluramine received FDA approval in 1996 for use as an appetite suppressant in the management of obesity.

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 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 ("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 shown 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. In the Phase 2 study, echocardiograms and cardiovascular monitoring were performed and no abnormalities were noted. 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 sale.

Previous published studies suggest that the administration of topiramate alone, in conjunction with diet and a behavioral modification program, results in weight reduction in obese patients. The most prominent side effect seen in the published studies was paresthesia, (tingling of the extremities) experienced by 42% to 59% of patients. Drop outs due to paresthesia were 5% or less. In the Phase 2 Duke study, paresthesia was experienced in 38% of the patients on Qnexa. There were no drop outs in the Qnexa group due to paresthesia. The other common adverse events experienced in the topiramate monotherapy studies were also central nervous system ("CNS") related including fatigue, difficulty with attention, memory and concentration and depression. In the Phase 2 study, these CNS related side effects were also experienced but the difference was not significant when compared to placebo. The pharmaceutical company performing research of topiramate alone announced they had discontinued development of a time-release formulation due to side effects at high doses.

The FDA has also recently begun the review of the correlation of certain centrally acting drugs on suicidal ideations. The agency has requested that as part of our Phase 3 trials for Qnexa, a standard suicidality analysis be performed. While we do not expect a negative impact from the completion of this analysis on the ultimate approval of Qnexa, the labeled use of Qnexa may exclude patients with suicidal tendencies.

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

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

We anticipate that the approved drugs that are combined to produce our product candidate, Qnexa, are likely to be commercially available at prices lower than the price at which we would seek to market our product candidate. We cannot be sure that physicians will view our products as sufficiently superior to a treatment regime of the individual active pharmaceutical ingredients as to justify the significantly higher cost we expect to seek for Qnexa, and they may prescribe the individual drugs already approved and marketed by other companies instead of our combination product. Even though our U.S. patent contains composition, product formulation and method-of-use claims that should 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 our product 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 Qnexa. Similar concerns could also limit the reimbursement amounts private health insurers or government agencies in the United States are prepared to pay for Qnexa, which could also limit market and patient acceptance of our product, and could negatively impact our revenues and net income, if any. 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 prescribed by physicians for a different, unapproved indication. Topiramate, one of the ingredients in Qnexa, is not approved for obesity treatment. With regard to off-label substitution at the pharmacy level, we expect to rely on the novel dose ratios and novel pharmacokinetic properties of our product candidate, to provide sufficient distinction such that generic preparations are not considered therapeutic equivalents by the FDA. State pharmacy laws in many instances preclude pharmacists from substituting with generic preparations if the products are not therapeutic equivalents. We believe there will be no commercially available doses of the active ingredients in Qnexa, when and if approved. Therefore, the lack of therapeutic equivalency restricts generic substitution by pharmacies and/or pharmacy benefit managers. However, we cannot be certain that pharmacists and/or pharmacy benefit managers will not substitute generics in place of Qnexa, which could significantly diminish its market potential. Physicians might also prescribe the individual components of a product candidate prior to Qnexa's approval, which could adversely affect our

development of the product candidate due to our lack of control over the administration to patients of the combination of active pharmaceutical ingredients in our product candidate, the occurrence of adverse effects, and other reasons. Such pre-approval use could also adversely affect our ability to market and commercialize Qnexa.

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

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

To obtain regulatory approval for Qnexa, we will be required to show that each active pharmaceutical ingredient in the product candidate makes a contribution to the combined product candidate's claimed effects and that the dosage of each component, including amount, frequency and duration, is such that the combination is safe and effective for a significant patient population. As a result, we will be required to include in our clinical trials an evaluation of each component drug as well as for the component drug in combination. This would likely require us to conduct more extensive and more expensive clinical trials than would be the case for many single agent pharmaceuticals. The need to conduct such trials could make it more difficult and costly to obtain

regulatory approval of Qnexa than of a new drug containing only a single active pharmaceutical ingredient. The FDA revised guidelines for obesity set forth the Phase 2 requirements for combination products. We intend to repeat the combination studies in parallel with the pivotal Phase 3 studies with a once-a-day formulation.

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

We have and will continue to in-license product candidates from third parties. The United States rights to Evamist and Luramist were licensed from Acrux Limited and its related affiliates. The rights to avanafil were licensed from Tanabe Seiyaku Co, LTD., a Japanese corporation. The rights to Evamist, under the Acrux Agreement, were sublicensed to K-V Pharmaceutical upon closing of the sale of Evamist to K-V. Each of these agreements contains 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 these 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 or sublicense agreements were terminated early or if the terms of the license or sublicense 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. In the event that the Acrux license was terminated, and at such time K-V was not in material breach of the sublicense, then we may be required to pay as liquidated damages an amount equal to the amounts paid by K-V for Evamist under our Asset Purchase Agreement with K-V.

On November 14, 2006,we received a letter from Manatt, Phelps & Phillips LLP (“Manatt”) on behalf of Acrux DDS Pty Ltd., FemPharm PTY Ltd., and Acrux Limited (collectively “Acrux”) notifying us of an alleged dispute under the Testosterone (“Luramist”) and Estradiol (“Evamist”) Development Agreements (the “Acrux Agreements”) between VIVUS and Acrux. Since that time VIVUS and Acrux have corresponded regarding the alleged dispute. The claims relating to Evamist have not progressed further, but, to date, such claims have not been formally withdrawn. Per the terms of our Asset Purchase Agreement with K-V, the license with Acrux related to Evamist is sublicensed to K-V. Although we have sublicensed our rights under the Acrux Agreement related to Evamist to K-V, we will continue to have certain obligations under this license in the event that K-V does not satisfy the requirements under the sublicense agreement. We believe that we have a meritorious defense to the claims made by Acrux in connection with the alleged dispute; however, in the event that Acrux should prevail in this matter relating to Evamist it could have a material adverse effect on our business, financial condition and results of operations, including the possible payment of liquidated damages up to the amount paid by K-V for Evamist.

On November 5, 2007, our legal counsel received a demand for arbitration under the Acrux Agreements regarding Luramist. Acrux’s demand seeks a reversion of all rights assigned to VIVUS regarding Luramist, monetary damages, a portion of a milestone payment for Luramist under the Acrux Agreements and declaratory relief. We believe that we are in compliance with all material aspects of the Acrux Agreements including those related to Luramist and that we currently do not owe damages or any milestone payment under the Acrux Agreements. If we are unable to resolve these Luramist related claims with Acrux, we intend to seek to enforce our rights under the Acrux Agreements in arbitration. Development and commercialization of Luramist continues. We believe that we have a meritorious defense to the claims made by Acrux in connection with the alleged dispute; however, in the event that Acrux should prevail in this matter relating to Luramist, it could have a material adverse effect on our business, financial condition and results of operations.

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 product candidates, particularly after the Phase 2 stage of clinical testing. These arrangements may place the development of our 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 Seiyaku Co., Ltd. and Mitsubishi Pharma Corporation completed their merger and announced their name change to Mitsubishi Tanabe Pharma Corporation. It is unclear at this time what effect, if any, the merger will have on our agreement with Tanabe. There can be no guarantee that the merger of Tanabe and Mitsubishi will not have an adverse material effect on our agreement with Tanabe, which in turn could lead to a material adverse effect on our business, financial condition and results of operations.

We may be unable to locate and enter into favorable agreements with third parties, which could delay or impair our ability to develop and commercialize our 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 product candidates;
- our collaborators may experience financial difficulties;
- 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 also adversely affect a collaborator’s willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing 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 product candidates.

We face significant governmental regulation during our product development activities.

The research, testing, manufacturing, selling and marketing of 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 product candidates currently under development. The FDA can suspend 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 June 2007, an FDA advisory panel recommended against approval of Rimonabant, an oral obesity treatment targeting the CB1 receptor system. 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 suicidality. In addition, concerns about Rimonabant's mechanism of action and interference with the CB1 receptor pathway were also voiced. The sponsor of Rimonabant withdrew its NDA shortly after the advisory panel meeting.

In December 2004, an FDA advisory panel recommended against approval of a testosterone patch under development by another company to address female sexual dysfunction, specifically hypoactive sexual desire disorder. The FDA indicated that more safety data would be required before it would be in a position to recommend approval. Subsequently, this company withdrew its New Drug Application. We are developing a transdermal testosterone product candidate, Luramist, which is designed to address hypoactive sexual desire disorder. In light of the FDA panel's recommendation, 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 product candidate to the FDA for consideration. In the end, we may be unsuccessful in obtaining FDA approval of our product candidate.

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 product candidates would delay or prevent our ability to generate revenue from our 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 product candidates from third parties.

We currently license some of our investigational product candidates from third parties. Our present development programs involving these product candidates rely in part upon previous development work conducted by third parties over whom we had no control and before we licensed the product candidates. In order to receive regulatory approval of a 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 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 a 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 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, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the product candidates. 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. Previously unknown problems with the 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 product candidates. We cannot predict the likelihood, nature, extent or effects of government regulation that may arise from future legislation or administrative action, either in the United States 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 product candidates in development and those third parties may not perform satisfactorily.

Like many companies our size, we do not have the ability to conduct pre-clinical or clinical studies for our product candidates without the assistance of third parties who conduct the studies on our behalf. These third parties are usually toxicology facilities 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. The CROs typically perform patient recruitment, project management, data management, statistical analysis, and other reporting functions. We intend to use several different toxicology facilities and CROs for all of our pre-clinical and clinical studies. If these third party toxicology facilities 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 proposed product candidates on a timely basis, if at all, and we may not be able to successfully commercialize these proposed product candidates. If these third party toxicology facilities or CROs do not perform satisfactorily, we may not be able to locate acceptable replacements or enter into favorable agreements with them, if at all.

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

We do not have the ability to manufacture the materials we use in our pre-clinical and clinical trials and future commercial operations. Rather, we rely on various third parties to manufacture these materials. There can be no assurance that we will be able to identify, qualify and obtain 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 proposed product candidates and may not be able to successfully commercialize these proposed 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 has scaled up in anticipation of the Phase 3 program. In addition, this contract manufacturer is our sole-source of clinical supplies for Qnexa.

There can be no assurance that the final once-a-day formulation will result in sufficient safety and efficacy for approval. A failure on the stability or manufacturability of our once-a-day formulation or the inability of this contract manufacturer to carry out its contractual duties or meet expected timelines, our Qnexa clinical studies would be delayed which may have a material adverse impact on our development plan, stock price and financial condition.

Risks Relating to our Operations

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

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

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

We are required to obtain FDA, European Medicines and Healthcare products Regulatory Agency (“MHRA”), and other regulatory agency approvals for any change in suppliers or service providers. For example, MUSE is supplied to the market with the MUSE applicator, containing the MUSE dosage, enclosed within a sealed foil pouch. Our previous supplier of the MUSE laminated foil has closed its business. The laminated foil is used to make the sealed foil pouch, described above, which is used to make the MUSE primary product container. Before this previous supplier closed its business, the supplier produced a bulk-quantity of foil that, at this time, is expected to be sufficient to support the production of MUSE for our international markets through the end of 2008. There can be no assurance that as this bulk supply is used through the end of 2008 for international product, that there will be a sufficient yield in the final quantity of foil with acceptable quality to support the international markets’ MUSE demand. Although the foil supplier produced this bulk unprinted foil, the label printing will be done periodically. As a consequence, if there are unacceptable quality issues with the bulk foil, they may not be discovered as the bulk material is used through the end of 2008. If such foil quality issues do occur, we may be unable to meet international MUSE demand in 2007 and 2008.

We have a new vendor for the MUSE laminated foil. As this laminated foil is used to make the MUSE primary product container, there are significant qualifications and regulatory approvals that must be obtained prior to using the new vendor to produce foil to meet MUSE demand. These include, but are not limited to, vendor qualification, foil material qualification, MUSE product suitability studies, electron beam irradiation suitability, FDA approval, and MHRA approval. Although the FDA has granted approval for the use of foil from our new vendor for U.S. MUSE product, there can be no assurance that these qualifications and approvals will be successfully obtained from the MHRA or Canadian market regulatory agency, or that they will be obtained within the time needed to support MUSE demand before our current supply of foil is exhausted. Failure to receive adequate supplies of foil, failure to receive appropriate regulatory approvals for the change in materials and vendors, and any unforeseen quality or production issues due to the use of the new materials or vendors could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

After product approval by the FDA, our labeling and marketing activities continue to 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. 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 products, such approval may involve limitations on the indicated uses or marketing claims we may make for our products. Further, later discovery of previously unknown problems 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 and financial condition. 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 and results of operations.

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

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

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

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

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

We support MUSE sales in the United States through a small direct sales force targeting major accounts. Telephone marketers also focus on urologists who prescribe MUSE. Physician and patient information/help telephone lines are available to answer additional questions that may arise after reading the inserts or after actual use of the product. There can be no assurance that our 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 product candidates, either by developing our own capabilities or entering into agreements with others, we will not be able to successfully launch our 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 our product in a manner consistent with their industry practices and perceived business

interests. Our sales are subject to the purchasing requirements of our major customers, which presumably are based upon projected volume levels. Purchases by any customer, during any period may be above or below the actual prescription volumes of our product during the same period, resulting in increases or decreases in inventory existing in the distribution channel.

Although the demand for MUSE has stabilized, given the loss of coverage under Medicare Part D and the volatility seen in the domestic credit markets, we are not able to anticipate if wholesalers will continue their historical pattern of making purchases in the fourth quarter that exceed expected quarterly demands. If wholesalers do not repeat this pattern of purchasing quantities of MUSE that exceed quarterly demands, revenues from the sale of MUSE in 2007 may be lower as compared to 2006.

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 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 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 developing. Such developments could render our products less competitive or possibly obsolete. We are also competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited experience.

Current anti-obesity products include Xenical (orlistat), marketed by Roche, and Meridia (sibutramine), marketed by Abbott Labs. Orlistat is marketed in the United States by Roche Laboratories, Inc. under the brand name Xenical. Orlistat works by inhibiting lipase, an enzyme that blocks the absorption of fat in the gastrointestinal tract. In 2006, Xenical accounted for approximately $93 million in sales, in the United States, according to IMS Health. Orlistat launched over-the-counter in the United States by GlaxoSmithKline under the brand name Alli, in June 2007. Phentermine is the largest selling anti-obesity therapeutic and is available in several generic forms. Topamax, marketed by Johnson and Johnson, is not approved for the treatment of obesity but analysts estimate Topamax is extensively used for this indication in an off-label manner.

Despite the large market opportunity for anti-obesity agents, there are relatively few competitive products in late stage clinical development. Rimonabant, which has been developed by Sanofi-Aventis under the U.S. brand name Zimulti and in Europe as Acomplia, is the most advanced. It has been approved in certain countries outside of the United States. Rimonabant is the first in a new class of anti-obesity drugs that work as antagonists at the cannabinoid type 1, or CB-1, receptor. This is the same receptor that is stimulated by cannabis. While rimonabant has shown efficacy (average 4.7kg or 4.85%) across several large Phase 3 clinical trials at the highest dose tested, it has also been associated with significant CNS side effects, including depression and related symptoms, according to a 2006 report published in Drugs. The overall risk-to-benefit profile of rimonabant is yet to be defined. In June 2007, an FDA panel unanimously rejected Sanofi-Aventis' U.S. Rimonabant product, Zimulti, on concerns the drug increases the number of psychiatric events like depression and suicidal thinking among users. Later that month, Sanofi-Aventis announced plans to withdraw its application with the FDA and to resubmit its request at a future date. Analysts had estimated that peak sales of Acomplia for obesity could exceed $3.0 billion.

All of these drugs are 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 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 product candidate.

Other products are also in mid to late stage development which could become successful competitors against our obesity product candidate, Qnexa. These include products being developed by Pfizer, Arena Pharmaceuticals, Inc., Amylin Pharmaceuticals, Inc., Alizyme plc, Merck & Co., Inc., and Orexigen Therapeutics, Inc., among others. With the exception of Orexigen Therapeutics, Inc., most of these efforts are directed toward a monotherapeutic approach which we would expect to be subject to the same early weight loss plateau typically seen.

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

Other treatments for erectile dysfunction 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.

Several companies are developing products that could compete with our product candidates for the treatment of FSD including: The Proctor & Gamble Company is developing Intrinsa, a testosterone patch for the treatment of HSDD; BioSante Pharmaceuticals, Inc. is developing forms of testosterone gels for HSDD and Palatin Technologies, Inc. is developing a nasal spray to treat FSD. None of these products has been approved by the FDA. In July 2006, the European Medicines Agency ("EMEA") 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 ("NHS") 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 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 product candidates.

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

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

Furthermore, our current supply of alprostadil is subject to periodic re-testing to ensure it continues to meet specifications. There can be no guarantees that our existing inventory of alprostadil will pass these re-testing procedures and continue to be usable material. There is a long lead-time for manufacturing alprostadil. A shortage in supply of alprostadil to be used in the manufacture of MUSE would have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

We rely on a single injection molding company, Medegen Medical Products, LLC ("Medegen"), for our supply of plastic applicator components. In turn, Medegen obtains its supply of resin, a key ingredient of the applicator, from a single source, Huntsman Corporation. There can be no assurance that we will be able to identify and qualify additional sources of plastic components or that Medegen will be able to identify and qualify additional sources of resin. We are required to receive FDA approval for new suppliers. Until we secure and qualify additional sources of plastic components, we are entirely dependent upon Medegen. If interruptions in this supply occur for any reason, including a decision by Medegen to discontinue manufacturing, labor disputes or a failure of Medegen to follow regulations, the manufacture and marketing of MUSE and other potential products could be delayed or prevented. An extended interruption in the supply of plastic components could have a material adverse effect on our business, financial condition or results of operations.

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 purchased two buildings with a total combined 90,000 square feet in Lakewood, New Jersey, which we previously leased, on December 22, 2005. This facility is used for our 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, technological changes or medical advancements could further diminish or eliminate the commercial viability of our product, the results of which could have a material effect on our business operations and results.

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

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

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

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

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

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

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 some other countries.

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

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

One of the active ingredients in Qnexa, phentermine is available as a generic. The other, topiramate, is subject to several patents, the first of which is set to expire in 2008. Based on the research we have completed to date, we have no reason to believe Qnexa would not be subject to reimbursement by third party payors. 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 from third party payors or the U.S. 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 product, Qnexa, if successfully developed, could be particularly subject to price reduction initiatives because it is based on combinations of lower priced existing drugs.

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

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

We may face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products. The Medicare Prescription Drug Improvement and Modernization Act of 2003 contains provisions that may change U.S. importation laws and expand consumers' ability to import lower priced versions of our product candidates and competing products from Canada, where there are government price controls. These changes to U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs and drug manufacturing operations. For example, the loss of clinical trial data from completed or ongoing clinical trials for our 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 product candidates could be delayed.

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

Our 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 on-going 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 (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.

In addition, third parties 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.

A recent 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 recent 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 drug 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 and male and female sexual health among other products. Qnexa is our product candidate involving low doses of topiramate and phentermine. On June 6, 2006, U.S. Patent No. 7,056,890 B2 was issued by the USPTO. This patent contains composition, product, and other claims that should protect Qnexa as a proprietary product for the treatment of obesity. The term of this patent extends into 2019. The corresponding European patent with similar claims has been approved for grant. We are in the process of prosecuting patent applications in other countries as well, to obtain significant foreign patent coverage for both Qnexa and future generations of Qnexa. Furthermore, we have filed additional patent applications in the United States to expand the coverage that will be provided by the initial U.S. patent. 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 have worked closely with our patent counsel to put together a cogent patent strategy and are building a strong patent portfolio, ensuring exclusivity for many years to come.

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 and consultants. Nevertheless, employees, collaborators or consultants 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 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 not be able to develop or commercialize our product candidates due to intellectual property rights held by third parties.

If a third party holds a patent to a composition or method of use of an approved drug that is a component of one or more of our product candidates, we may not be able to develop or commercialize such product candidates without first obtaining a license to such patent, or waiting for the patent to expire. Our business will be harmed if we are unable to use the optimal formulation or methods of use of the component drugs that comprise our product candidates. This may occur because the formulations or methods of use are covered by one or more third party patents, and a license to such patents is unavailable or is available on terms that are unacceptable to us.

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 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 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 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.

Our capital resources are expected to continue to decline over the next several quarters as the result of spending on research and development projects, including clinical trials. On July 14, 2006, VIVUS, Inc. filed with the SEC a shelf Registration Statement on Form S-3. The shelf Registration Statement (File Number 333-135793) was declared effective by the SEC on August 16, 2006, providing us with the ability to offer and sell up to an aggregate of $80.0 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 November 17, 2006, we raised $33.6 million in a registered direct offering of our common stock pursuant to this shelf Registration Statement. Under the terms of this financing, we sold and issued a total of 6,750,000 shares of our common stock at a price of $3.50 per share in an initial closing and an additional 2,850,000 shares in a second closing on December 8, 2006. On May 10, 2006, we raised $12.0 million in a registered direct offering under an earlier shelf Registration Statement (File Number 333-121159) in which we sold and issued 3,669,725 shares our common stock to two institutional investors at a price of $3.27 per share.

On January 4, 2006, we obtained a $5.4 million loan from Crown Bank, N.A. (“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 this 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%. 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 of restricted cash, 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.

We expect that our existing capital resources combined with future anticipated cash flows will be sufficient to support our operating activities through 2008. 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 testing and clinical trials;
- patient recruitment and enrollment in planned and future clinical trials;
- the costs involved in seeking regulatory approvals for our product candidates;
- the costs involved in filing and pursuing patent applications, defending and enforcing patent claims;
- the establishment of collaborations and strategic alliances and the related costs;
- the cost of manufacturing and commercialization activities and arrangements;
- the results of operations;
- demand for MUSE;
- the cost, timing and outcome of regulatory reviews;

- the rate of technological advances;
- ongoing determinations of the potential commercial success of our products under development;
- the level of resources devoted to sales and marketing capabilities; and
- the activities of competitors.

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. We are continually evaluating our existing portfolio and we may choose to divest, sell or spin-off one or more of our products or product candidates at any time. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, 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 $180.2 million as of September 30, 2007 and we may continue to incur substantial operating losses for the future.

We have generated a cumulative net loss of $180.2 million for the period from our inception through September 30, 2007, and we anticipate losses in future years due to increased investment in our research and development programs. There can be no assurance that we will be able to achieve or maintain profitability or that we will be successful in the future.

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

As of December 31, 2006, we had approximately $125.7 million of net operating loss ("NOL") carryforwards with which to offset our future taxable income for federal income tax reporting purposes. We believe that we can use some of these NOLs to offset our federal tax liability related to the $150.0 million in payments received from K-V. 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.

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

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

Risks Relating to an Investment in our Common Stock

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

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

- the Phase 3 program for Qnexa;
- announcements of technological innovations or new products by us or our competitors;
- announcements by licensors of our technology;
- our ability to increase demand for our products in the United States and internationally;
- 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;
- comments by or changes in assessments of us or financial estimates by security analysts;
- adverse regulatory actions or decisions;
- any loss of key management;

- the results of our clinical trials or those of our competitors;
- developments or disputes concerning patents or other proprietary rights;
- 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 key employees, all of whom have been granted stock options.

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 that have often been unrelated or disproportionate to the operating performance of those companies. 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 VIVUS 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, 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 ("SFAS 123R"), *Share-Based Payment*, which requires that we record compensation expense in the statement of operations for share-based payments, such as employee stock options, using the fair value method. The adoption of this new standard is expected to continue to have a significant effect on our reported earnings, although it will not affect our cash flows, and could adversely impact our ability to provide accurate guidance on our future reported financial results due to the variability of the factors used to estimate the values of share-based payments. If factors change and we employ different assumptions or different valuation methods in the application of SFAS 123R in future periods, the compensation expense that we record under SFAS 123R may differ significantly from what we have recorded in the current period, which could negatively affect our stock price.

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ Global Market rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors' audit of that assessment 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.

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.

A. EXHIBITS:

EXHIBIT NUMBER	DESCRIPTION
2.1(1)†	Asset Purchase Agreement, by and among the Registrant and K-V Pharmaceutical Company, dated as of March 30, 2007.
3.1(2)	Amended and Restated Certificate of Incorporation of the Registrant.
3.2(3)	Amended and Restated Bylaws of the Registrant.
3.3(4)	Amended and Restated Certificate of Designation of the Registrant.
4.1(2)	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.
10.61(6)†	Termination and Release executed by Tanabe Holding America, Inc. dated May 1, 2007.
10.62(7)†	Master Services Agreement dated as of September 12, 2007 between the Registrant and Medpace, Inc.
10.63(8)†	Amendment Four to the Manufacturing Agreement by and between the Registrant and CHINOIN Pharmaceutical and Chemical Works Private Co. Ltd., effective as of December 31, 2006.
10.64(9)	VIVUS, Inc. Performance Incentive Plan Fiscal 2007.

31.1	Certification of Chief Executive Officer, dated November 9, 2007, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer, dated November 9, 2007, 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 Form 8-K filed with the Commission on May 21, 2007.

(2) 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.

(3) Incorporated by reference to Exhibit 3.1 filed with the Registrant's Form 8-K filed with the Commission on March 28, 2007.

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

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

(6) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form 8-K (File No. 001-33389) filed with the Commission on May 4, 2007.

(7) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form 8-K (File No. 001-33389) filed with the Commission on September 18, 2007.

(8) Incorporated by reference to Exhibit 10.60 filed with the Registrant's Registration Statement on Form 8-K (File No. 001-33389) filed with the Commission on May 8, 2007.

(9) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Registration Statement on Form 8-K (File No. 001-33389) filed with the Commission on April 26, 2007.

† Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

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

Date: November 9, 2007

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.

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† Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 31.1

CERTIFICATION

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

1. I have reviewed this quarterly report on Form 10-Q of VIVUS, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2007

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

Exhibit 31.2

CERTIFICATION

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

1. I have reviewed this quarterly report on Form 10-Q of VIVUS, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2007

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

Exhibit 32

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

I, Leland F. Wilson, President and Chief Executive Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended September 30, 2007 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: November 9, 2007

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

I, Timothy E. Morris, Vice President, Finance and Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended September 30, 2007 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: November 9, 2007

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