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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2006

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 ☒ 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 ☒ 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 ☒ No

At April 25, 2006, 44,641,591 shares of common stock were outstanding.

VIVUS, INC.

Quarterly Report on Form 10-Q

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

PART I: FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

VIVUS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	MARCH 31 2006 (UNAUDITED)	DECEMBER 31 2005*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,180	$ 22,236
Available-for-sale securities	7,850	4,770
Accounts receivable, net of allowance for doubtful accounts of $120 and $202 at March 31, 2006 and December 31, 2005, respectively	656	7,604
Inventories, net	4,710	4,504
Prepaid expenses and other assets	1,023	1,024
Total current assets	35,419	40,138
Property and equipment, net	9,022	9,144
Restricted cash	700	—
Total assets	$ 45,141	$ 49,282
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,298	$ 3,779
Product returns	2,406	3,016
Accrued research and clinical expenses	1,363	1,886
Accrued licensing fees	600	1,972
Accrued chargeback reserve	1,333	1,832
Accrued employee compensation and benefits	920	1,280
Income taxes payable	1,216	1,215
Accrued and other liabilities	2,396	1,589
Total current liabilities	13,532	16,569
Notes payable	10,785	5,164
Deferred revenue	2,532	948
Total liabilities	26,849	22,681
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; $1.00 par value; 5,000 shares authorized; no shares issued and outstanding at March 31, 2006 and December 31, 2005	—	—
Common stock; $.001 par value; 200,000 shares authorized; 44,642 shares issued and outstanding at March 31, 2006 and December 31, 2005	45	45
Additional paid-in capital	174,103	173,613
Accumulated other comprehensive loss	(3)	(30)
Accumulated deficit	(155,853)	(147,027)
Total stockholders' equity	18,292	26,601
Total liabilities and stockholders' equity	$ 45,141	$ 49,282

* Derived from audited consolidated financial statements filed in the Company's 2005 Annual Report on Form 10K.

See accompanying notes to condensed consolidated financial statements.

VIVUS, INC.

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

	THREE MONTHS ENDED	
	MARCH 31 2006 (UNAUDITED)	MARCH 31 2005 (UNAUDITED)
Revenue:		
United States product, net	$ 963	$ 396
International product	188	192
Other revenue	116	41
Total revenue	1,267	629
Operating expenses:		
Cost of goods sold and manufacturing	3,020	2,090
Research and development	3,560	4,265
Selling, general and administrative	3,672	3,221
Total operating expenses	10,252	9,576
Loss from operations	(8,985)	(8,947)
Interest and other income (expense):		
Interest income	327	192
Interest expense	(162)	(58)
Other expense	—	(11)
Loss before provision for income taxes	(8,820)	(8,824)
Provision for income taxes	(6)	(13)
Net loss	$ (8,826)	$ (8,837)
Other comprehensive loss:		
Unrealized gain (loss) on securities	27	(17)
Comprehensive loss	$ (8,799)	$ (8,854)
Net loss per share:		
Basic and diluted	$ (0.20)	$ (0.22)
Shares used in per share computation:		
Basic and diluted	44,642	39,380

See accompanying notes to condensed consolidated financial statements.

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	THREE MONTHS ENDED MARCH 31	
	2006 (UNAUDITED)	2005 (UNAUDITED)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (8,826)	$ (8,837)
Adjustments to reconcile net loss to net cash used for operating activities:		
Provision for doubtful accounts	(82)	(24)
Depreciation	271	475
Stock-based compensation expense	490	9
Loss on disposal of property and equipment	—	29
Changes in assets and liabilities:		
Accounts receivable	7,030	9,245
Inventories	(206)	(716)
Prepaid expenses and other assets	1	(6)
Accounts payable	(481)	139

Product returns	(610)	(321)
Accrued research, clinical and licensing fees	(1,895)	351
Accrued chargeback reserve	(499)	249
Accrued employee compensation and benefits	(360)	(369)
Accrued and other liabilities	2,391	(203)
Net cash (used in) provided by operating activities	(2,776)	21
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(148)	(11)
Restricted cash	(700)	—
Investment purchases	(4,953)	(191)
Proceeds from sale/maturity of securities	1,900	13,250
Net cash (used in) provided by investing activities	(3,901)	13,048
CASH FLOWS FROM FINANCING ACTIVITIES:		
Borrowing under note agreements	5,621	700
Exercise of common stock options	—	300
Proceeds from issuance of common stock	—	19,569
Net cash provided by financing activities	5,621	20,569
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(1,056)	33,638
CASH AND CASH EQUIVALENTS:		
Beginning of period	22,236	8,304
End of period	$ 21,180	$ 41,942
NON-CASH INVESTING ACTIVITIES:		
Unrealized gain (loss) on securities	$ 27	$ (17)

See accompanying notes to condensed consolidated financial statements.

VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2006

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the quarter ended March 31, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006. The unaudited financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2005, as filed on March 13, 2006 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.

2. STOCK-BASED COMPENSATION

On January 1, 2006, the Company adopted SFAS 123(revised 2004), *Share-Based Payment* (“SFAS 123(R)”), which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and directors, including employee stock options, restricted stock, and stock appreciation rights (SARS) based on estimated fair values. The Company adopted SFAS 123(R) using the modified prospective transition method, which requires application of the accounting standard as of January 1, 2006, the first day of fiscal year 2006. The Unaudited Condensed Consolidated Financial Statements as of and for the three months ended March 31, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, the Consolidated Financial Statements for prior periods have not been restated to reflect the impact of SFAS 123(R). Therefore, the results for the first quarter of fiscal 2006 are not directly comparable to the same period in the prior year.

On November 10, 2005, the FASB issued FASB Staff Position No. SFAS 123(R)-3, *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards*. The Company has elected to adopt the alternative transition method provided in this FASB Staff Position for calculating the tax effects of share-based compensation pursuant to SFAS 123(R). The alternative transition method includes a simplified method to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee share-based compensation, which is available to absorb tax deficiencies recognized subsequent to the adoption of SFAS 123(R).

Prior to the adoption of SFAS 123(R)

Prior to the adoption of SFAS 123(R), as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation*, (“SFAS 123”) and SFAS No. 148, *Accounting for Stock-Based Compensation – Transition and Disclosure*, the Company applied the existing accounting rules under APB Opinion No. 25, *Accounting for Stock Issued to Employee*s, (“APB 25”) which provided that no compensation expense was charged for options granted at an exercise price equal to the market value of the underlying common stock on the date of grant.

The following table illustrates the effect on net loss and net loss per share as if the Company had applied the fair value recognition provisions of SFAS 123 to awards granted under the Company’s stock-based compensation plans prior to the adoption. For purposes of this pro forma disclosure, the value of the

options was estimated using a Black-Scholes option-pricing model (Black-Scholes Model) and amortized on an accelerated basis over the requisite service period of the individual grants, which generally equals the vesting period. In the pro forma information for the periods prior to 2006, the Company accounted for forfeitures as they occurred. The disclosure for the first quarter of fiscal 2006 was not presented because stock-based awards were accounted for under SFAS 123(R)'s fair-value method during this period.

	Three months ended March 31, 2005
Net loss, as reported	$ (8,837)
Deduct total stock-based employee compensation expense determined under fair-value-based method for all rewards, net of tax	(323)
Pro forma net loss	$ (9,160)
Pro forma net loss per share:	
Basic and diluted	$ (0.23)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for grants in the first quarter of 2005: no dividend yield, expected volatility of 49%, risk-free interest rate of 3.77% and an expected life of 5 years.

Total estimated share-based compensation expense, related to all of the Company's share-based awards, recognized for the three months ended March 31, 2006 was comprised as follows (in thousands, except per share data):

	Three Months Ended March 31, 2006
Cost of goods sold and manufacturing	$ 99
Research and development	111
Selling, general and administrative	280
Share-based compensation expense before taxes	490
Related income tax benefits	—
Share-based compensation expense, net of taxes	$ 490
Net share-based compensation expense, per common share:	
Basic and diluted	$ 0.01

At March 31, 2006, a total of 4,600,654 stock options were outstanding under the Company's stock option plans. Stock-based compensation expense recognized for the first quarter of fiscal 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 in the first quarter of fiscal 2006 was $435,000 related to stock options and $55,000 related to the employee stock purchase plan, net of the estimated forfeitures.

As of March 31, 2006, unrecognized estimated compensation expense totalled $2.4 million related to non-vested stock options and $11,000 related to the employee stock purchase plan. The weighted average remaining requisite service period of the non-vested options was 1.5 years and the remaining requisite service period of the employee stock purchase plan was 1 month.

Valuation Assumptions

The fair value of stock options granted was estimated at March 31, 2006 using a Black-Scholes Model with the following weighted average assumptions:

	Three months ended March 31 2006
Expected life (in years)	6.22
Volatility	76.77%
Risk-free interest rate	4.82%
Dividend yield	0.00%

The fair value of each outstanding stock option award in prior years was estimated on the date of grant using a Black-Scholes Model. Assumptions used in the model for the prior year grants are described in the Company's Annual Report on Form 10-K.

Expected Term: The Company's expected term represents the period that the Company's 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 its contractual 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; options are non-transferable and non-hedgeable.

Expected Volatility: We estimated volatility using the historical share price performance over the expected life of the option. We also considered other factors such as our current clinical trials and other company activities that may affect volatility of our stock in the future but determined that at this time, the historical volatility was more indicative of our expected future stock performance. The range of expected volatility used in the Black-Scholes Model was 68% to 77%.

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. The risk-free interest rate used in the Black-Scholes Model was 4.82%.

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

3. CASH AND CASH EQUIVALENTS

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

4. INVENTORIES

Inventories are recorded net of reserves of $3.7 million and $3.8 million as of March 31, 2006 and December 31, 2005, respectively. Inventory balances, net of reserves, consist of (in thousands):

	MARCH 31, 2006	DECEMBER 31, 2005
Raw materials	$ 3,594	$ 3,666
Work in process	80	33
Finished goods	1,036	805
Inventory, net	$ 4,710	$ 4,504

As noted above, the Company has recorded significant reserves against the carrying value of its inventory of raw material and certain component parts. The reserves relate primarily to inventory that the Company previously estimated would not be used. In the fourth quarter of 2004, the Company determined that it would likely not use the fully reserved raw materials inventory in future production and, consequently, none of the reserved raw materials was used in either the first quarter 2005 or 2006. As of March 31, 2006 we do not intend to use any of the reserved raw materials in production. In the first quarter of 2005, the Company determined that it likely would continue to use some portion of the fully reserved component parts in production. The Company used $15,000 and $20,000 of its fully reserved component parts inventory during the first three months of 2006 and 2005, 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 $902,000 as of the end of the first three months of 2006, and we intend to continue to use this reserved component parts inventory in production when appropriate.

5. NOTES PAYABLE

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 erectile dysfunction compound that has completed Phase 2 clinical trials. The secured line of credit may be drawn upon quarterly and each quarterly borrowing has a 48-month term and bears interest at the annual rate of 2%. There are no financial covenants associated with this secured line of credit. Under certain conditions, at the Company's option, payments on this secured line of credit may be made, in whole or in part, in common stock. As of March 31, 2006, we had long-term notes payable to Tanabe of $5.5 million, and $3.0 million of available credit under this agreement. All the assets of the Company, except land and buildings, and restricted cash of $700,000 serve as collateral for this line of credit.

The amount of each quarterly borrowing and its due date are (in thousands):

Date of Note	Amount of Note	Due Date
March 31, 2004	$ 315	March 31, 2008
June 30, 2004	883	June 30, 2008
September 30, 2004	1,007	September 30, 2008
December 31, 2004	1,034	December 31, 2008
March 31, 2005	700	March 31, 2009
June 30, 2005	417	June 30, 2009
September 30, 2005	573	September 30, 2009
December 31, 2005	235	December 31, 2009
March 31, 2006	370	March 31, 2010
Total	$ 5,534	

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, 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 will be fixed at 8.25%, which is the prime rate plus 1% at the time of funding and then will be 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 of $46,202 are payable monthly for the first 12 months 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 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 Agreements are secured by the Facility, assignment of rents and leases on the Facility, and a $700,000 Certificate of Deposit held by Crown, classified as restricted cash.

6. AGREEMENTS

During the first quarter of 2004, VIVUS initiated a Phase 2 clinical trial with avanafil, its 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 accrued through March 31, 2006, a $2.0 million license fee obligation to Tanabe. $1.4 million of this licensing fee was paid in March 2006, with the balance paid in April 2006. 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 and a subsidiary of Acrux under which it has agreed to develop and commercialize Testosterone MDTSâ (metered-dose transdermal spray) and Evamistä in the United States for various female health applications. Under the terms of the agreements, the Company 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. In particular, there will be a $1.0 million milestone payment due to Acrux upon the submission of a New Drug Application ("NDA") to the FDA for Evamist, which the Company anticipates filing in 2006. The Company expensed $0 and $375,000 of milestone and licensing fees under the terms of the agreements in the first quarter of 2006 and 2005, respectively.

The Company has entered into several agreements to license patented technologies that are essential to the development and production of the Company's transurethral products for the treatment of erectile dysfunction (ED). These agreements generally required milestone payments during the development period. In connection with these agreements, the Company is obligated to pay royalties on product sales covered by the license agreements (4% of United States and Canadian product sales and 3% of sales elsewhere in the world).

International sales are transacted through distributors. The distribution agreements include certain milestone payments from the distributors to the Company upon achieving established sales thresholds.

7. NET LOSS PER SHARE

Net 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 loss per share is based on the weighted average number of common shares outstanding during the period. Diluted 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. Potentially dilutive options outstanding of 134,616 and 230,219 at March 31, 2006 and 2005, respectively, are excluded from the computation of diluted EPS for the first quarter of 2006 and 2005 because the effect would have been anti-dilutive.

8. STOCK OPTION AND PURCHASE PLANS

Stock Option Plan

Under the 2001 Stock Option Plan, or the 2001 Plan, which was approved by the stockholders at the annual meeting held on June 5, 2002, the Company may grant incentive or non-statutory stock options or stock purchase rights, or SPRs. The maximum aggregate number of shares that may be optioned and sold under the 2001 Plan is 1,000,000 shares plus (a) any shares that have been reserved but not issued under the Company's 1991 Incentive Stock Option Plan, or the 1991 Plan; (b) any shares returned to the 1991 Plan as a result of termination of options or repurchase of shares issued under the 1991 Plan; and (c) an annual increase to be added on the first day of the Company's fiscal year beginning 2003, equal to the lesser of (i) 1,000,000 shares, (ii) 2.5% of the outstanding shares on such date, or (iii) a lesser amount determined by the Board. The 2001 Plan allows the Company to grant incentive stock options to employees at not less than 100% of the fair market value of the stock (110% of fair market value for individuals who control more than 10% of the Company stock) at the date of grant, as determined by the Board of Directors. The 2001 Plan allows the Company to grant non-statutory stock options to employees, directors and consultants at a price to be determined by the Board of Directors. The term of the option is determined by the Board of Directors on the date of grant but shall not be longer than ten years. The 2001 Plan allows the Company to grant SPRs to employees and consultants. Sales of stock under SPRs are made pursuant to restricted stock purchase agreements containing provisions established by the Board of Directors. The Company has a right, but not the obligation, to repurchase the shares at the original sale price, which expires at a rate to be determined by the Board of Directors. As of March 31, 2006, no SPRs have been granted under the 2001 Plan.

Under the 2001 Plan, non-employee directors will receive an option to purchase 32,000 shares of common stock when they join the Board of Directors. These options vest 25% after one year and 25% annually thereafter. Each non-employee director shall automatically receive an option to purchase 8,000 shares of the Company's common stock annually upon his or her re-election and these options are fully exercisable ratably over eight months. Non-employee directors are also eligible to receive additional stock option grants.

Details of option activity under these plans are as follows:

	Three Months Ended			
	March 31, 2006		March 31, 2005	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	4,404,664	$ 4.31	4,114,785	$ 4.56
Granted	368,435	$ 3.14	407,813	$ 4.15
Exercised	—	$ —	(96,625)	$ 3.11
Cancelled	(172,445)	$ 3.75	(434,555)	$ 5.50
Outstanding at end of period	4,600,654	$ 4.24	3,991,418	$ 4.45
Options exercisable at end of period	2,994,228		2,878,454	
Weighted average fair value of options granted		$ 2.21		$ 2.34

At March 31, 2006, stock options were outstanding and exercisable as follows:

Options Outstanding				Options Exercisable	
Range of Exercise Prices	Number Outstanding at March 31, 2006	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number Exercisable March 31, 2006	Weighted-Average Exercise Price
$2.00 – $3.73	1,788,669	6.7 years	$ 3.15	829,586	$ 2.80
$3.75 – $4.58	1,871,211	6.4 years	$ 4.18	1,360,377	$ 4.14
$4.59 – $8.08	940,774	5.9 years	$ 6.45	804,265	$ 6.58
$2.00 – $8.08	4,600,654	6.4 years	$ 4.24	2,994,228	$ 4.42

The aggregate intrinsic value of outstanding options as of March 31, 2006 was $533,000, of which $444,000 related to exercisable options.

At March 31, 2006, 1,347,807 options remain available for grant. Options under these plans generally vest over four years, and all options expire after ten years.

Stock Purchase Plan

Under the 1994 Employee Stock Purchase Plan, or the Stock Purchase Plan, the Company reserved 800,000 shares of common stock for issuance to employees pursuant to the Stock Purchase Plan, under which eligible employees may authorize payroll deductions of up to 10% of their base compensation (as defined) to purchase common stock at a price equal to 85% of the lower of the fair market value as of the beginning or the end of the offering period.

At the annual meeting held on June 4, 2003, the stockholders approved amendments to the Stock Purchase Plan to (i) extend the original term of the Stock Purchase Plan by an additional 10 years such that the Stock Purchase Plan will now expire in April 2014 (subject to earlier termination as described in the Stock Purchase Plan) and (ii) increase the number of shares of Common Stock reserved for issuance under the Stock Purchase Plan by 600,000 shares to a new total of 1,400,000 (collectively referred to herein as the 1994 Purchase Plan Amendments).

As of March 31, 2006, 920,754 shares have been issued to employees and there are 479,246 available for issuance under the Stock Purchase Plan.

9. COMMITMENTS AND CONTINGENCIES

The Company purchased its previously leased manufacturing facilities in Lakewood, New Jersey on December 22, 2005. In January 2000, the Company entered into a seven-year lease for its corporate headquarters in Mountain View, California, which expires in January 2007. The Company intends to seek appropriate facilities to house its corporate headquarters and will enter into a long-term lease under acceptable terms.

In November 2002, the Company entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. The Company's remaining commitment under this agreement is to purchase a minimum total of $2.3 million of product from 2006 through 2008. There were no purchases made from this supplier in the first three months of 2006.

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. In 2005, the Company purchased $240,000 of product and in the first three months of 2006, there were no purchases from this supplier. Per the terms of the amended agreement, the Company will be required to purchase a minimum total of $1.5 million of additional product from 2006 through 2008.

The Company provides for costs related to contingencies when a loss is probable and the amount is reasonably estimable. In the first quarter of 2006, the Company recorded a $762,000 loss contingency related to a purchase commitment of alprostadil, considered to be in excess of production needs, that it expects to receive in the second quarter of 2006.

10. CONCENTRATION OF CUSTOMERS AND SUPPLIERS

During the first three months of 2006 and 2005, sales to significant customers as a percentage of total revenues were as follows:

	2006	2005
Customer A	43%	2%
Customer B	1%	46%
Customer C	20%	23%
Customer D	12%	13%

The Company did not have any suppliers making up more than 10% of operating costs.

11. RESEARCH AND DEVELOPMENT

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

12. EQUITY TRANSACTIONS

On January 7, 2005, the Securities and Exchange Commission declared effective the shelf Registration Statement the Company filed on Form S-3 on December 22, 2004. The shelf Registration Statement (File Number 333-12159) allows the Company to offer and sell up to an aggregate of $50 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, the Company filed a prospectus supplement with the Securities and Exchange Commission relating to an underwritten public offering of 7,500,000 shares of common stock under the existing shelf Registration Statement (File Number 333-12159) 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.

There were no equity transactions entered into by the Company during the quarter ended March 31, 2006.

13. 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 three months of 2006 and 2005, we paid $73,000 and $31,000, respectively, to Wilson Sonsini Goodrich & Rosati.

14. 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 has received notice from a former employee seeking payment due to their termination in 2005. The Company believes the employee has no claim to additional compensation and it will seek to conclude this matter without a material impact on its financial position. The Company is not aware of any asserted or unasserted claims against it where an unfavorable resolution would have an adverse material impact on the operations or financial position of the Company.

ITEM 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 regulations; (8) the safety and effectiveness of our clinical candidates; (9) the timing of our clinical trials and filings with the United States Food and Drug Administration; and (10) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, including those set forth in this filing as "Risk Factors Affecting Operations and Future Results."

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the quarter ended March 31, 2006 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 an emerging pharmaceutical company focused on the research, development and commercialization of products to restore sexual function in women and men. Our product pipeline includes four clinical stage product candidates, each of which targets an estimated existing or potential market in excess of $1 billion annually. Evamist™, is our product candidate to alleviate symptoms associated with menopause and recently completed the treatment stage of Phase 3 trials. Avanafil, which completed Phase 2 trials, is our phosphodiesterase type 5, or PDE5, inhibitor product candidate for the treatment of erectile dysfunction. ALISTA™, currently in Phase 2B trials, is our product candidate for the treatment of female sexual arousal disorder (FSAD). Testosterone MDTS®, which completed a positive Phase 2 trial, is our product candidate to treat hypoactive sexual desire disorder (HSDD).

In 1997, we launched MUSE® (alprostadil) in the United States and, together with our partners in 1998, internationally. We market MUSE as a prescription product for the treatment of erectile dysfunction. For international markets, we have entered into supply and distribution agreements with established pharmaceutical companies to market and distribute MUSE in various foreign countries.

Year to Date 2006 Update

Highlights year to date include:

- Grant of Key Patent for MDTS® Delivery System – An additional patent relating to the Metered Dose Transdermal Spray (MDTS®) was granted by the U.S. Patent and Trademark Office to Acrux (ASX: ACR). This patent, which expires July 31, 2022, provides protection for the MDTS applicator, which is currently used in two of VIVUS' women's health products under clinical development: Testosterone MDTS® for the treatment of decreased libido; and Evamist™ (Estradiol MDTS®) for the treatment of menopausal symptoms. VIVUS licensed the U.S. rights to these products from Acrux in 2004.

- Purchase of Manufacturing Facility – In January 2006, VIVUS finalized the purchase of land and buildings previously leased by VIVUS by entering into a mortgage note agreement with Crown Bank, N.A. of New Jersey. In December 2005, VIVUS purchased the land and buildings for $7.1 million funded by $3.3 million, which had previously been classified as restricted cash, and the remainder from its general cash account. In January 2006, VIVUS received proceeds from the mortgage note of $5.4 million. Together, the note and the previously restricted cash allowed VIVUS to purchase the facility with no additional out-of-pocket cash.

- Receipt of Milestone Payment from European Distributor – In January 2006, VIVUS received a milestone payment from its European distributor, MEDA AB of $2 million. The milestone payment provides MEDA with the right to continue to sell and distribute MUSE in its European territories. VIVUS and MEDA entered into a ten-year distribution agreement in 2002. In September of 2005, MEDA finalized its acquisition of the German pharmaceutical group Viatris. This acquisition significantly strengthened their sales and marketing capabilities in the major European markets.

Our Product Pipeline

We currently have four research and development programs targeting female and male sexual health:

Product	Indication	Status	Patent Expiry and Number
Evamist (Estradiol-MDTS)	Menopausal symptoms	Phase 3 completed	2017 (US 6,818,226)
ALISTA (topical alprostadil)	Female sexual arousal disorder (FSAD)	Phase 2B ongoing	2017 (US 5,877,216)
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)

Female Sexual Health

We believe the market for the treatment of female sexual health is large and underserved. Issues related to female sexual health include sexual disorders, such as FSAD and HSDD, as well as vasomotor symptoms associated with menopause. A paper published in the *Journal of the American Medical Association* in 1999 noted that 43% of women between the ages of 18 and 59 identified themselves as afflicted with a sexual disorder, reporting female sexual arousal disorder and hypoactive sexual desire disorder as the two most common conditions of female sexual dysfunction, or FSD. Currently, there are no pharmaceutical treatments on the market that have been approved by the United States Food and Drug Administration, or the FDA, for the treatment of these sexual disorders in women.

Evamist

Menopausal Vasomotor Symptoms

Vasomotor symptoms such as hot flashes and vaginal atrophy are reported to be among the most common medical complaints of women going through menopause. Each year an estimated 1.5 million women in the United States enter menopause. As many as 75% of menopausal women experience vasomotor symptoms at some time during menopause, although the frequency and severity may vary. The cause of vasomotor symptoms is related to a decrease in estrogen production by the ovaries that accompanies menopause. As a result, temperature regulation is altered, resulting in increased vasodilation of skin blood vessels and feelings of hot flashes and sweating. Estrogen and estradiol products are generally considered to be highly effective treatments for menopausal vasomotor symptoms. Sales of estrogen products in the United States in 2005 were estimated to be $1.5 billion.

Premarin®, an oral preparation of conjugated equine estrogens, is the most widely prescribed estrogen therapy in the United States. In 2004, a long-term, large-scale study that evaluated the effects of Premarin was terminated by the National Institutes of Health. This study, called the Women's Health Initiative (WHI), demonstrated an increase in the number of strokes and deep vein thromboses in women receiving Premarin as compared to placebo. This finding may be explained by previously published studies, which showed that when given orally, conjugated equine estrogens are associated with potentially deleterious changes in triglycerides, inflammatory mediators, and certain clotting factors. We believe that these changes may be the result of the liver's metabolism of oral conjugated equine estrogens.

In contrast to orally administered conjugated estrogens, the use of transdermal estradiol, which avoids first pass metabolism by the liver, has been shown in studies to result in little or no significant changes in triglycerides, inflammatory mediators or clotting factors. Therefore, we believe transdermal estradiol may offer a safer means of treating vasomotor symptoms associated with menopause.

A recently published study, called the Nurses' Health Study involving over 120,000 women, suggested that initiating hormone therapy at the onset of menopause resulted in an approximate 30% reduction in the risk of coronary heart disease compared to women who never used hormones. These results support that early initiation of hormone therapy in relation to the onset of menopause might have a positive influence on reducing the risk of coronary heart disease in women.

Our Clinical Candidate

Evamist is our patented estradiol spray being developed for the treatment of vasomotor symptoms associated with menopause. Evamist uses our proprietary, metered-dose transdermal spray, or MDTS, applicator that delivers a precise amount of estradiol to the skin. We believe that the MDTS technology has significant advantages over patches and gels. The applied dose dries in approximately 60 seconds. It is not messy. It is easy to apply and becomes invisible. We licensed the U.S. rights for this product from Acrux Limited ("Acrux") in 2004. Acrux's studies have demonstrated that the Estradiol-MDTS system delivers sustained levels of estradiol in women over a 24-hour period. We have also completed various additional studies with Evamist to measure the effects of washing, transfer and the application of sunscreen.

Clinical Status

In December 2004, we initiated our Phase 3 study of Evamist in the United States to evaluate its safety and efficacy in menopausal women suffering from vasomotor symptoms. We received a Special Protocol Assessment (SPA) from the FDA, which is an official agreement that documents the agreed upon terms and conditions under which we will conduct and analyze the data from our Phase 3 trial. The primary endpoint is to assess the decrease in the frequency and severity of hot flashes at 4 and 12 weeks of treatment. In September 2005, we completed enrollment for this trial. In March 2006, the final subject completed the last visit. Results from this study are expected to be available in the second quarter of 2006. Assuming favorable study results, we anticipate submitting the New Drug Application (NDA) for Evamist mid year 2006.

ALISTA

Female Sexual Arousal Disorder

FSAD, the persistent or recurrent inability to attain or maintain sufficient sexual excitement resulting in personal distress, has been reported to occur in 20% to 25% of women suffering from FSD. Sexual arousal in females involves vasodilation, or increased genital blood flow, which results in increased clitoral sensation and vaginal lubrication. Reduced vasodilation and lubrication resulting from atherosclerosis, diabetes and advancing age as well as surgeries such as hysterectomies can deleteriously affect a woman's ability to become sexually aroused.

There are no FDA-approved medical treatments for FSAD.

Our Clinical Candidate

ALISTA is a patented formulation of alprostadil that is intended for topical application to the female genitalia prior to sexual activity as an on-demand treatment for FSAD. ALISTA has been designed to increase blood flow in the genital region, allowing for greater sensitivity and sexual arousal. These positive effects have been observed as early as 5 to 15 minutes after application of ALISTA and may last up to two hours.

The active ingredient in ALISTA, alprostadil, is a synthetic version of a naturally occurring molecule found in humans. Alprostadil has been approved by the FDA for other indications, including erectile dysfunction in men. We believe the combination of alprostadil's ability to achieve vasodilation in genital tissues, its long-standing safety record, and short half-life makes it an ideal agent for the treatment of FSAD.

Clinical Status

We have completed three double-blind, randomized, placebo-controlled Phase 2 studies of ALISTA, all of which demonstrated statistically significant increases in arousal and/or satisfying sexual encounters in pre- and post-menopausal women with FSAD. One of these studies was a double-blind, placebo-controlled, crossover-design trial to evaluate the response to ALISTA administered at home by 51 women. The study showed that 64 percent of ALISTA doses resulted in Satisfactory Sexual Events (SSEs) and the use of ALISTA also resulted in significant improvement in orgasm. This was the first trial that evaluated the use of ALISTA in premenopausal women in the home setting. No serious adverse events were reported during this study.

We initiated a clinical trial of ALISTA in 2004 in post-menopausal women with FSAD. In mid 2004 the FDA revised the guidance on the endpoints necessary for approval of products to treat FSAD. The primary endpoint of the current study is the increase in the number of SSEs per month during the 24-week treatment period relative to the initial 8-week baseline period. The trial will also measure changes in arousal and distress associated with the patients' FSAD; however the trial was not designed for co-primary endpoints. Over 300 women who have undergone a hysterectomy and who have been diagnosed with FSAD were enrolled at 45 centers throughout the United States. In December 2005, we announced that we had completed enrollment in this multi-center, randomized, double-blind, placebo-controlled Phase 2B study. Patients are expected to complete the trial late in the third quarter of 2006. Pending completion of the study the data will be compiled and analyzed, and the results announced before the end of 2006. Our development plan for ALISTA calls for subsequent large-scale confirmatory studies following completion of the current clinical trial. For regulatory approval, the FDA now requires co-primary endpoints that must include statistically significant increases in both the number of SSEs and improvement in the self-assessed level of sexual arousal using validated questionnaires.

Testosterone MDTS

Hypoactive Sexual Desire Disorder

Hypoactive sexual desire disorder, 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.

Double-blind, multicenter, placebo-controlled clinical trials conducted by The Procter & Gamble Company to assess the effects of 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 demonstrated that transdermally applied testosterone has the ability to improve sexual desire in pre-menopausal women with HSDD.

Our Clinical Candidate

Testosterone MDTS is our patent protected, transdermal product for the treatment of HSDD in women. The active ingredient in Testosterone MDTS is the synthetic version of the testosterone that is present naturally in women and men.

Testosterone MDTS 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 Limited 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' studies have demonstrated that the Testosterone MDTS system delivers sustained levels of testosterone in women over a 24-hour period, achieves efficacy in increasing the number of satisfying sexual events, and results in substantially lower rates of application site skin irritation than reported in women using testosterone patches.

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

Clinical Status

In February 2005, we announced along with Acrux, positive Phase 2 results for Testosterone MDTS, which showed a statistically significant improvement in the number of satisfying sexual events in pre-menopausal patients with hypoactive sexual desire disorder.

Earlier clinical trials to assess the MDTS technology were conducted by Acrux. These studies demonstrated that application of Testosterone MDTS to the skin resulted in absorption of predictable amounts of testosterone. The amount absorbed was comparable to that absorbed on a daily basis from the Procter and Gamble transdermal testosterone patch that was shown in Phase 3 trials to improve sexual desire in women with HSDD.

We have met with the FDA to share results from our Phase 2 clinical study and to discuss the Phase 3 study requirements for obtaining approval for this indication. Although final Phase 3 protocols have not been agreed upon, the FDA provided guidance to us on the size of and endpoints for the Phase 3 program. Based on the meetings and the discussions with the FDA, we intend to complete the design of the Phase 3 safety and efficacy studies for the use of Testosterone MDTS to treat HSDD over the next several months. We intend to submit our Phase 3 safety and efficacy protocol under a Special Protocol Assessment (SPA) in the second quarter of 2006.

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 (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 2005 of PDE5 inhibitor products for ED were in excess of $2.7 billion, including approximately $1.6 billion in sales of Viagra, approximately $747 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

We are developing avanafil, an orally administered PDE5 inhibitor, 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 currently approved PDE5 inhibitors; and
- is fast-acting.

While PDE5 inhibitors currently on the market are often effective in treating ED, newer drugs that possess better specificity for the PDE5 enzyme may be safer. In addition to PDE5, there are at least ten other types of PDE enzymes in the human body. Drugs that inhibit more than one of these enzymes can potentially cause significant adverse effects, depending on the enzymes that are affected. In an in vitro study conducted by Tanabe comparing the activity of avanafil, sildenafil, tadalafil and vardenafil against all 11 of the known PDE enzymes, Tanabe found that avanafil demonstrated the best specificity for PDE5, with little activity against the other enzymes.

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. In general, the shorter the half-life, the less potential there is for the drug to interact with other drugs that may also be in the bloodstream. All approved PDE5 inhibitors are required by the FDA to include warnings against taking nitrates after administration. For example, Cialis's label warns patients not to take nitrates within 48 hours of administration. Approximately 5.5 million men take nitrates on a regular basis for angina pectoris and another half million annually will experience a heart attack and are potential candidates for emergency nitrate therapy. Sildenafil and vardenafil possess plasma half-lives of approximately four

hours, and tadalafil has an extended half-life of 17 to 18 hours. The plasma half-life of avanafil, however, is approximately 90 minutes, which means that it is removed from the bloodstream faster than the other currently available PDE5 inhibitors. We believe avanafil's short half-life, high specificity and fast onset of action are ideal characteristics for an on-demand treatment for 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.

In June 2005, we 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.

In May 2005, we 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.

In April 2005, 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) were announced. Results revealed that avanafil had less impact on blood pressure and heart rate than Viagra.

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 will be completing several non-clinical and one clinical Phase 1 study prior to the initiation of Phase 3. In addition, it is our intention to request a Special Protocol Assessment for our Phase 3 protocol from the FDA.

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.

MUSE is designed to overcome the limitations of other available therapies through its unique product attributes. 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. Because it mimics the normal vasoactive process, MUSE produces an erection that is more natural than those resulting from needle injection therapy, vacuum constriction devices or penile implants. Over 11 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 without the use of erectogenic agents.

Other Programs

We have licensed and intend to continue to license from third parties the rights to other products to treat various sexual and nonsexual disorders. We also sponsor early stage clinical trials at various research institutions. 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. At the present time one of these products, outside the area of sexual dysfunction, is being considered for further development. Initial development plans include working with the FDA on the design of additional studies, prosecuting filed and pending patents and developing a formulation. Depending on the outcome of these activities we may allocate certain resources towards this program. However there can be no assurance that we will be successful with any or all of these activities or that we will pursue the development of this program at all.

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 on going basis, we evaluate our estimates, including those related to product returns, rebates and sales reserves, research and development expenses, doubtful accounts, income taxes, inventories and contingencies and litigation. 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 consolidated financial statements:

- Revenue Recognition: We recognize revenue when persuasive evidence of an arrangement exists, shipment has occurred, the sales price is fixed or determinable and collectibility is reasonably assured.

- Product Returns: We have estimated reserves for product returns from wholesalers, hospitals and pharmacies. We estimate our reserves by utilizing historical information and data obtained from external sources. We record reserves for anticipated returns of expired or damaged product in the United States. We follow this method since reasonably dependable estimates of product returns can be made based on historical experience. Revisions in returns estimates are charged to income in the period in which the facts that give rise to the revision become known. There is no right-of-return on product sold internationally subsequent to shipment; thus, no returns reserve is needed. We routinely assess our experience with product returns and adjust the reserves accordingly. For example, in the quarter ended June 30, 2005, we reduced our product returns reserve by $245,000 based on a decrease in historical returns experience. If actual product returns are greater than our estimates, additional reserves may be required.

- Rebates and Sales Reserves: We have estimated reserves for government chargebacks for goods purchased by certain Federal government organizations including the Veterans Administration, Medicaid rebates to states for goods purchased by patients covered by Medicaid, other rebate programs and cash discounts for prompt payment. We estimate our reserves by utilizing historical information and data obtained from external sources. In estimating government chargeback reserves, we analyze actual chargeback amounts and apply historical chargeback rates to estimates of the quantity of units sold subject to chargebacks. Revisions to chargebacks estimates are charged to income in the period in which the facts that give rise to the revisions become known. We routinely reassess the chargeback estimates and adjust the reserves accordingly. Revisions to chargebacks estimates are charged to income in the period in which the facts that give rise to the revision become known. In estimating Medicaid and other rebates, the historical rebate percentage is used to estimate future rebates. Effective January 1, 2006, MUSE will no longer qualify for Medicaid reimbursement, which we do not believe will have a significant impact on our business. For qualified customers, we grant payment terms of 2%, net 30 days. Allowances for cash discounts are estimated based upon the amount of trade accounts receivable subject to the cash discounts. We routinely assess our experience with cash discounts, Medicaid and other rebates and government chargebacks and adjust the reserves accordingly. If actual government chargebacks, Medicaid rebates, rebate and cash discounts are greater than our estimates, additional reserves may be required.

- Research and Development Expenses: Research and development (R&D) expenses include license fees, related compensation, contractor fees, facilities costs, administrative expenses and clinical trials at other companies and research institutions under agreements which are generally cancelable, among other related R&D costs. All such costs are charged to R&D expense as incurred. We review and accrue clinical trials and other R&D expense based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of studies and other events. We follow this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical costs and other R&D expenses are subject to revisions as work progresses to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

- Allowance for Doubtful Accounts: We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances could be required.

- Income Taxes: We record a valuation allowance to reduce our deferred tax assets to the amount

that is more likely than not to be realized. For all periods presented, we have recorded a full valuation allowance against our net deferred tax asset. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the deferred tax asset would increase income in the period such determination was made. We have also recorded income taxes payable for estimated current tax liabilities. We monitor these estimated liabilities and adjust them as conditions warrant.

- Inventories: We record inventory reserves for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. During the quarter ended September 30, 1998, we established significant reserves against our inventory to align with new estimates of expected future demand for MUSE. VIVUS had built up its inventory level prior to and after the launch of Viagra and had not anticipated the impact that Viagra would have on the demand for MUSE. As of March 31, 2006, the remaining inventory reserve balance is $3.8 million relating to raw materials and components. Some portion of the fully reserved inventory was used in production in the first quarters of 2006 and 2005. In the fourth quarter of 2004, we stopped using the fully reserved raw materials inventory in production and determined that we would not likely use this inventory in future production. In the first quarter of 2005, we determined that we likely would continue to use some portion of the fully reserved component parts in production. To the extent that this fully reserved inventory was used in production in the first quarters of 2006 and 2005, 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 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 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 grant options to purchase our common stock to our employees and directors under our stock option plans. Eligible employees can also purchase shares of our common stock at 85% of the lower of the fair market value on the first or the last day of each six-month offering period under our employee stock purchase plans. The benefits provided under these plans are share-based payments subject to the provisions of revised Statement of Financial Accounting Standards No. 123 (“SFAS 123(R)”), *Share-Based Payment*. Effective January 1, 2006, we use the fair value method to apply the provisions of SFAS 123(R) with a modified prospective application which provides for certain

changes to the method for valuing share-based compensation. The valuation provisions of SFAS 123(R) apply to new awards and to awards that are outstanding on the effective date and subsequently modified or cancelled. Under the modified prospective application, prior periods are not revised for comparative purposes.

On November 10, 2005, the FASB issued FASB Staff Position No. SFAS 123(R)-3, Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards. The Company has elected to adopt the alternative transition method provided in this FASB Staff Position for calculating the tax effects of share-based compensation pursuant to SFAS 123R. The alternative transition method includes a simplified method to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee share-based compensation, which is available to absorb tax deficiencies recognized subsequent to the adoption of SFAS 123(R).

Prior to the adoption of SFAS 123(R)

Prior to the adoption of SFAS 123(R), as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation*, ("SFAS 123") and SFAS No. 148, *Accounting for Stock-Based Compensation – Transition and Disclosure,* the Company applied the existing accounting rules under APB Opinion No. 25, *Accounting for Stock Issued to Employees,* ("APB 25") which provided that no compensation expense was charged for options granted at an exercise price equal to the market value of the underlying common stock on the date of grant.

As of March 31, 2006, a total of 4,600,654 stock options were outstanding under the Company's stock option plans. Stock-based compensation expense recognized for the first quarter of fiscal 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 in the first quarter of fiscal 2006 was $435,000 related to stock options and $55,000 related to the employee stock purchase plan, net of the estimated forfeitures.

As of March 31, 2006, unrecognized estimated compensation expense totaled $2.4 million related to non-vested stock options and $11,000 related to the employee stock purchase plan. The weighted average remaining requisite service period of the non-vested options was 1.5 years and the remaining requisite service period of the employee stock purchase plan was 1 month.

Valuation Assumptions

The fair value of stock options granted was estimated at March 31, 2006 using a Black-Scholes Model with the following weighted average assumptions:

	Three months ended March 31 2006
Expected life (in years)	6.22
Volatility	76.77%
Risk-free interest rate	4.82%
Dividend yield	0.00%

Expected Term: The Company's expected term represents the period that the Company's 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; options are non-transferable and non-hedgeable.

Expected Volatility: We estimated volatility using the historical share price performance over the expected life of the option. We also considered other factors such as our current clinical trials and other company activities that may affect volatility of our stock in the future but determined that at this time, the historical volatility was more indicative of our expected future stock performance. The range of expected volatility used in the Black-Scholes Model in the first quarter of 2006 was 68% to 77%.

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

The determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends.

If factors change and we employ different assumptions in the application of SFAS 123(R) in future periods, the compensation expense that we record under SFAS 123(R) may differ significantly from what we have recorded in the current period. Therefore, we believe it is important for investors to be aware of the high degree of subjectivity involved when using option pricing models to estimate share-based compensation under SFAS 123(R). Option-pricing models were developed for use in estimating the value of traded options that have no vesting or hedging restrictions, are fully transferable and do not cause dilution. Because our share-based payments have characteristics significantly different from those of freely traded options, and because changes in the subjective input assumptions can materially affect our estimates of fair values, in our opinion, existing valuation models, including the Black-Scholes and lattice binomial models, may not provide reliable measures of the fair values of our share-based compensation. Consequently, there is a risk that our estimates of the fair values of our share-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, expiration, early termination or forfeiture of those share-based payments in the future. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared

to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, value may be realized from these instruments that is significantly in excess of the fair values originally estimated on the grant date and reported in our financial statements. There is currently no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust

the estimates to actual values. Although the fair value of employee share-based awards is determined in accordance with SFAS 123(R) and the Securities and Exchange Commission's Staff Accounting Bulletin No. 107 (SAB 107) using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

Estimates of share-based compensation expenses are significant to our financial statements, but these expenses are based on option valuation models and will never result in the payment of cash by us. For this reason, and because we do not view share-based compensation as related to our operational performance, we exclude estimated share-based compensation expense when evaluating the business performance of our operating segments.

The guidance in SFAS 123(R) and SAB 107 is relatively new, and best practices are not well established. The application of these principles may be subject to further interpretation and refinement over time. There are significant differences among valuation models, and there is a possibility that we will adopt different valuation models in the future. This may result in a lack of consistency in future periods and materially affect the fair value estimate of share-based payments. It may also result in a lack of comparability with other companies that use different models, methods and assumptions.

Theoretical valuation models and market-based methods are evolving and may result in lower or higher fair value estimates for share-based compensation. The timing, readiness, adoption, general acceptance, reliability and testing of these methods is uncertain. Sophisticated mathematical models may require voluminous historical information, modeling expertise, financial analyses, correlation analyses, integrated software and databases, consulting fees, customization and testing for adequacy of internal controls. Market-based methods are emerging that, if employed by us, may dilute our earnings per share and involve significant transaction fees and ongoing administrative expenses. The uncertainties and costs of these extensive valuation efforts may outweigh the benefits to investors.

Recent Accounting Pronouncements

In May 2005, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 154, *Accounting Changes and Error Corrections—A Replacement of APB Opinion No. 20 and FASB Statement No. 3*. SFAS 154 requires retrospective application to prior periods' financial statements for changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS 154 also requires that retrospective application of a change in accounting principle be limited to the direct effects of the change. Indirect effects of a change in accounting principle, such as a change in non-discretionary profit-sharing payments resulting from an accounting change, should be recognized in the period of the accounting change. SFAS 154 also requires that a change in depreciation, amortization, or depletion method for long-lived non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of this provision during the first quarter of 2006 did not have a material impact on our results of operations or financial condition.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*, an amendment of ARB No. 43, Chapter 4. This Statement is meant to eliminate any differences existing between the FASB standards and the standards issued by the International Accounting Standards Board by clarifying that any abnormal idle facility expense, freight, handling costs and spoilage be recognized as current-period charges. The adoption of this Statement by VIVUS in the first quarter of 2006 did not have a material impact on results of operations, financial position or cash flows as we had previously expensed a portion of our manufacturing overhead as period cost due to excess capacity.

RESULTS OF OPERATIONS

Three Months Ended March 31, 2006 and 2005

For the three months ended March 31, 2006, we reported a net loss of $8.8 million, or $0.20 net loss per share, as compared to a net loss of $8.8 million, or $0.22 net loss per share, during the same period in 2005. The net loss was similar in the first quarter 2006 as compared to 2005. Revenues were higher by $638,000 and operating expenses were higher by $676,000 in 2006. Contributing to the increase in operating expenses was $490,000 of stock compensation expense in the first quarter of 2006 from the adoption of SFAS 123(R). There was no corresponding expense in the first quarter of 2005.

We anticipate continued losses over the next several years 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

	(In thousands, except percentages) Three Months Ended March 31,		Increase/ (Decrease)	% Change
	2006	2005		
United States product, net	$ 963	$ 396	$ 567	143%
International product	188	192	(4)	(2)%
Other revenue	116	41	75	183%
Total revenues	$ 1,267	$ 629	$ 638	101%

Total revenue for the quarter ended March 31, 2006 was $1.3 million, compared to $629,000 for the quarter March 31, 2005. United States product revenue in the first quarter 2006 increased to $963,000 from $396,000 in 2005. International product revenue was $188,000 for the quarter ended March 31, 2006, compared to $192,000 in the same period last year. Other revenue increased by $75,000 to $116,000 in the first quarter of 2006 as compared to the first quarter of 2005.

The increase in United States product revenue included the impact of changes in reserves for government discounts, also known as chargebacks. In the quarter ended March 31, 2005, revenues were negatively impacted due to changes in the chargeback reserve to reflect the revised United States government pricing for purchases of MUSE. In the first quarter of 2006, the revenues were higher as compared to the same period last year due to refinements of the chargeback reserve based upon updated wholesaler inventory estimates of MUSE.

Similar to prior years, wholesalers made purchases in the fourth quarter of 2005 that were greater than demand, however the buy-in for 2005 was lower than the buy-in for 2004. Based on the fourth quarter 2005 demand for MUSE, we estimate purchases made by wholesalers in the fourth quarter of 2005 represented approximately four months of excess demand. We estimate that the inventory at the wholesale level has decreased since the beginning of 2006. U.S quarterly demand for MUSE, as measured by independent third-party prescription data and data from our distributors, has been consistent over the last five quarters, approaching 200,000 units per quarter. The increase in other revenue is primarily due to the amortization of a $2.0 milestone payment from our European Distributor, Meda AB, that we received in the first quarter of 2006.

Given the stabilization of demand and the strategic buying in the fourth quarter of 2005, we anticipate worldwide revenues of MUSE in 2006 will be similar to those seen in 2005.

Cost of goods sold and manufacturing.

	(In thousands, except percentages) Three Months Ended March 31,			
	2006	2005	Increase	% Change
Cost of goods sold and manufacturing	$ 3,020	$ 2,090	$ 930	44%

Cost of goods sold and manufacturing ("cost of goods sold") in the first quarter of 2006 increased $930,000, or 44%, to $3.0 million, as compared to $2.1 million for the first quarter of 2005. Cost of goods sold increased in the first quarter of 2006 as compared to the same period of 2005, primarily due to the recording of a loss contingency of $762,000 related to an alprostadil purchase commitment in excess of production needs and the recording of $99,000 of stock compensation expense as a result of the adoption of SFAS 123(R). There were no comparable charges in the first quarter of 2005.

We anticipate that cost of goods sold in 2006 will remain consistent with 2005 costs.

Research and development.

	(In thousands, except percentages) Three Months Ended March 31,			
	2006	2005	(Decrease)	% Change
Research and development	$ 3,560	$ 4,265	$ (705)	(17)%

Research and development expenses for the first quarter of 2006 were $3.6 million, as compared to $4.3 million for the three months ended March 31, 2005. Decreased clinical trial and project activity for Testosterone MDTS, Evamist, avanafil and ALISTA resulted in decreased spending for these projects of $1.5 million during the first quarter of 2006, as compared to the same period last year. This decrease was partially offset by an increase of $537,000 in other project expenses, outside the area of sexual dysfunction, and a $206,000 increase in other clinical spending in the first quarter of 2006, as compared to the quarter ended March 31, 2005.

We anticipate that our research and development expenses will decrease in 2006 as compared to 2005; however, based upon results of clinical trials or other new information, results of obtaining additional funding or as a result of entering into a collaborative arrangement, we may decide to increase research and development expenses at any time to pursue additional projects or studies. We do not expect to recognize revenue from sales of any new product candidates being developed through our research and development efforts for several years.

Selling, general and administrative.

	(In thousands, except percentages) Three Months Ended March 31,			
	2006	2005	Increase	% Change
Selling, general and administrative	$ 3,672	$ 3,221	$ 451	14%

Selling, general and administrative expenses in the three months ended March 31, 2006 of $3.7 million increased $451,000, or 14% as compared to the three months ended March 31, 2005. This increase is primarily due to $280,000 in additional stock compensation expense as a result of the adoption of SFAS 123(R) in the first quarter of 2006, an incremental increase in legal fees of $254,000, and $145,000 in additional product marketing and sales related expenses partially offset by a $189,000 decrease in accounting and audit fees expense, primarily related to compliance with the requirements of Sarbanes-Oxley, in the quarter ended March 31, 2006, as compared to the quarter ended March 31, 2005.

Interest income and expense.

Interest income for the quarter ended March 31, 2006 was $327,000, as compared to $192,000 for the quarter ended March 31, 2005. The increase is primarily due to an increase in our investment yields from the quarter ended March 31, 2005 as compared to the quarter ended March 31, 2006. Interest

expense for the quarter ended March 31, 2006 was $162,000 as compared to $58,000 during the same period last year. The increased interest expense is primarily due to the Crown Bank loan which was obtained on January 4, 2006 and a higher loan balance outstanding for the Tanabe loan.

LIQUIDITY AND CAPITAL RESOURCES

Cash. Unrestricted cash, cash equivalents and available-for-sale securities totaled $29.0 million at March 31, 2006, as compared to $27.0 million at December 31, 2005. The increase in cash, cash equivalents and available-for-sale securities of $2.0 million is the net result of the $5.4 million loan obtained from Crown Bank, N.A., the collection of amounts owed at December 31, 2005 from customers as measured by a decrease in accounts receivable offset by cash used in operations and investment activities for the quarter.

Since inception, we have financed operations primarily from the issuance of equity securities. Through March 31, 2006, we raised $174.1 million from financing activities and had an accumulated deficit of $155.9 million at March 31, 2006.

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 March 31, 2006 was $656,000, as compared to $7.6 million at December 31, 2005. The 91% decrease in the accounts receivable balance at March 31, 2006 is primarily due to the collection of 96% of the accounts receivable outstanding at December 31, 2005. Currently, we do not have any significant concerns related to accounts receivable or collections.

Liabilities. Total liabilities were $26.8 million at March 31, 2006, $4.2 million higher than at December 31, 2005. The change in total liabilities is primarily due to the $5.4 million loan received from Crown Bank on January 4, 2006.

We have entered into manufacturing agreements with suppliers to purchase raw materials. As of March 31, 2006, our remaining commitment under these agreements is to purchase a minimum of $3.8 million of product from 2006 through 2008. In the first quarter of 2006, the Company recorded a $762,000 loss contingency related to a purchase commitment of alprostadil that it expects to receive in the second quarter of 2006. Should our inventory of raw materials exceed our future production needs, it may be necessary to write-off any additional excess inventory.

Operating Activities. Our operating activities used $2.8 million and provided $21,000 of cash during the three months ended March 31, 2006 and 2005, respectively. During the first three months of 2006, our net operating loss of $8.8 million was offset by a $7.0 million reduction in our accounts receivable due to the collection of monies owed to us. During the first three months of 2005 our net operating loss of $8.8 million was offset by a $9.2 million reduction in our accounts receivable due to the collection of monies owed to us.

Investing Activities. Our investing activities used $3.9 million and provided $13.0 million in cash during the three months ended March 31, 2006 and 2005, 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 provided cash of $5.6 million and $20.6 million during the three months ended March 31, 2006 and 2005, respectively. In the first quarter of 2006, this is primarily due to the $5.3 million net proceeds from Crown Bank loan we entered into on January 4, 2006. In the quarter ended March 31, 2005, these amounts include the March 15, 2005 sale of 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 and proceeds from the exercise of stock options. In both the first three months of 2006 and 2005, these amounts also include borrowings under note arrangements.

In the first quarter of 2004, we signed an agreement for a line of credit with Tanabe, allowing us to borrow up to $8.5 million to be used for the development of avanafil. The secured line of credit may be drawn upon quarterly and each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of 2%. As of March 31, 2006, we had a long-term notes payable balance of $5.5 million and $3.0 million remaining available on the credit line. We borrowed an additional $370,000 under this credit line in the first three months of 2006 as compared to $700,000 in the quarter ended March 31, 2005.

On December 22, 2004, we filed a shelf registration statement on Form S-3 with the SEC, which allows us to offer and sell up to an aggregate of $50 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 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”), secured by the land and buildings, among other assets, located at our principal manufacturing facility and a $700,000 Certificate of Deposit held by Crown. The loan is payable over a 10-year term and the interest rate will be fixed at 8.25%, which is the prime rate plus 1% at the time of funding and then will be adjusted annually to a fixed rate for the year equal to the prime rate plus 1% with a floor of 7.5%.

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 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 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 clinical trails, 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 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 into 2007. However, we anticipate that we will 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. 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 will result in increased losses from operations. 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.

Overview of Contractual Obligations

		Payments Due by Fiscal Year (in thousands)			
Contractual Obligations	Total	2006 (9 months)	2007-2009	2010-2011	Thereafter
Operating Leases (1)	$ 612	$ 612	—	—	—
Purchases (2)	3,825	1,530	$ 2,295	—	—
Notes Payable (3)	10,895	80	5,547	$ 684	$ 4,584
Other Long Term Liabilities (4)	600	600	—	—	—
Total	$ 15,932	$ 2,822	$ 7,842	$ 684	$ 4,584

(1) We purchased our previously leased manufacturing facilities in Lakewood, New Jersey on December 22, 2005. In January 2000, we entered into a seven-year lease for our corporate headquarters in Mountain View, California, which expires in January 2007.

(2) In November 2002, we entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. Our remaining commitment under this agreement is to purchase a minimum total of $2.3 million of product from 2006 through 2008. In 2005 we purchased $765,000 of product. We did not purchase any product from this supplier in the first quarter of 2006.

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. In 2005 we purchased $240,000 of product. We did not purchase any product from this supplier in the first quarter of 2006.

(3) In the first quarter of 2004, we signed an agreement for a secured line of credit with Tanabe, allowing us to borrow up to $8.5 million to be used for the development of avanafil. The secured line of credit may be drawn upon quarterly and each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of 2%. There are no financial covenants associated with this secured line of credit. Under certain conditions, at the Company's option, payments on this secured line of credit may be made, in whole or in part, in common stock. As of March 31, 2006, we have $3.0 million of available credit under this agreement.

On January 4, 2006, we obtained a $5.4 million loan from Crown Bank, N.A. ("Crown"), secured by the land and buildings, among other assets, located at our principal manufacturing facility and a $700,000 Certificate of Deposit held by Crown. The loan is payable over a 10-year term and the interest rate will be fixed at 8.25%, which is the prime rate plus 1% at the time of funding and then will be adjusted annually to a fixed rate for the year equal to the prime rate plus 1% with a floor of 7.5%.

(4) Other Long Term Liabilities at December 31, 2005 includes $2.0 million for a licensing fee obligation, due under the terms of our 2001 Development, Licensing and Supply Agreement with Tanabe related to a Phase 2 clinical trial with avanafil initiated in the first quarter of 2004 and completed in 2005. We paid $1.4 million of this licensing fee in March 2006, with the $600,000 balance paid in April 2006.

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 March 31, 2006, 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 $5.4 million loan from Crown Bank, N.A. obtained on January 4, 2006. The loan is payable over a 10-year term and the interest rate will be fixed at 8.25%, which is the prime rate plus 1% at the time of funding and then will be adjusted annually to a fixed rate for the year equal to the prime rate plus 1% with a floor of 7.5%.

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), the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and the Company's Chief Financial Officer, of the effectiveness of the design and operation of the Company's 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. We have received notice from a former employee seeking payment due to their termination in 2005. We believe the employee has no claim to additional compensation and we will seek to conclude this matter without a material impact on our financial position. We believe that we have meritorious claims and defenses and intend to pursue any such matters vigorously. We are not aware of any 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 (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 early 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 was 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.

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

All of the drug candidates that we are currently developing require extensive pre-clinical and clinical testing before we can submit any application for regulatory approval. Before obtaining regulatory approvals for the commercial sale of any of our proposed drug products, we must demonstrate through pre-clinical testing and 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:

- inability to manufacture sufficient quantities of compounds for use in clinical trials;
- failure to receive approval by the United States Food and Drug Administration, or FDA, of our clinical trial protocols;
- changes in clinical trial protocols 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; or
- government or regulatory delays.

To date, the clinical results we have obtained do not necessarily predict that the results of further testing, including later 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.

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

We are, and in the future expect to be, dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of some of our drug candidates particularly after the Phase 2 stage of clinical testing. These arrangements may place the development of our drug candidates outside of our control, may require us to relinquish important rights, or may otherwise be on terms unfavorable to us.

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 drug 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 drug 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 drug 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 drug candidates.

We face significant governmental regulation during our product development activities.

The research, testing, manufacturing, selling and marketing of drug 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, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional pre-clinical trials and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. The FDA could determine that additional studies are required before and after a product candidate will be approved.

For example, in December 2004, an FDA advisory panel recommended against approval of a testosterone patch being developed by another company to address female sexual dysfunction, specifically hypoactive sexual desire disorder, and 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, or NDA. We are also developing a transdermal testosterone product candidate, Testosterone MDTS, 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. As a result, we could experience significant delays in our ability to submit our product candidate to the FDA for consideration, and we may be unsuccessful in obtaining FDA approval of our product candidate.

We are not permitted to market any of our 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 drug 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 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 which 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 drug 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 drug candidates is approved by the FDA or by another regulatory authority for a territory outside of the United States, we would 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 drug candidates. Potentially costly follow-up or 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 drug 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 drug candidates. We cannot predict the likelihood, nature or extent of adverse 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 drugs 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 products on a timely basis, if at all, and we may not be able to successfully commercialize these proposed products. 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 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. Rather, we rely on various third parties to manufacture these materials. There can be no assurance that we will be able to identify and qualify additional sources for clinical materials. If interruptions in this supply occur for any reason, including a decision by the third parties to discontinue manufacturing, labor disputes or a failure of the third parties to follow regulations, we may not be able to obtain regulatory approvals for our proposed products and may not be able to successfully commercialize these proposed products.

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 drug 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 cGMPs. 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 approval 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 supplier that produces the MUSE laminated foil has closed their 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 the supplier closed their business, the supplier produced a bulk-quantity of foil that, at this time, is expected to be sufficient to support MUSE production through the end of 2006. There can be no assurance that as this bulk supply is used over the next year there will be a sufficient yield in the final quantity of foil with acceptable quality to support MUSE demand through 2006. Although the foil supplier produced this bulk unprinted foil, the label printing will be done periodically during 2006. As a consequence, if there are unacceptable quality issues with the bulk foil, they may not be discovered until sometime in 2006. If such foil quality issues do occur, we may be unable to meet MUSE demand during 2006.

We have identified a new potential 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 European Medicines and Healthcare products Regulatory Agency approval. There can be no assurance that these qualifications and approvals will be successfully obtained, or that they will be obtained within the time needed to support MUSE demand before the supply of foil from our current vendor 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.

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 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.

Results from a single center study reported in mid-2005 show a potential benefit from the therapeutic use of MUSE following radical prostatectomy. MUSE is indicated for the treatment of erectile dysfunction caused by trauma including surgeries such as a radical prostatectomy. We are sponsoring clinical trials to study the effects of MUSE therapy following radical prostatectomy. We believe physicians are beginning to prescribe MUSE for use following radical prostatectomy. All promotional materials and efforts are subject to FDA review. If our promotional materials and efforts are altered, modified or halted by the FDA for any reason, future sales of MUSE could be negatively affected.

We must continue to monitor the use of our approved drugs 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, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. 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. The sales force actively participates in national urologic and sexual dysfunction forums and conferences, such as the American Urological Association annual and regional meetings and the International Society for Impotence Research. 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.

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. Consistent with the pharmaceutical industry, 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.

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. Several pharmaceutical companies are also actively engaged in the development of therapies for the treatment of erectile dysfunction and female sexual dysfunction. 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.

The most significant competitive therapy for MUSE is an oral medication marketed by Pfizer, Inc. under the name Viagraâ, which received regulatory approvals in the United States in March 1998 and in the European Union in September 1998. The commercial launch of Viagra in the United States in April 1998 significantly decreased demand for MUSE. In February 2003, a new oral medication under the name Cialisâ was launched in Europe by Lilly ICOS LLC and in Australia and New Zealand by Eli Lilly and Company alone. Lilly ICOS LLC launched Cialis in the United States in November 2003. Bayer AG and GlaxoSmithKline plc launched Levitraâ in the European Union and the United States in March and September 2003, respectively.

If our raw material suppliers fail to supply us with alprostadil, 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 Co., Ltd., in Hungary. We have manufacturing agreements with Chinoin and NeraPharm to produce additional quantities of alprostadil for us. We are currently in the process of investigating additional sources for our future alprostadil supplies. However, there can be no assurance that we will be able to identify and qualify additional suppliers of alprostadil in a timely manner, or at all.

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.

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 source could harm our business.

We rely on a single injection molding company, Medegen Medical Products, LLC, 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. 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 immediate 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, 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. While a large percentage of prescriptions in the United States for MUSE have been reimbursed 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. We are currently assessing the impact that this legislation will have on our business. However, historically the volume of MUSE sales to Medicaid and Medicare patients has not been 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 MUSE. A reduction or elimination in the reimbursement by the U.S. government would have a material adverse impact on our revenues and business operations.

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.

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 clinical trials could be delayed or disrupted indefinitely upon the occurrence of a natural disaster. For example, 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.

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 (USPTO) issued to Pfizer a method of use 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.

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 male and female sexual health among other products. 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 position, 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.

As is commonplace in the pharmaceutical industry, 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.

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 January 4, 2006, we obtained a $5.4 million loan from Crown Bank, N.A. (“Crown”), secured by the land and buildings, among other assets, located at our principal manufacturing facility and a $700,000 Certificate of Deposit held by Crown. The loan is payable over a 10-year term and the interest rate will be fixed at 8.25%, which is the prime rate plus 1% at the time of funding and then will be 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. 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.

We expect that our existing capital resources combined with future cash flows will be sufficient to support our operating activities into 2007. 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 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 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.

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 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 $155.9 million as of March 31, 2006 and expect to continue to incur substantial operating losses for the foreseeable future.

We have generated a cumulative net loss of $155.9 million for the period from our inception through March 31, 2006, and

we anticipate losses for the next several years due to increased investment in our research and development programs and limited revenues. There can be no assurance that we will be able to achieve profitability or that we will be successful in the future.

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:

- 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 materially 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 National 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 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 National 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.

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 123(R)”), *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 123(R) in future periods, the compensation expense that we record under SFAS 123(R) may differ significantly from what we have recorded in the current period, which could negatively affect our stock price and our stock price volatility.

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 National 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 Securities and Exchange Commission. 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
3 .2(2)	Amended and Restated Certificate of Incorporation of the Company
3 .3(1)	Bylaws of the Registrant, as amended
3 .4(3)	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock
4 .1(2)	Specimen Common Stock Certificate of the Registrant

EXHIBIT NUMBER	DESCRIPTION
4 .5(3)	Second Amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between the Registrant and Harris Trust Company of California, including the Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively
10.53A††	First Amendment and Waiver Manufacture and Supply Agreement, dated February 21, 2006 by and between the Company and NeraPharm spol, s.r.o.
31 .1	Certification of Chief Executive Officer, dated May 4, 2006, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
31 .2	Certification of Chief Financial Officer, dated May 4, 2006, 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

†† Confidential treatment requested.

(1) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 24, 1996.

(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 99.1 filed with Registrant's Amendment Number 2 to the Registration Statement of Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.

SIGNATURES

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

Date: May 4, 2006

VIVUS, Inc.

/s/ TIMOTHY E. MORRIS

Timothy E. Morris
Vice President, Finance and Chief Financial Officer

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

VIVUS, INC.

INDEX TO EXHIBITS

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†† Confidential treatment requested.

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

(2) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 25, 1996.

(3) Incorporated by reference to exhibit 99.1 filed with Registrant's Amendment Number 2 to the Registration Statement of Form 8-A (File No. 0-23490) filed with the Commission on April 23, 1997.

FIRST AMENDMENT AND WAIVER

MANUFACTURE AND SUPPLY AGREEMENT

EFFECTIVE FEBRUARY 13, 2006

This first amendment and waiver (the "**Amendment and Waiver**") to the Manufacture and Supply Agreement dated December 22, 2003 (the "**Original Agreement**"), by and between VIVUS, Inc., having a principal place of business at 1172 Castro Street, Mountain View, California 94040, United States of America ("**VIVUS**"), and NeraPharm spol., s.r.o., having a place of business at Ulice Prace 657, 277 11 Neratovice, Czech Republic ("**NeraPharm**") (each, a "**Party**" and collectively, the "**Parties**").

WHEREAS, Article 2 of the Original Agreement obligates NeraPharm to supply VIVUS specific amounts of the Product and VIVUS to purchase from NeraPharm minimum quantities of the Product;

WHEREAS FURTHER, given the failure by VIVUS to order minimum quantities of the Product during calendar year 2005 and the current market conditions for VIVUS' product, the Parties wish to amend the Original Agreement to provide that (i) VIVUS shall order the minimum quantity of the Product for calendar year 2005 (i.e., [***]) for delivery by NeraPharm on or before April 30, 2006 and (ii) the minimum quantity of the Product to be ordered by VIVUS in 2006 (i.e., [***]) shall be postponed until 2008, with such order and delivery occurring on or before December 31, 2008;

WHEREAS FURTHER, NeraPharm desires to waive any and all alleged past breaches of the Original Agreement by VIVUS (e.g., the minimum quantity purchase requirements and the forecasting requirements of Article 2 of the Original Agreement);

NOW, THEREFORE, the Parties agree as follows:

1. Section 2.3 of the Original Agreement shall be amended and restated in its entirety to read as follows:

Obligation to Supply. Subject to the terms of this Article 2, NeraPharm shall accept and fill all orders placed by VIVUS for the Product quantities set forth in binding six (6) month forecasts as provided for herein. Per Section 2.1 of this Agreement, the yield of the manufactured lot size that NeraPharm will validate for Product supply to VIVUS under this Agreement is expected to be [***] to [***]. Forecasts provided by VIVUS to NeraPharm for Product supply will be in whole lot quantities with a target yield of [***] per lot. Beginning in 2006, VIVUS shall provide to NeraPharm a binding six (6) month forecast and a non-binding twelve (12) month forecast

*** Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

starting from the end of the binding six (6) month period. The non-binding twelve (12) month forecast will assist NeraPharm in planning and capacity allocation and the binding six (6) month forecast will set forth quantities, if any, that VIVUS will be obligated to order and that NeraPharm will be obligated to deliver; provided that due to manufacturing batch yield variances, NeraPharm shall supply quantities in amounts that are plus or minus [***] of the VIVUS ordered quantity in [***]; provided further that VIVUS may order an additional [***] per quarter above the binding forecast amount and up to [***] per four (4) quarter period not to exceed [***] per quarter. Such binding and non-binding forecasts shall be updated by VIVUS on February 28, May 30, August 30 and November 30 for eighteen (18) month periods starting from the first day of the first subsequent calendar quarter. The total of the quantities indicated for the first three (3) months of such updated binding forecasts including the firm orders already placed, but not including back orders, if any, shall be not less than [***] per quarter less the quantities indicated for the same calendar period in the binding forecast issued three (3) months before. As VIVUS, from time to time, may need to purchase quantities in excess of [***] per quarter above the binding forecast or more than [***] per four (4) quarter period, NeraPharm agrees to use its best efforts to supply VIVUS' requirements. Notwithstanding anything to the contrary herein, the Parties agree that if VIVUS fails to provide NeraPharm with the forecast(s) on the due dates as set forth above, the forecast(s) shall be deemed to be provided by VIVUS with the quantities set at [***].

2. Section 2.5 of the Original Agreement shall be amended and restated in its entirety to read as follows:

Minimum Quantities. VIVUS agrees to order at least [***] batches [***] of Product for delivery during the calendar years 2004, 2005 and 2008; provided that the Parties agree that (i) VIVUS' order and delivery for calendar year 2005 will occur on or before April 30, 2006, and (ii) VIVUS' order and delivery for calendar year 2008 will occur on or before December 31, 2008.

3. Section 2.7.1 of the Original Agreement shall be amended and restated in its entirety to read as follows:

The price of the Product delivered for the first [***] during the calendar years 2004, 2005 and 2008 (as set forth in Section 2.5 of this Agreement) shall be [***] per [***].

4. By executing this Amendment and Waiver, NeraPharm hereby waives any and all alleged past breaches by VIVUS of the minimum order and forecasting obligations under Article 2 of the Original Agreement.

5. This Amendment and Waiver may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original and all of which shall constitute the same

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instrument. This Amendment and Waiver may be executed by facsimile signature, which shall be deemed to be effective.

6. Upon the execution of this Amendment and Waiver by VIVUS and NeraPharm this Amendment and Waiver shall be binding upon all Parties to the Original Agreement, effective February 13, 2006.

7. Sections 11.2 and 11.3 of the Original Agreement shall govern the choice of law applicable to this Amendment and Waiver and the resolution of any disputes or claims associated with this Amendment and Waiver.

8. Except as set forth in this Amendment and Waiver, the remainder of Original Agreement shall remain in full force and effect and shall be binding on the Parties. All terms not otherwise defined herein shall have the meanings prescribed to them in the Original Agreement.

IN WITNESS WHEREOF, the Parties have duly executed this Amendment and Waiver as of the day and year first set forth above.

VIVUS, INC.

/s/ Timothy E. Morris
(Signature)

Timothy E. Morris
(Print Name)

Vice President Finance, CFO
(Print Title)

NERAPHARM, SPOL., S.R.O.

/s/ M. Spacek
(Signature)

Miroslav Spacek
(Print Name)

Managing Director
(Print Title)

NERAPHARM, SPOL., S.R.O.

/s/ Vratislav Hlubucek
(Signature)

Vratislav Hlubucek
(Print Name)

BOD Member
(Print Title)

*** Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

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: May 4, 2006

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: May 4, 2006

By: /s/ TIMOTHY E. MORRIS

Timothy E. Morris
Vice President, Finance and Chief Financial Officer

Exhibit 32

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

I, Leland F. Wilson, President and Chief Executive Officer of VIVUS, Inc., certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended March 31, 2006 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: May 4, 2006

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

I, Timothy E. Morris, Vice President, Finance and Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ended March 31, 2006 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of VIVUS, Inc. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Quarterly Report on Form 10-Q. A signed original of this statement has been provided to VIVUS, Inc. and will be retained by VIVUS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: May 4, 2006

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