VIVUS INC
Form 10-Q
May 05, 2005

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2005

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 94040

(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES AND 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 ýNo o

Indicate by check mark whether Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act.) Yes ý No o

At April 25, 2005, 44,473,488 shares of common stock were outstanding.

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VIVUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

ASSETS

	MARCH 31 2005 (UNAUDITED)	DECEMBER 31 2004*
Current assets:		
Cash and cash equivalents	$ 41,942	$ 8,304
Available-for-sale securities	5,077	16,739
Accounts receivable, net of allowance for doubtful accounts of $80 and $104 at March 31, 2005 and December 31, 2004, respectively	323	9,544
Inventories	4,571	3,855
Prepaid expenses and other assets	1,465	1,459
Total current assets	53,378	39,901
Property and equipment, net	5,901	6,394
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	3,356	4,770
Total assets	$ 65,959	$ 54,389

LIABILITIES AND STOCKHOLDERS EQUITY

Current liabilities:		
Accounts payable	$ 3,259	$ 3,120
Product returns	2,890	3,211
Accrued research and clinical expenses	1,501	1,192
Accrued licensing fees	2,876	972
Accrued chargeback reserve	1,875	1,626
Accrued employee compensation and benefits	1,073	1,442
Income taxes payable	1,215	1,214
Accrued and other liabilities	1,494	1,658
Total current liabilities	16,183	14,435

ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 193

Notes payable	3,939	3,239
Accrued restructuring reserve	3,021	3,021
Deferred revenue	1,070	1,110
Accrued licensing fees		1,862
Total liabilities	24,213	23,667
Commitments and contingencies		
Stockholders equity:		
Preferred stock; $1.00 par value; shares authorized 5,000; shares issued and outstanding 0 at March 31, 2005 and December 31, 2004		
Common stock; $.001 par value; shares authorized 200,000; shares issued and outstanding 44,473 at March 31, 2005 and 38,127 at December 31, 2004	44	38
Additional paid-in capital	173,147	153,275
Accumulated other comprehensive loss	(65)	(48)
Accumulated deficit	(131,380)	(122,543)
Total stockholders equity	41,746	30,722
Total liabilities and stockholders equity	$ 65,959	$ 54,389

* Derived from audited consolidated financial statements filed in the Company s 2004 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		MARCH 31	
	2005 (UNAUDITED)		2004 (UNAUDITED)	
Revenue:				
United States product	$	396	$	572
International product		192		1,332
Other revenue		41		38
Total revenue		629		1,942
Operating expenses:				
Cost of goods sold and manufacturing		2,090		2,280
Research and development		4,265		7,721
Selling, general and administrative		3,221		3,008
Total operating expenses		9,576		13,009
Loss from operations		(8,947)		(11,067)
Interest and other income:				
Interest income		192		160
Foreign exchange gain (loss)		(11)		10
Interest expense		(58)		
Loss before provision for income taxes		(8,824)		(10,896)
Provision for income taxes		(13)		(3)
Net loss	$	(8,837)	$	(10,899)
Other comprehensive loss:				
Unrealized loss on securities		(17)		(12)
Comprehensive loss	$	(8,854)	$	(10,911)
Net loss per share:				
Basic and diluted	$	(0.22)	$	(0.29)
Shares used in per share computation:				
Basic and diluted		39,380		37,881

See accompanying notes to condensed consolidated financial statements.

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ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 193

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	THREE MONTHS ENDED MARCH 31	
	2005 (UNAUDITED)	2004 (UNAUDITED)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (8,837)	$ (10,899)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:		
Provision for doubtful accounts	(24)	(89)
Depreciation and amortization	475	490
Stock compensation costs	9	10
(Gain) loss on disposal of property and equipment	29	(1)
Changes in assets and liabilities:		
Accounts receivable	9,245	2,032
Inventories	(716)	(306)
Prepaid expenses and other assets	(6)	72
Accounts payable	139	1,139
Product returns	(321)	103
Accrued research, clinical and licensing fees	351	3,118
Accrued chargeback reserve	249	116
Accrued employee compensation and benefits	(369)	(270)
Accrued and other liabilities	(203)	(447)
Net cash provided by (used for) operating activities	21	(4,932)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(11)	(26)
Proceeds from sale of property and equipment		1
Investment purchases	(191)	(14,226)
Proceeds from sale/maturity of securities	13,250	9,164
Net cash provided by (used for) investing activities	13,048	(5,087)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Borrowing under note agreements	700	316
Exercise of common stock options	300	687
Proceeds from issuance of common stock	19,569	
Net cash provided by financing activities	20,569	1,003
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	33,638	(9,016)
CASH AND CASH EQUIVALENTS:		
Beginning of period	8,304	13,097
End of period	$ 41,942	$ 4,081
NON-CASH INVESTING ACTIVITIES:		
Unrealized (loss) on securities	$ (17)	$ (12)
SUPPLEMENTAL CASH FLOW DISCLOSURE:		

Income taxes paid	$	$	13

See accompanying notes to condensed consolidated financial statements.

VIVUS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2005

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 Regulations 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 three-month period ended March 31, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005. The unaudited financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2004, as filed on March 16, 2005 with the Securities and Exchange Commission. The accompanying balance sheet has been derived from the audited financial statements at that date. 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.

Certain reclassifications have been made to the Company s 2004 consolidated financial statements to conform to current period presentations.

2. STOCK-BASED COMPENSATION

The Company applies the intrinsic-value-based method of accounting prescribed by Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees,* and related interpretations including Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions involving Stock Compensation, an Interpretation of APB Opinion No. 25,* issued in March 2000, to account for its fixed-plan stock options. Under this method, compensation expense is recorded on the date of the grant only if the current market price of the underlying stock exceeds the exercise price. Statement of Financial Accounting Standards FAS No. 123, *Accounting for Stock Based Compensation,* establishes accounting and disclosure requirements using a fair-value-based method of accounting for stock-based employee compensation plans. As allowed by FAS No. 123, the Company has elected to continue to apply the intrinsic-value-based method of accounting described above, and has adopted only the disclosure requirements of FAS No. 123. The following table illustrates the effect on net income if the fair-value-based method has been applied to all outstanding and unvested awards during the three months ended March 31, 2005 and 2004 (in thousands, except per share data):

	Three months ended	
	March 31, 2005	**March 31, 2004**
Net loss, as reported	$ (8,837)	$ (10,899)
Deduct total stock-based employee compensation expense determined under fair-value-based method for all rewards, net of tax	(323)	(401)

Pro forma net loss	$	(9,160)	$	(11,300)
Pro forma net loss per share:				
Basic and diluted	$	(0.23)	$	(0.30)

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 and 2004: no dividend yield, expected volatility of 49% and 71%, respectively, risk-free interest rates of 3.77% and 2.99%, respectively and an expected life of 5 years for both periods.

Effective February 28, 2005, the vesting of the 359,682 outstanding stock options granted to employees on January 21, 2002, of which 82,479 were unvested options, was accelerated. The options were originally scheduled to vest during the period from January 2002 to January 2012. On the accelerated vesting date, the per share market value of VIVUS stock of $3.98 was less than the strike price of the options, which was $8.08 per share. When considering this action, the Compensation Committee took into account that accelerating the vesting of these out-of-the money options prior to when the Company expected to adopt FAS 123R, would further reduce the amount of compensation expense that the Company would be required to record in 2006 and beyond as a result of the previously granted equity incentive awards. In addition, by accelerating these options before the implementation of FAS 123R the expenses associated with the implementation of FAS 123R will be lower in future periods. The acceleration of these out-of-the money options will not cause any additional compensation expense in 2005. Under FAS 123R the compensation expense associated with these out-of-the-money options would have been significant.

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 $4.6 million and $3.9 million as of March 31, 2005 and December 31, 2004, respectively, and consist of (in thousands):

	MARCH 31, 2005	DECEMBER 31, 2004
Raw materials	$ 3,321	$ 3,260
Work in process	64	22
Finished goods	1,186	573
Inventory, net	$ 4,571	$ 3,855

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. Some portion of the fully reserved inventory has been used in production. The Company used $20,000 and $256,000 of its fully reserved inventory during the first quarter of 2005 and 2004, 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. In the fourth quarter of 2004, the Company determined that it will likely not use the fully reserved raw materials inventory in future 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 remaining value of the fully reserved inventory related to component parts is $1.0 million as of the end of the first quarter of 2005.

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 (formerly TA-1790), an erectile dysfunction compound currently in 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. As of March 31, 2005 we had long-term notes payable to Tanabe of $3.9 million, and $4.6 million of available credit under this agreement. All the assets of the Company 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
Total	$	3,939	

6. LICENSE AGREEMENTS

During the first quarter of 2004, we initiated a Phase 2 clinical trial with avanafil, our oral PDE5 inhibitor being studied for the treatment of erectile dysfunction. Under the terms of our 2001 development agreement, we have accrued through the first quarter of 2005, a $1.9 million license fee obligation to Tanabe. We intend to pay this license fee, with a future value of $2.0 million, in March 2006. We expect to make other substantial payments to Tanabe in accordance with our agreements with them. 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.

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-MDTS and Evamist in the United States for various female health applications. Under the terms of the agreements, VIVUS agreed to pay to Acrux combined licensing fees of $3.0 million over the 17 month period beginning in February 2004, 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. The Company expensed $375,000 and $2.9 million of milestone and licensing fees under the terms of the agreements in the first quarter of 2005 and 2004, respectively.

7. RESTRUCTURING RESERVE

In 1998, the Company restructured its operations and recorded related costs and write-downs in accordance with Emerging Issues Task Force, or EITF, 94-3. The property write-downs were calculated in accordance with the provisions of FAS No. 121 and represent the excess of the carrying value of property and equipment, primarily the Company s New Jersey manufacturing leaseholds and equipment, over the projected future discounted cash flows for the Company.

Restructuring reserve and related balances at March 31, 2005 were $3.0 million, remaining the same as at December 31, 2004.

The remaining balance in the restructuring reserve is related to the restoration liability for our leased manufacturing facilities. This liability will remain in effect through the end of the lease term, including any renewals. The Company has exercised its first option to renew the original lease, thereby extending any cash payments to be made relating to this liability out to 2007. The second renewal term, if exercised, would then extend the liability out an additional five years, to 2012.

8. NET LOSS PER SHARE

Net loss per share is calculated in accordance with FAS 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 230,219 and 1,005,725 at March 31, 2005 and 2004, respectively, are excluded from the computation of diluted EPS for the first quarter of 2005 and 2004 because the effect would have been anti-dilutive.

9. COMMITMENTS AND CONTINGENCIES

We lease our manufacturing facilities in Lakewood, New Jersey under a non-cancelable operating lease expiring in 2007 and have the option to extend this lease for one additional renewal term of five years. In January 2000, we entered into a seven-year lease for our corporate headquarters in Mountain View, California, which expires in January 2007.

In November 2002, we entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. In 2004, we purchased $762,000 of product and are committed to purchase a minimum total of $3.1 million of product from 2005 through 2008. There were no purchases made from this supplier in the first quarter of 2005.

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 2004, we purchased $475,000 of product from this supplier and in the first quarter of 2005 we purchased $240,000 of product. We will be required to purchase a minimum total of $1.5 million of product from 2005 through 2006.

From time to time, the Company may become involved in claims and other legal matters arising in the ordinary course of business. Management is not currently aware of any matters that will have a material adverse affect on the financial position, results of operations or cash flows of the Company.

10. CONCENTRATION OF CUSTOMERS AND SUPPLIERS

During the first three months of 2005 and 2004, sales to significant customers as a percentage of total revenues were as follows:

	2005	2004
Customer A	2%	49%
Customer B	46%	14%
Customer C	0%	11%
Customer D	23%	11%
Customer E	13%	7%

Customer C merged with customer D in 2004. The Company did not have any suppliers making up more than 10% of operating costs.

11. EQUITY TRANSACTIONS

On January 7, 2005, the Securities and Exchange Commission (SEC) 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.

12. RELATED PARTY TRANSACTIONS

The only transaction between the Company and a related party during the first quarter of 2005 was with Mario M. Rosati, one of our directors, who 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 2005 and 2004, we paid $31,200 and $59,200, respectively, to Wilson Sonsini Goodrich & Rosati.

13. FUTURE ACCOUNTING REQUIREMENTS

In December 2004, the Financial Accounting Standards Board (FASB) issued revised statement No. 123 (FAS 123R) which requires companies to expense the estimated fair value of employee stock options and similar awards. In April 2005, the SEC announced the adoption of a new rule that amended the compliance dates for FAS 123R. The accounting provisions of FAS 123R will now be effective for the first quarter of fiscal 2006. We will adopt the provisions of FAS 123R using a modified prospective application. Under modified prospective application, FAS 123R, which provides certain changes to the method for valuing stock-based compensation among other changes, will apply to new awards and to awards that are outstanding on the effective date and are subsequently modified or cancelled. Further compensation expense for outstanding awards for which the requisite service had not been rendered as of the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123R. We are in the process of determining how the new method of valuing stock-based compensation as prescribed in FAS 123R will be applied to valuing stock-based awards granted after the effective date and the impact the recognition of compensation expense related to such awards will have on our consolidated financial statements.

In March 2005, the SEC staff issued guidance on FAS 123R. Staff Accounting Bulletin No. 107 (SAB 107) was issued to assist preparers by simplifying some of the implementation challenges of FAS 123R while enhancing the information that investors receive. SAB 107 creates a framework that is premised on two overarching themes: (a) considerable judgment will be required by preparers to successfully implement FAS 123R, specifically when valuing employee stock options; and (b) reasonable individuals, acting in good faith, may conclude differently on the fair value of employee stock options. Key topics covered by SAB 107 include: (a) valuation models SAB 107 reinforces the flexibility allowed by FAS 123R to choose an option-pricing model that meets the standard s fair value measurement objective; (b) expected volatility the SAB provides guidance on when it would be appropriate to rely exclusively on either historical or implied volatility in estimating expected volatility; and (c) expected term the new guidance includes examples and some simplified approaches to determining the expected term under certain circumstances. The Company will apply the principles of SAB 107 in conjunction with its adoption of FAS 123R.

In November 2004, the FASB issued FAS 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. This Statement is required to be adopted by the Company in the first quarter of 2006; however, early application is permitted. We do not expect the adoption of this Statement to have a material impact on results of operations, financial position or cash flows as we currently do expense a portion of our manufacturing overhead as period cost due to excess capacity.

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-l 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 three-month period ended March 31, 2005 are not necessarily indicative of the results that may be expected for the full fiscal year or any future period.

BUSINESS OVERVIEW

VIVUS, Inc. is a specialty 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. ALISTA®, currently in Phase 3 trials, is our product candidate for the treatment of female sexual arousal disorder. Testosterone-MDTS, which recently completed a positive Phase 2 trial, is our product candidate to treat hypoactive sexual desire disorder. Evamist®, currently in Phase 3 development, is our product candidate to alleviate symptoms associated with menopause. Avanafil, currently in Phase 2 trials, is our phosphodiesterase type 5, or PDE5, inhibitor product candidate for the treatment of erectile dysfunction.

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. MUSE was the first minimally invasive therapy for erectile dysfunction available at a time when only more invasive therapies existed. Developing and bringing MUSE to the market provided us with experience in clinical and regulatory matters when the market for erectile dysfunction was in its infancy.

Our Product Pipeline

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

Product	Indication	Status	Patent Expiry and Number
ALISTA (topical alprostadil)	Female sexual arousal disorder (FSAD)	Phase 3 ongoing	2017 (US 5,877,216)
Testosterone-MDTS	Hypoactive sexual desire disorder (HSDD)	Phase 2 completed	2017 (US 6,818,226)
Evamist (estradiol-MDTS)	Menopausal symptoms	Phase 3 ongoing	2017 (US 6,818,226)
Avanafil (PDE5 inhibitor)	Erectile dysfunction (ED)	Phase 2 ongoing	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.

ALISTA

Female Sexual Arousal Disorder

FSAD, the persistent or recurrent inability to attain or maintain sufficient sexual excitement resulting in personal distress, occurs 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 and 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. We initiated a Phase 3 clinical trial of ALISTA in 2004 in post-menopausal women with FSAD. We anticipate that enrollment in this study will be completed by the end of 2005.

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 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 suggested that testosterone plays an important role in 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 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 has 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 30 to 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, along with Acrux, we announced 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 has been shown in Phase 3 trials to improve sexual desire in women with HSDD.

We are currently consulting with the FDA on the development of protocols for our Phase 3 testosterone-MDTS clinical studies.

Evamist

Menopausal Vasomotor Symptoms

Vasomotor symptoms such as hot flashes and vaginal atrophy are 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 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 2004 were estimated to be $1.4 billion.

Premarin®, an oral preparation of conjugated 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, 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 conjugated 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 conjugated estrogens taken orally.

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.

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 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 30 to 60 seconds and becomes invisible. Acrux studies have demonstrated that the estradiol-MDTS system delivers sustained levels of estradiol in women over a 24-hour period.

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 have received a Special Protocol Assessment 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. We anticipate that enrollment for this trial will be complete by the end of 2005, with an anticipated NDA filing in 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. Erectile dysfunction, 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 2004 of PDE5 inhibitor products for ED were in excess of $2.4 billion, including approximately $1.7 billion in sales of Viagra, approximately $550 million in sales of Cialis and approximately $150 million in sales of Levitra. Based on the aging baby boomer population and their 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 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 internal 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 of a drug, 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 between approximately 60 and 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 on-set of action are ideal characteristics for an on-demand treatment for ED.

Clinical Status

We have completed enrollment of a Phase 2, double blind, placebo-controlled, dose ranging study for avanafil and we anticipate data will be available in 2005. We anticipate that results from this study will allow us to finalize plans for Phase 3 studies.

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. An at-home double-blind, randomized, Phase 2 cross-over study compared the onset of action and efficacy of avanafil with that of Pfizer s sildenafil (Viagra®). A total of 51 men with erectile dysfunction were randomized for this study, and data from 43 of the subjects who reported on the use of at least four doses of avanafil and four doses of sildenafil were analyzed. During the avanafil portion of the study treatment was successful in providing an erection enabling vaginal penetration on 79% of sexual attempts, while during the sildenafil dosing part of the study 85% of the attempts resulted in an erection enabling vaginal penetration; the differences between the two groups were not statistically significant. Successful attempts occurred, on average, within 20 minutes of dosing in both arms of this study.

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

Other Programs

We have licensed and will 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 will 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. We have several programs in early clinical development. Depending on the outcomes of these early studies, we may continue development of these products.

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, doubtful accounts, government chargeback reserves, Medicaid and other rebate reserves, income taxes, restructuring, inventories and contingencies and litigation. (See Critical Accounting Policies and Estimates on page 28 of the Company s Annual Report on Form 10-K for the year ended December 31, 2004.) We base our estimates on historical experience 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.

Product Returns, Rebates and Sales Reserves

We have estimated reserves for product returns from wholesalers, hospitals and pharmacies, 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.

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.

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. In estimating Medicaid and other rebates the historical rebate percentage is used to estimate future rebates.

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 product returns, cash discounts, Medicaid and other rebates and government chargebacks and adjust the reserves accordingly. If actual product returns, government chargebacks, Medicaid rebates, rebate and cash discounts are greater than our estimates additional reserves may be required.

RESULTS OF OPERATIONS

Three Months Ended March 31, 2005 and 2004

For the three months ended March 31, 2005, we reported a net loss of $8.8 million, or $0.22 net loss per share as compared to a net loss of $10.9 million, or $0.29 net loss per share, during the same quarter in 2004. The net loss was lower than the same period last year primarily due to lower research and development expenses in the first quarter of 2005 compared with the same quarter of 2004 offset by lower revenues in the first quarter 2005 compared with 2004.

We anticipate continued losses over the next several years because we expect MUSE sales to continue to decline, 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,				
	2005	2004	Increase/ (Decrease)	% Change	
United States product, net	$	**396**	$ 572	$ (176)	(31)%
International product		192	1,332	(1,140)	(86)%
Other revenue		41	38	3	8%
Total revenues	$	629	$ 1,942	$ (1,313)	(68)%

Product revenue in the United States for the quarter ended March 31, 2005 was $396,000 compared to $572,000 in the comparable period last year. International product revenue was $192,000 for the three months ended March 31, 2005 compared to $1.3 million in the same period last year.

Worldwide product revenues from the sales of MUSE were $570,000 in the first quarter of 2005, a decrease of $1.3 million, or 70%, from the worldwide sales of MUSE in the first quarter of 2004. The change in revenues is primarily due to a decrease in international revenue due to lower shipments of MUSE to our international distribution partners. In the first quarter of 2004 our international distributors purchased quantities of MUSE in anticipation of a multi-country promotion effort. A similar purchasing pattern did not occur in the first quarter of 2005.

Revenues from the sales of MUSE domestically in the first quarter of 2005 compared to 2004 were lower due to several factors. In the fourth quarter of 2004, we estimate purchases made by our domestic wholesale partners represented approximately 6-7 months of demand as measured by independent third party prescription data. The high level of purchases in the fourth quarter of 2004 was expected to lead to lower U.S. product revenues in 2005. In the first quarter of 2005 the demand, as measured by third party prescription data, in the United States for PDE5 inhibitors used to treat penile dysfunction did not grow as compared to the first quarter of 2004. In the first quarter of 2005 new pricing for purchases made by the United States government went into effect. Additional reserves for government discounts, also known as chargebacks, were recorded in the first quarter of 2005 to reflect the revised United States government pricing and for the effect of future chargebacks on the sale of MUSE from inventory on hand at wholesalers at the end of the first quarter of 2005. The lack of growth in the demand for approved PDE5 inhibitors, the large volume of purchases made by the wholesalers in the fourth quarter of 2004, the lower volume of purchases made by our international distributors and the revised U.S. government pricing accounted for the decrease in revenue from the sale of MUSE in the United States in the first quarter of 2005 as compared to the first quarter of 2004. We expect this trend to continue throughout 2005.

Cost of goods sold and manufacturing.

	(In thousands, except percentages) Three Months Ended March 31,			
	2005	2004	(Decrease)	% Change
Cost of goods sold and manufacturing	$ 2,090	$ 2,280	$ (190)	(8)%

Cost of goods sold and manufacturing (cost of goods sold) in the first quarter of 2005 decreased $190,000, or 8%, to $2.1 million, as compared to $2.3 million for the first quarter of 2004. Cost of goods sold decreased because of lower sales in the first quarter of 2005 versus the same period in 2004. However, we expensed approximately $1.8 million of manufacturing overhead costs in the first quarter of 2005, as compared to $1.3 million during the same period in 2004 as period costs because of excess manufacturing capacity at our New Jersey facility. This accounting treatment is based on the determination made during the 1998 restructuring that the manufacturing capacity of the New Jersey plant far exceeds the level of production required to meet estimated future market demand.

Additionally, in accordance with GAAP, in 1998 we reduced the carrying cost of alprostadil, the active ingredient in MUSE, and its component parts to zero due to excess quantities on hand at that time. Although the cost basis for alprostadil was reduced to zero we continued to use this active ingredient as allowed by the FDA in the production of MUSE, in 2004. By utilizing the inventory that had previously been written down to zero, we lowered our cost of sales for the three months ended March 31, 2004 by $256,000. In the fourth quarter of 2004 we determined that we will likely not use the fully reserved raw materials inventory in future production. In the first quarter of 2005, we used component parts of this fully reserved inventory resulting in a favorable impact on our cost of goods sold of $20,000. We expect cost of goods sold to increase in 2005 as we are no longer using the fully reserved raw materials in production although we do plan to continue to use certain of the fully reserved component parts in production.

Research and development.

	(In thousands, except percentages) Three Months Ended March 31,			
	2005	2004	Decrease	% Change
Research and development	$ 4,265	$ 7,721	$ (3,456)	(45)%

Research and development expenses for the first quarter of 2005 were $4.3 million, as compared to $7.7 million for the three months ended March 31, 2004. Increased clinical trial and project activity for ALISTA and estradiol resulted in incremental spending for these projects of $1.0 million during the first quarter of 2005 as compared to the same period last year. This increase was offset by $4.7 million in one-time charges for licensing and milestone payments in the first quarter of 2004 associated with three of the development programs in the pipeline in 2004.

During 2004, we entered into exclusive licensing agreements with a subsidiary of Acrux under which we will develop and commercialize, in the United States, an estradiol spray for the alleviation of the symptoms of menopause and a testosterone spray for the treatment of hypoactive sexual desire disorder in women. During the first quarter of 2004, we reported a total $2.9 million of licensing fees incurred under the terms of the agreements. In addition, during the first quarter of 2004, we initiated a phase 2 clinical trial with avanafil, our oral phosphodiesterase type 5 (PDE5) inhibitor being studied for the treatment of erectile dysfunction. Under the terms of our 2001 development, licensing and supply agreement with Tanabe we reported a $1.8 million licensing fee obligation to Tanabe in the first quarter of 2004. We intend to pay this obligation in March 2006.

We anticipate that our research and development expenditures will continue to increase in 2005 and 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,			
	2005	2004	Increase	% Change
Selling, general and administrative	$ 3,221	$ 3,008	$ 213	7%

Selling, general and administrative expenses in the first quarter of 2005 of $3.2 million were $213,000 higher than the same period last year due to several factors. In the first quarter of 2005 two of our largest wholesalers commenced charging us a distribution service fee based upon either the quantity of product purchased or sold by the respective wholesaler. We recorded expense of $220,000 for this distribution service fee in the first quarter of 2005 to selling, general and administrative expenses. We expect that these distribution service fees will continue into the future. In addition, we recorded $200,000 of incremental accounting and audit fees expense primarily related to compliance with the requirements of Sarbanes-Oxley in the first quarter of 2005. These increases were offset by $214,000 of reduced advertising and marketing program expenses in the first quarter of 2005 as compared to the first quarter of 2004.

Interest income and expense. Interest income for the three months ended March 31, 2005 was $192,000 as compared to $160,000 for the three months ended March 31, 2004. The increase is primarily due to an increase in our investments from March 31, 2004 to March 31, 2005. Interest expense of $58,000 in the first quarter of 2005 was related to the Acrux milestone liabilities and Tanabe license fees and loan. We did not have any interest expense for the comparable prior year period.

Provision for income taxes. During the first quarter of 2005, we recorded a net tax provision of $13,000 based on minimum state income taxes due as compared to $3,000 during the first quarter of 2004.

LIQUIDITY AND CAPITAL RESOURCES

Cash. Unrestricted cash, cash equivalents and available-for-sale securities totaled $50.4 million at March 31, 2005 as compared to $29.8 million at December 31, 2004. The increase is primarily due to 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.

Since inception, we have financed operations primarily from the issuance of equity securities. Through March 31, 2005, we raised $194.1 million from financing activities and had an accumulated deficit of $131.4 million at March 31, 2005.

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, 2005 was $323,000 as compared to $9.5 million at December 31, 2004. The 97% decrease in the accounts receivable balance at March 31, 2005 is primarily due to the collection of $9.5 million of accounts receivable outstanding at December 31, 2004. Currently, we do not have any significant concerns related to accounts receivable or collections.

Liabilities. Total liabilities were $24.2 million at March 31, 2005, $546,000 higher than at December 31, 2004. The largest change in liabilities was a $700,000 increase in notes payable due to the additional borrowings on the Tanabe line of credit in the first quarter of 2005.

Operating Activities. Our operating activities provided $21,000 and used $4.9 million of cash during the three months ended March 31, 2005 and 2004, respectively. During the first quarter of 2005, our net operating loss was offset by a $9.2 million reduction in our accounts receivable due to the collection of monies owed to us. During the first quarter of 2004, our net operating loss of $10.9 million was offset by a $3.1 million increase in accrued research, clinical and licensing fees primarily due to $2.9 million related to the future payment of milestone and licensing fees to Acrux and Tanabe, a $2.0 million reduction in our accounts receivable due to the collection of monies owed to us and a $1.1 million increase in accounts payable primarily due to the timing of payments.

Investing Activities. Our investing activities provided $13.0 million and used $5.1 million in cash during the three months ended March 31, 2005 and 2004, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities.

Financing Activities. Financing activities provided cash of $20.6 million and $1.0 million during the three months ended March 31, 2005 and 2004, respectively. These amounts include the proceeds from 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, the proceeds from the exercise of stock options and borrowings under note arrangements in both the first quarter of 2005 and 2004.

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 (TA-1790), our erectile dysfunction compound currently in Phase 2 clinical trials. 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 two percent. As of March 31, 2005 we had a long-term notes payable balance of $3.9 million and $4.6 million remaining available on the credit line. We borrowed an additional $700,000 under this credit line in the first quarter of 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 Securities and Exchange Commission 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.

We expect to evaluate other potential financing sources, including, but not limited to, the issuance of additional equity or debt securities, corporate alliances, joint ventures, and licensing agreements to fund the development and possible commercial launch of any future products. The sale of additional equity securities would result in additional dilution to our stockholders. Our working capital and additional funding requirements will depend upon numerous factors, including:

the progress of our research and development programs;

the timing and results of pre-clinical testing and clinical trials;

results of operations;

demand for MUSE;

technological advances;

the level of resources that we devote to our 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 2006. 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. 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.

In December 2004, the Financial Accounting Standards Board (FASB) issued revised statement No. 123 (FAS 123R) which requires companies to expense the estimated fair value of employee stock options and similar awards. In April 2005, the SEC announced the adoption of a new rule that amended the compliance dates for FAS 123R. The accounting provisions of FAS 123R will now be effective for the first quarter of fiscal 2006. We will adopt the provisions of FAS 123R using a modified prospective application. Under modified prospective application, FAS 123R, which provides certain changes to the method for valuing stock-based compensation among other changes, will apply to new awards and to awards that are outstanding on the effective date and are subsequently modified or cancelled. Further compensation expense for outstanding awards for which the requisite service had not been rendered as of the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123. We are in the process of determining how the new method of valuing stock-based compensation as prescribed in FAS 123R will be applied to valuing stock-based awards granted after the effective date and the impact the recognition of compensation expense related to such awards will have on our consolidated financial statements.

In March 2005, the SEC staff issued guidance on FASB FAS 123R. Staff Accounting Bulletin No. 107 (SAB 107) was issued to assist preparers by simplifying some of the implementation challenges of FAS 123R while enhancing the information that investors receive. SAB 107 creates a framework that is premised on two overarching themes: (a) considerable judgment will be required by preparers to successfully implement FAS 123R, specifically when valuing employee stock options; and (b) reasonable individuals, acting in good faith, may conclude differently on the fair value of employee stock options. Key topics covered by SAB 107 include: (a) valuation models SAB 107 reinforces the flexibility allowed by FAS 123R to choose an option-pricing model that meets the standard s fair value measurement objective; (b) expected volatility the SAB provides guidance on when it would be appropriate to rely exclusively on either historical or implied volatility in estimating expected volatility; and (c) expected term the new guidance includes examples and some simplified approaches to determining the expected term under certain

circumstances. The Company will apply the principles of SAB 107 in conjunction with its adoption of FAS 123R.

In November 2004, the FASB issued FAS 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. This Statement is required to be adopted by the Company in the first quarter of 2006; however, early application is permitted. We do not expect the adoption of this Statement to have a material impact on results of operations, financial position or cash flows as we currently do expense a portion of our manufacturing overhead as period cost due to excess capacity.

Overview of Contractual Obligations

	Payments Due by Period (in thousands)				
Contractual Obligations	**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**
Operating Leases (1)	$ 2,540	$ 1,370	$ 1,170		
Purchases (2)	4,590	1,530	2,295	$ 765	
Notes Payable (3)	3,939		315	3,624	
Other Long Term Liabilities (4)	5,897	2, 876	3,021		
Total	$ 16,966	$ 5,776	$ 6,801	$ 4,389	

(1) We lease our manufacturing facilities in Lakewood, New Jersey under a non-cancelable operating lease expiring in 2007 and have the option to extend this lease for one additional renewal term of five years. 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. We are committed to purchase a minimum total of $3.1 million of product from 2005 through 2008. We did not purchase any product from this supplier in the first quarter of 2005.

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 2004 we purchased $475,000 of product and in the first quarter of 2005 we purchased $240,000 of product. We will be required to purchase a minimum total of $1.5 million of product from 2005 through 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 (formerly TA-1790), our erectile dysfunction compound currently in Phase 2 clinical trials. 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. As of March 31, 2005 we have $4.6 million of available credit under this agreement.

(4) Other Long Term Liabilities includes the restoration liability of $3.0 million for our leased manufacturing facilities. This liability will remain in effect through the end of the lease term, including any renewals. We have exercised our first option to renew the original lease, thereby extending any cash payments to be made relating to this liability out to 2007. The second renewal term, if exercised, would then extend the liability out an additional five years, to 2012.

During the first quarter of 2004, we initiated a Phase 2 clinical trial with avanafil. Under the terms of our 2001 development, licensing and supply agreement with Tanabe we accrued an expense of $1.9 million for a licensing fee obligation to Tanabe during 2004. We intend to pay the entire obligation, with a future value of $2.0 million, in March 2006.

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-MDTS and Evamist in the United States for various female health applications. Under the terms of this agreement, we have accrued an expense of $986,000 through March 31, 2005 for the licensing fee related to Evamist that we intend

to pay, with a future value of $1.0 million, in June 2005.

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 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 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;

the effectiveness of our product candidates;

slower than expected rate 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, that 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 clinical trials 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 clinical studies for our product candidates by ourselves without the assistance of third parties who conduct the studies on our behalf. These third parties are usually clinical research organizations, or CROs, that have significant resources and experience in the conduct of clinical studies. The CROs typically perform patient recruitment, project management, data management, statistical analysis, and other reporting functions. We intend to use several different CROs for all of our clinical studies. If these third party 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 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.

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 has been closed.

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 Viagra, 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 Cialis 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 Levitra 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 short 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 for us 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 lease 90,000 square feet of space in Lakewood, New Jersey 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 Medicare and other third-party payors may limit our ability to market and sell our products.

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 hope to further qualify MUSE for reimbursement in the managed care environment. However, 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 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.

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.

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. 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 United States Patent and Trademark Office, 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.

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 increased spending on research and development projects, including clinical trials. 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 2006. 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 clinical trials;

patient recruitment and enrollment in current and future clinical trials;

the results of operations;

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. 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 $131.4 million as of March 31, 2005 and expect to continue to incur substantial operating losses for the foreseeable future.

We have generated a cumulative net loss of $131.4 million for the period from our inception through March 31, 2005 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 the Company and may make some transactions more difficult or impossible to complete without the support of these stockholders.

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

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. Factors contributing to these fluctuations include, among other items, the timing and enrollment rates of clinical trials for our drug candidates, the timing of significant purchases of MUSE by distributors, our need for clinical supplies and the re-measurement of certain deferred stock compensation. 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.

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

Some provisions of our Amended and Restated Certificate of Incorporation and Bylaws could also 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 accounting standards regarding stock option plans could limit the desirability of granting stock options, which could harm our ability to attract and retain employees, and could also reduce our profitability.

Effective January 1, 2006, the Financial Accounting Standards Board requires all companies to treat the value of stock options granted to employees as an expense. This expense would be spread over the vesting period of the stock option. Currently, we account for stock compensation under Accounting Principles Board, or APB, No. 25, Accounting for Stock Issued to Employees, which results in no compensation expenses recorded in connection with stock options granted to our employees. When we are required to expense stock option grants, it will reduce the attractiveness of granting stock options because of the additional expense associated with these grants, which will reduce our profitability. However, stock options are an important employee recruitment and retention tool, and we may not be able to attract and retain key personnel if we reduce the scope of our employee stock option program. Accordingly, when we are required to expense stock option

grants, our profitability would be reduced, as would our ability to use stock options as an employee recruitment and retention tool.

In December 2004, the Financial Accounting Standards Board (FASB) issued revised statement No. 123 (FAS 123R), *Share-Based Payment*, which requires companies to expense the estimated fair value of employee stock options and similar awards. In April 2005, the Securities and Exchange Commission (SEC) announced the adoption of a new rule that amended the compliance dates for FAS 123R. The accounting provisions of FAS 123R will now be effective for the first quarter of fiscal 2006. We will adopt the provisions of FAS 123R using a modified prospective application. Under modified prospective application, FAS 123R, which provides certain changes to the method for valuing stock-based compensation among other changes, will apply to new awards and to awards that are outstanding on the effective date and are subsequently modified or cancelled. Further compensation expense for outstanding awards for which the requisite service had not been rendered as of the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123. We are in the process of determining how the new method of valuing stock-based compensation as prescribed in FAS 123R will be applied to valuing stock-based awards granted after the effective date and the impact the recognition of compensation expense related to such awards will have on our consolidated financial statements.

In March 2005, the SEC staff issued guidance on FASB FAS 123R. Staff Accounting Bulletin No. 107 (SAB 107) was issued to assist preparers by simplifying some of the implementation challenges of FAS 123R while enhancing the information that investors receive. SAB 107 creates a framework that is premised on two overarching themes: (a) considerable judgment will be required by preparers to successfully implement FAS 123R, specifically when valuing employee stock options; and (b) reasonable individuals, acting in good faith, may conclude differently on the fair value of employee stock options. Key topics covered by SAB 107 include: (a) valuation models SAB 107 reinforces the flexibility allowed by FAS 123R to choose an option-pricing model that meets the standard s fair value measurement objective; (b) expected volatility the SAB provides guidance on when it would be appropriate to rely exclusively on either historical or implied volatility in estimating expected volatility; and (c) expected term the new guidance includes examples and some simplified approaches to determining the expected term under certain circumstances. The Company will apply the principles of SAB 107 in conjunction with its adoption of FAS 123R.

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. We are not exposed to market risks from changes in foreign currency exchange rates or commodity prices. We do not hold derivative financial instruments nor do we hold securities for trading or speculative purposes. At March 31, 2005, we had drawn $3.9 million of the $8.5 million secured line of credit with Tanabe. Each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of two percent. We, however, are exposed to changes in interest rates on our investments in cash equivalents and available-for-sale securities. A significant portion of all of our investments in cash equivalents and available-for-sale securities are in money market funds that hold short-term investment grade commercial paper, treasury bills or other United States government obligations. Currently, this reduces our exposure to long-term interest rate changes.

ITEM 4. CONTROLS AND PROCEDURES

(a.) Evaluation of disclosure controls and procedures. Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

(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

None

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

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
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
31.1		Certification of Chief Executive Officer, dated May 5, 2005, 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 5, 2005, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
32		Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to the same numbered exhibit filed with the Registrant s Form 8-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 5, 2005 .

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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