SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2004

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number 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 [X] No [_]

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

At July 30, 2004, 38,048,401 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

	JUNE 30 2004 (UNAUDITED)	DECEMBER 31 2003*
Current assets:		
Cash and cash equivalents	$ 3,965	$ 13,097
Available-for-sale securities	27,467	21,488
Accounts receivable, net	1,929	2,623
Inventories, net	3,861	3,109
Prepaid expenses and other assets	1,540	1,108
Total current assets	38,762	41,425
Property and equipment, net	7,313	8,220
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	6,760	13,763
Total assets	$ 56,159	$ 66,732

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 2,973	$ 2,917

Accrued and other liabilities	9,865	8,409
Total current liabilities	12,838	11,326
Notes payable	1,198	--
Accrued and other long-term liabilities	5,904	4,171
Total liabilities	19,940	15,497
Stockholders' equity:		
Preferred stock; $1.00 par value; shares authorized 5,000; shares issued and outstanding - 0 at June 30, 2004 and December 31, 2003	--	--
Common stock; $.001 par value; shares authorized 200,000; shares issued and outstanding - 38,046 at June 30, 2004, and 37,788 at December 31, 2003	38	38
Additional paid-in capital	152,963	152,093
Accumulated other comprehensive (loss) income	(43)	64
Accumulated deficit	(116,739)	(100,960)
Total stockholders' equity	36,219	51,235
Total liabilities and stockholders' equity	$ 56,159	$ 66,732

* The Condensed Consolidated Balance Sheet at December 31, 2003 has been derived from the Company's audited financial statements at that date.

See accompanying notes to the condensed consolidated financial statements.

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	THREE MONTHS ENDED		SIX MONTHS ENDED	
	JUNE 30 2004	JUNE 30 2003	JUNE 30 2004	JUNE 30 2003
	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
Revenue				
United States product	$ 2,677	$ 2,961	$ 3,340	$ 6,769
International product	742	960	2,112	1,838
Returns provision	(217)	(273)	(308)	(690)
Total revenue	3,202	3,648	5,144	7,917
Cost of goods sold	2,324	2,424	4,604	5,208
Gross profit	878	1,224	540	2,709
Operating expenses:				
Research and development	3,052	1,846	10,773	4,130
Selling, general and administrative	2,814	2,492	5,822	5,064
Total operating expenses	5,866	4,338	16,595	9,194
Loss from operations	(4,988)	(3,114)	(16,055)	(6,485)
Interest and other income:				
Interest income	156	173	316	360
Gain (loss) on disposal of property and equipment	--	--	1	(1)
Foreign exchange (loss) gain	(3)	16	7	10
Interest expense	(43)	--	(43)	--
Loss before provision for income taxes	(4,878)	(2,925)	(15,774)	(6,116)
Provision for income taxes	(2)	--	(5)	--
Net loss	$ (4,880)	$ (2,925)	$ (15,779)	$ (6,116)
Net loss per share:				
Basic	$ (0.13)	$ (0.08)	$ (0.42)	$ (0.18)
Diluted	$ (0.13)	$ (0.08)	$ (0.42)	$ (0.18)
Shares used in per share computation:				
Basic	38,028	35,073	37,954	34,048
Diluted	38,028	35,073	37,954	34,048

See accompanying notes to the condensed consolidated financial statements.

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	THREE MONTHS ENDED		SIX MONTHS ENDED	
	JUNE 30 2004	JUNE 30 2003	JUNE 30 2004	JUNE 30 2003
	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
Net loss	$ (4,880)	$ (2,925)	$ (15,779)	$ (6,116)
Other comprehensive loss:				
Change in unrealized loss on securities	(95)	(51)	(107)	(123)
Comprehensive loss	$ (4,975)	$ (2,976)	$ (15,886)	$ (6,239)

See accompanying notes to the condensed consolidated financial statements.

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	SIX MONTHS ENDED JUNE 30	
	2004	2003
	(UNAUDITED)	(UNAUDITED)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (15,779)	$ (6,116)
Adjustments to reconcile net loss to net cash used for operating activities:		
Provision for doubtful accounts	87	(70)
Depreciation and amortization	976	1,088
Stock compensation costs	20	19
(Gain) loss on disposal of property and equipment	(1)	1
Changes in assets and liabilities:		
Accounts receivable	607	1,628
Inventories	(752)	(335)
Prepaid expenses and other assets	(432)	192
Accounts payable	56	(136)
Accrued and other liabilities	3,189	(871)
Net cash used for operating activities	(12,029)	(4,600)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(69)	(88)
Proceeds from sale of property and equipment	1	--
Investment purchases	(18,538)	(27,177)
Proceeds from sale/maturity of securities	19,455	11,252
Net cash provided by (used for) investing activities	849	(16,013)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Borrowing under note agreements	1,198	--
Exercise of common stock options	692	180
Sale of common stock through employee stock purchase plan	158	162
Proceeds from issuance of common stock	--	17,500
Common stock issuance costs	--	(1,090)
Net cash provided by financing activities	2,048	16,752
NET DECREASE IN CASH	(9,132)	(3,861)
CASH:		
Beginning of period	13,097	12,296
End of period	$ 3,965	$ 8,435
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Change in unrealized loss on securities	$ (107)	$ (123)
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Income taxes paid	$ 13	$ 15

See accompanying notes to the condensed consolidated financial statements.

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 six-month period ended June 30, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2003. Certain reclassifications have been made to the Company's 2003 consolidated financial statements to conform to the current period presentations.

2. SIGNIFICANT ACCOUNTING POLICIES

STOCK OPTIONS

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 exceeded the exercise price. SFAS No. 123, ACCOUNTING FOR STOCK BASED COMPENSATION, established accounting and disclosure requirements using a fair-value-based method of accounting for stock-based employee compensation plans. As allowed by SFAS 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 SFAS No. 123. The following table illustrates the effect on net income if the fair-value-based method had been applied to all outstanding and unvested awards during the three and six months ended June 30, 2004 and 2003.

	Three months ended		Six months ended	
	June 30 2004	June 30 2003	June 30 2004	June 30 2003
Net loss, as reported	$ (4,880)	$ (2,925)	$(15,779)	$ (6,116)
Deduct total stock-based employee compensation expense determined under fair-value-based method for all rewards, net of tax	(486)	(439)	(887)	(865)
Pro forma net loss	$ (5,366)	$ (3,364)	$(16,666)	$ (6,981)
Pro forma net loss per share:				
Basic	$ (0.14)	$ (0.10)	$ (0.44)	$ (0.21)
Diluted	$ (0.14)	$ (0.10)	$ (0.44)	$ (0.21)

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 second quarter of 2004 and 2003: no dividend yield, expected volatility of 68% and 66%, respectively, risk-free interest rates of between 1% and 5% and 1% to 4%, respectively and an expected life of 5 years for both periods.

3. INVENTORIES

Inventories are recorded net of reserves of $5.0 million and $5.6 million as of June 30, 2004 and December 31, 2003, respectively, and consist of (in thousands):

	JUNE 30, 2004	DECEMBER 31, 2003
Raw materials	$ 2,571	$ 2,370
Work in process	97	81
Finished goods	1,193	658
Inventory, net	$ 3,861	$ 3,109

As noted above, the Company has recorded significant reserves against the carrying value of its inventories. The reserves relate primarily to raw materials inventory that the Company previously estimated would not be used. The Company now estimates that at least some portion of the fully reserved inventory will now be used in production. The Company used $535,000 and $482,000 of its fully reserved raw materials inventory during the first six months of 2004 and 2003, respectively. The fully reserved used raw materials were charged to cost of goods sold at a zero basis, which had a favorable impact on gross profit.

4. NOTES PAYABLE

In the first quarter of 2004, we signed an agreement for a secured line of credit with Tanabe Holding America, Inc., a subsidiary of Tanabe Seiyaku Co., Ltd., or Tanabe, allowing us to borrow up to $8.5 million to be used for the development of avanafil (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 two percent. There are no financial covenants associated with this secured line of credit. As of June 30, 2004 we had long-term notes payable to Tanabe of $1.2 million, and $7.3 million of available credit under this agreement.

5. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities as of June 30, 2004 and December 31, 2003 consist of (in thousands):

Short-term accrued and other liabilities	JUNE 30, 2004	DECEMBER 31, 2003
Product returns	$ 2,697	$ 2,932
Income taxes	1,187	1,216
Research and clinical expenses	2,620	458
Royalties	424	629
Deferred revenue	281	281
Employee compensation and benefits	1,061	1,249
Chargebacks and rebates	404	900
Customer liabilities	629	135
Other	562	609
Total short-term accrued and other liabilities	$ 9,865	$ 8,409

Long-term accrued and other liabilities	JUNE 30, 2004	DECEMBER 31, 2003
Restructuring	$ 3,021	$ 3,021
Research and clinical expenses	1,808	--
Deferred revenue	1,075	1,150
Total long-term accrued and other liabilities	$ 5,904	$ 4,171

6. RESTRUCTURING RESERVE

During 1998, VIVUS, Inc. experienced a significant decline in market demand for MUSE(R) due to the market launch of sildenafil, the first oral treatment for erectile dysfunction. During the second and third quarters of 1998, the Company took significant steps to restructure its operations in an attempt to bring the cost structure in line with current and projected revenues. (See Notes 1 and 6 to the Consolidated Financial Statements for the year ended December 31, 2003 included in the Company's Annual Report on Form 10-K.) The restructuring reserve balance at June 30, 2004 was $3.0 million, remaining the same as at December 31, 2003.

	PROPERTY AND RELATED COMMITMENTS
Balance at December 31, 2003	$ 3,021
Activity in first quarter 2004	--
Activity in second quarter 2004	--
Balance at June 30, 2004	$ 3,021

The 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 for this liability out to 2007. The second renewal term, if exercised, would then extend the liability out an additional five years, to 2012.

7. NET INCOME PER SHARE

Net income per share is calculated in accordance with Statement of Financial Accounting Standards No. 128, EARNINGS PER SHARE, which requires a dual presentation of basic and diluted earnings per share, or EPS. Basic income per share is based on the weighted average number of common shares outstanding during the period. Diluted income per share is based on the weighted average number of common and potentially dilutive shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options. Potentially dilutive options outstanding of 728,290 and 782,485 at June 30, 2004 and 2003, respectively, are excluded from the computation of diluted EPS for the second quarter of 2004 and 2003 because the effect would have been anti-dilutive. Potentially dilutive options outstanding of 873,646 and 623,667 at June 30, 2004 and 2003, respectively, are excluded from the computation of diluted EPS for the first six months of 2004 and 2003 because the effect would have been anti-dilutive.

8. COMMITMENTS

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 2003, we purchased $2.1 million of product and are required to purchase a minimum total of $3.8 million of product from 2004 through 2008. As of June 30, 2004, we have not purchased any additional product from this supplier.

In January 2004, we entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. We will be required to purchase a minimum total of $2.3 million of product from 2004 through 2006. As of June 30, 2004, we purchased $234,000 of product from this supplier.

In January 2004, we entered into exclusive licensing agreements with a subsidiary of Acrux Limited, a specialty pharmaceutical company based in Melbourne, Australia, under which we will develop and commercialize an estradiol spray for the alleviation of the symptoms of menopause and a testosterone spray for the treatment of low sexual desire in women. We reported a total $2.9 million of licensing fees incurred under the terms of the agreements. Portions of these licensing fees will be paid in September 2004 ($250,000) and June 2005 ($930,000). We expect to make other substantial payments to Acrux 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 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 Seiyaku Co., LTD.,

or Tanabe, a Japanese pharmaceutical company, we reported a $1.8 million milestone obligation to Tanabe in the first quarter of 2004. The payment of this milestone will be made 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.

9. CONCENTRATION OF CUSTOMERS AND SUPPLIERS

During the first six months of 2004 and 2003, sales to significant customers as a percentage of total revenues were as follows:

	2004	2003
Customer A	36%	30%
Customer B	31%	18%
Customer C	13%	19%
Customer D	6%	5%

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

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

This Management's Discussion and Analysis of Financial Conditions and Results of Operations and other parts of this Form 10-Q contain "forward-looking" statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as "believe," "expect," "intend," "anticipate," "should," "planned," "estimated," and "potential," among others. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our history of losses and variable quarterly results; (2) substantial competition; (3) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (4) our reliance on sole source suppliers; (5) our limited sales and marketing efforts and our reliance on third parties; (6) failure to continue to develop innovative products; (7) risks related to noncompliance with United States Food and Drug Administration regulations; and (8) 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 six-month period ended June 30, 2004 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 men and women. In addition to our currently marketed therapies, we have a pipeline that includes both new chemical entities and existing compounds that are being developed to address unmet medical needs. Our business strategy is to apply our scientific and medical expertise to identify, develop and commercialize therapies that restore sexual function. In the United States, we market MUSE(R) (alprostadil) and ACTIS(R), two products for the treatment of erectile dysfunction. We have entered into supply agreements with Meda AB to market and distribute MUSE and ACTIS in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. In Canada, we have entered into a license and supply agreement with Paladin Labs, Inc. to market and distribute MUSE.

We currently have four significant research and development programs in progress targeting male and female sexual function:

- ALISTA(TM) to treat female sexual arousal disorder;
- Estradiol MDTS(R), a short-term therapy to alleviate symptoms associated with menopause;
- Testosterone MDTS(R) for treating women with low sexual desire; and
- Avanafil, formerly known as TA-1790, for the treatment of erectile dysfunction.

The first two research and development programs are entering Phase 3 clinical development and the second two research and development programs are in Phase 2 clinical development. We believe that each of these programs addresses either established markets with sales in excess of $1.0 billion annually or potential markets with sales that could exceed $1.0 billion annually.

When we were founded in 1991, our sole purpose was to develop a therapy for men suffering from erectile dysfunction. In 1997, we commercially launched MUSE in the United States. At that time, MUSE revolutionized erectile dysfunction therapy at a time when few effective therapies existed. Developing and bringing MUSE to the market provided us experience in clinical and regulatory matters when no intra-urethral drugs had been approved for this indication. This experience serves us well today in making progress towards developing and commercializing product candidates in our research and development programs.

OUR FUTURE

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

SECOND QUARTER 2004 UPDATE

FEMALE SEXUAL HEALTH

We believe that the market for the treatment of sexual disorders in women is large and underserved. Today, there are no treatments on the market that have been approved by the United States Food and Drug Administration, or the FDA, for the treatment of sexual disorders in women. A paper by Lauman, et. al., published in the Journal of the American Medical Association in 1999, noted 43% of women between the ages of 18 and 65 identified themselves as afflicted with a sexual disorder, with two prevalent conditions being low sexual desire and arousal disorder. VIVUS' research and development programs in female sexual health address both of these conditions.

ALISTA

ALISTA is a topical formulation of alprostadil applied locally to the female genitalia as an on-demand treatment for female sexual arousal disorder. It increases blood flow in the genital region, allowing for greater sensitivity and sexual arousal. ALISTA has a fast onset of action with low systemic distribution.

In the second quarter of 2004, we completed an at-home Phase 2 study to assess the efficacy and safety of ALISTA when used by pre-menopausal women with female sexual arousal disorder. The study demonstrated that ALISTA significantly increased the percentage of satisfying sexual events in pre-menopausal women when compared with placebo. Results from this Phase 2 clinical trial were similar to the results from earlier clinical trials in post-menopausal women.

We plan to begin the first Phase 3 clinical trial of ALISTA in 2004.

Metered Dose Transdermal Spray, or MDTS

In the first quarter of 2004, we entered into license agreements with a subsidiary of Acrux Limited, a specialty pharmaceutical company based in Melbourne, Australia, pursuant to which we have the exclusive rights to market two drugs in the United States, estradiol and testosterone, using Acrux's Metered Dose Transdermal Spray, or MDTS. The MDTS is a small, easy-to-use, handheld spray that delivers either estradiol or testosterone topically to the skin. It dries in approximately 30 seconds, and when dry, is invisible. Data generated to date suggests that, once dry, there is little chance for transfer or removal by washing. We believe that MDTS will have high patient acceptability.

The MDTS drug formulations utilize proprietary skin penetration enhancers commonly found in sunscreens. The once-per-day dosing has demonstrated a sustained plasma level of drug over a 24-hour period.

- Estradiol MDTS - The estradiol spray is a low-dose estrogen-only treatment addressing the symptoms associated with menopause, primarily hot flashes. This proprietary spray product utilizes the MDTS technology, which is patented. This transdermal spray product is simple to apply and may have safety benefits compared to oral estrogen pills.

  We plan to begin the Phase 3 clinical trial of the estradiol spray in 2004.

- Testosterone MDTS - This proprietary spray product is designed to treat females with low sexual desire. There are estimated to be over 10 million women in the United States afflicted with low sexual desire and there are no FDA approved therapies for this condition.

  The testosterone spray is currently in a Phase 2 clinical trial with 200 patients. Under the terms of our license agreement, Acrux has the responsibility to complete this Phase 2 trial, which is being conducted in Australia under an Investigational New Drug application on file with the FDA. We expect the results of this Phase 2 study to be available in early 2005. All clinical development following this Phase 2 clinical trial will be our responsibility. Assuming that the Phase 2 study is successful, we plan to initiate a Phase 3 clinical trial with Testosterone MDTS by the end of 2005.

MALE SEXUAL HEALTH

The erectile dysfunction market produces revenues in excess of $2.0 billion annually. Pfizer reported that it sold approximately $1.8 billion of Viagra(R), a phosphodiesterase type 5 (PDE5) inhibitor, worldwide in 2003. Pfizer received clearance from the FDA to market Viagra in 1998. In late 2003, two additional phosphodiesterase type 5 (PDE5) inhibitors were approved by the FDA: Levitra(R), launched by Bayer and GlaxoSmithKlineBeecham, and Cialis(R), launched by Lilly ICOS LLC. Based on the aging baby boomer population and their desire to maintain a healthy sexual lifestyle, we believe the market for PDE5 inhibitors should continue to grow.

AVANAFIL

We are developing avanafil, an orally administered PDE5 inhibitor, licensed from Tanabe Seiyaku Co., Ltd., or Tanabe, in 2001. Avanafil, formerly known as TA-1790, is currently in Phase 2 clinical development. Pre-clinical and clinical data to date suggests the product candidate is:

- Highly selective to PDE5, which we believe should result in a favorable side effect profile; and
- Fast acting, which should promote spontaneity.

In March 2004, we began enrolling patients in an at-home, double blind, randomized, parallel design Phase 2 clinical study to evaluate the safety and efficacy of avanafil. One of the primary goals of this study is to confirm the appropriate dose range in a large group of patients. Enrollment is anticipated to be completed by the end of 2004 and data from this study should be available during the first half of 2005. VIVUS plans to initiate drug interaction studies with avanafil during 2004 and anticipates completing Phase 2 development in 2005.

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, income taxes, restructuring, inventories and contingencies and litigation. (See Critical Accounting Policies and Estimates on page 23 of the Company's Annual Report on Form 10-K for the year ended December 31, 2003.) 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.

RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2004 AND 2003

For the three months ended June 30, 2004, we reported a net loss of ($4.9) million, or ($0.13) net loss per share as compared to a net loss of ($2.9) million, or ($0.08) net loss per share, during the same quarter in 2003. Lower product sales in the United States as well as increased clinical trial activity for ALISTA and avanafil were the primary reasons for the change from the same period last year.

We anticipate continued losses over the next several years because: (1) we expect MUSE sales to remain relatively flat year-over-year, and (2) 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. United States net product revenue for the quarter ended June 30, 2004 was $2.5 million compared to $2.7 million for the quarter ended June 30, 2003.

We expect U.S. quarterly sales levels to increase through the remainder of 2004 consistent with historical wholesale ordering patterns. However, we expect 2004 total annual MUSE sales will be lower than 2003 total annual MUSE sales.

International product revenue was $742,000 for the second quarter of 2004, a decrease of $218,000 compared to the same period last year. Based on current forecasts, we anticipate that 2004 international revenue will increase over 2003 levels.

COST OF GOODS SOLD AND GROSS PROFIT. Cost of goods sold in the second quarter of 2004 was $2.3 million, as compared to $2.4 million for the second quarter of 2003. During the three months ended June 30, 2004 and 2003, we used certain raw material inventory, the cost basis of which had been reduced to zero in prior years. This had a favorable impact on our cost of sales in the second quarter of 2004 and 2003 of $279,000 and $293,000, respectively. The lower gross profit in the second quarter of 2004 was primarily due to lower revenues in the quarter and increased costs for labor, benefits and utilities at the New Jersey manufacturing facility.

RESEARCH AND DEVELOPMENT EXPENSES. Research and development expenses for the second quarter of 2004 were $3.1 million, as compared to $1.8 million for the three months ended June 30, 2003. 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. The initiation of this Phase 2 clinical trial resulted in a $657,000 increase in expenses over the three months ended June 30, 2003. An additional $495,000 was spent during the three months ended June 30, 2004 for increased clinical trial and project activity for ALISTA, estradiol and testosterone. We do not expect to recognize revenue from sales of any new product candidates being developed through our research and development efforts until 2007 at the earliest.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses in the second quarter of 2004 of $2.8 million were $322,000 higher than the same period last year primarily due to an increase in spending for investor and public relations activities of $118,000 and marketing programs of $186,000.

INTEREST INCOME. Interest income for the three months ended June 30, 2004 was $156,000 as compared to $173,000 for the three months ended June 30, 2003. Declining interest rates and declining balances of cash, cash equivalents and available-for-sale securities contributed to the reduction in interest income.

PROVISION FOR INCOME TAXES. During the second quarter of 2004, we recorded a net tax provision of $2,000 for UK income taxes due for 2004. During the second quarter of 2003, there was no such provision.

SIX MONTHS ENDED JUNE 30, 2004 AND 2003

For the six months ended June 30, 2004, we reported a net loss of ($15.8) million, or ($0.42) net loss per share as compared to a net loss of ($6.1) million, or ($0.18) net loss per share, during the same period in 2003. Lower product sales in the United States, $4.7 million of charges for licensing and milestone payments associated with three of our four late-stage development programs in the pipeline and increased clinical trial and project activity for ALISTA and avanafil were the primary reasons for the change from the same period last year.

We anticipate continued losses over the next several years because: (1) we expect MUSE sales to remain relatively flat year-over-year, and (2) 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. United States net product revenue for the six months ended June 30, 2004 was $3.0 million compared to $6.1 million for the six months ended June 30, 2003. A decrease in sales in the first quarter of 2004 was anticipated as wholesale customers ordered large quantities of MUSE in the fourth quarter of 2003, in anticipation of a first quarter 2004 price increase.

We expect U.S. quarterly sales levels to increase through the remainder of 2004 consistent with historical wholesale ordering patterns. However, we expect 2004 total annual MUSE sales will be lower than 2003 total annual MUSE sales.

International product revenue was $2.1 million for the first six months of 2004, an increase of $274,000 compared to the same period last year. Based on current forecasts, we anticipate that 2004 international revenue will increase over 2003 levels.

COST OF GOODS SOLD AND GROSS PROFIT. Cost of goods sold in the first half of 2004 was $4.6 million, as compared to $5.2 million for the first half of 2003. Cost of goods sold decreased because of lower sales in the first half of 2004 versus the same period in 2003. During the six months ended June 30, 2004 and 2003, we used certain raw material inventory, the cost basis of which had been reduced to zero in prior years. This had a favorable impact on our cost of sales in the first half of 2004 and 2003 of $535,000 and $482,000, respectively. The lower gross profit in the first half of 2004 was also attributable to increased international sales, which carry lower sales prices and higher material costs than U.S. product, as well as increased costs for labor, benefits and utilities at the New Jersey manufacturing facility.

RESEARCH AND DEVELOPMENT EXPENSES. Research and development expenses for the six months ended June 30, 2004 were $10.8 million, as compared to $4.1 million for the six months ended June 30, 2003. During the first half of 2004, we entered into exclusive licensing agreements in the United States with a subsidiary of Acrux under which we will develop and commercialize an estradiol spray for the alleviation of the symptoms of menopause and a testosterone spray for the treatment of low sexual desire in women. We reported a total $2.9 million of licensing fees incurred under the terms of the agreements. Portions of these licensing fees will be paid in September 2004 ($250,000) and June 2005 ($930,000). In addition, during the first half 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 milestone obligation to Tanabe in the first quarter of 2004. The payment of this milestone will be made in March 2006. The initiation of the avanafil Phase 2 clinical trial in 2004 resulted in an additional $1.3 million increase in expenses over the six months ended June 30, 2003. We do not expect to recognize revenue from sales of any new product candidates being developed through our research and development efforts until 2007 at the earliest.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES. Selling, general and administrative expenses in the first half of 2004 of $5.8 million were $758,000 higher than the same period last year primarily due to an increase in spending for investor and public relations activities of $160,000 and marketing programs of $334,000.

INTEREST INCOME. Interest income for the six months ended June 30, 2004 was $316,000 as compared to $360,000 for the six months ended June 30, 2003. Declining interest rates and declining balances of cash, cash equivalents and available-for-sale securities contributed to the reduction in interest income.

PROVISION FOR INCOME TAXES. During the first half of 2004, we recorded a net tax provision of $5,000 for minimum state income taxes and UK income taxes, both due for 2004. During the six months ended June 30, 2003, there was no such provision.

LIQUIDITY AND CAPITAL RESOURCES

CASH. Unrestricted cash, cash equivalents and available-for-sale securities totaled $38.2 million at June 30, 2004 as compared to $48.3 million at December 31, 2003. The decrease is primarily due to low U.S. sales in the first half of 2004, normal operating expenses and a $1.8 million milestone payment to Acrux for our licensing agreement.

Since inception, we have financed operations primarily from the issuance of equity securities. Through June 30, 2004, we raised $173.9 million from financing activities and had an accumulated deficit of $116.7 million at June 30, 2004.

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.

We sequence the maturities of our investments consistent with our cash forecasts. The weighted average maturity of our portfolio is not to exceed 18 months. As investments mature, we re-invest the money by purchasing additional securities. We sell such investment securities based upon our need for cash for the payment of operating expenses. Gains and losses on sales of securities are typically insignificant because we sequence maturities consistent with our cash forecasts.

ACCOUNTS RECEIVABLE. Accounts receivable (net of allowance for doubtful accounts) at June 30, 2004 was $1.9 million as compared to $2.6 million at December 31, 2003. The 26.5% decrease in the accounts receivable balance at June 30, 2004 is due to a 37.1% decrease in the number of units sold in June 2004 as compared to December 2003. Currently, we do not have any significant concerns related to accounts receivable or collections.

LIABILITIES. Total liabilities were $19.9 million at June 30, 2004, $4.4 million higher than at December 31, 2003. Accrued research and development expenses increased $3.0 million due to the future payment of milestones to Acrux and Tanabe and notes payable increased $1.2 million due to borrowing under the agreement we signed with Tanabe in the first quarter of 2004 for a line of credit of up to $8.5 million to be used for the development of avanafil.

OPERATING ACTIVITIES. Our operating activities used $12.0 million and $4.6 million of cash during the six months ended June 30, 2004 and 2003, respectively. During the first six months of 2004, our net operating loss of $15.8 million was offset by a $3.0 million increase in accrued and other liabilities for the future payment of milestones to Acrux and Tanabe, as well as depreciation expense of $976,000. During the first six months of 2003, our net operating loss of $6.1 million was offset by a $1.6 million reduction in our accounts receivable due to the collection of monies owed to us.

INVESTING ACTIVITIES. Net cash provided by investing activities was $849,000 compared to the use of $16.0 million during the six months ended June 30, 2004 and 2003, 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 $2.0 million and $16.8 million during the six months ended June 30, 2004 and 2003, respectively. These amounts include the proceeds from the exercise of stock options in both the first six months of 2004 and 2003, borrowings from Tanabe in the first half of 2004 and the private placement of 4,375,000 shares of common stock for aggregate net proceeds of $16.4 million in the second quarter of 2003.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs for at least the coming year. 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 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 two percent. There are no financial covenants associated with this secured line of credit. As of June 30, 2004 we had long-term notes payable to Tanabe of $1.2 million, and $7.3 million of available credit under this agreement.

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.

OVERVIEW OF CONTRACTUAL OBLIGATIONS

Contractual Obligations	Payments Due by Period (in thousands)				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Leases (1)	3,452	1,317	2,135	--	--
Purchases (2)	5,886	2,061	3,060	765	--
Notes Payable (3)	1,198	--	--	1,198	--
Other Long Term Liabilities (4)	6,022	1,194	1,807	3,021	--
Total	16,558	4,572	7,002	4,984	--

(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. In 2003, we purchased $2.1 million of product and are committed to purchase a minimum total of $3.8 million of product from 2004 through 2008. As of June 30, 2004, we have not purchased any additional product from this supplier.

In January 2004, we entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. We will be required to purchase a minimum total of $2.3 million of product from 2004 through 2006. As of June 30, 2004, we have purchased $234,000 of product from this supplier.

(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 two percent. There are no financial covenants associated with this secured line of credit. As of June 30, 2004 we have $7.3 million of available credit under this agreement.

(4) Other Long Term Liabilities includes the restoration liability 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.

In January 2004, we entered into exclusive licensing agreements with a subsidiary of Acrux under which we will develop and commercialize an estradiol spray for the alleviation of the symptoms of menopause and a testosterone spray for the treatment of low sexual desire in women. We reported a total $2.9 million of licensing fees incurred under the terms of the agreements. Portions of these licensing fees will be paid in September 2004 ($250,000) and June 2005 ($930,000). 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 milestone obligation to Tanabe in the first quarter of 2004. The payment of this milestone will be made in March 2006.

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.

IF WE WERE UNABLE TO CONTINUE TO DEVELOP, MARKET AND OBTAIN REGULATORY APPROVAL FOR NEW PRODUCT CANDIDATES, OUR BUSINESS WOULD BE HARMED.

The process of developing new drugs and/or therapeutic products is inherently complex and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will eventually result in products that will receive regulatory approval and achieve market acceptance. As with any pharmaceutical product under development, there are significant risks in development, regulatory approval and commercialization of new compounds. During the product development phase, there is no assurance

that the United States Food and Drug Administration will approve our clinical trial protocols. There is no guarantee that future clinical studies, if performed, will demonstrate the safety and efficacy of any product in development or that we will receive regulatory approval for such products. Further, the United States Food and Drug Administration 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.

We cannot predict with certainty if or when we might submit for regulatory review those product candidates currently under development. Once we submit our potential products for review, we cannot assure you that the United States Food and Drug Administration or other regulatory agencies will grant approvals for any of our proposed products on a timely basis or at all. Further, even if we receive regulatory approval for a product, there can be no assurance that such product will prove to be commercially successful or profitable.

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 United States Food and Drug Administration 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.

In February 2004, we entered into exclusive license agreements with a subsidiary of Acrux for the development and commercialization of topically applied Testosterone MDTS and Estradiol MDTS, in the United States only, for the treatment of low sexual desire and menopausal symptoms in women, respectively. Acrux has conducted clinical trials for both products under Investigational New Drug Applications on file with the United States Food and Drug Administration. Acrux is currently conducting a 200-patient Phase 2 study in Australia for Testosterone MDTS, which is expected to be completed in early 2005. We will conduct all other future development and clinical work for Testosterone MDTS. Assuming favorable results, we anticipate that we will begin Phase 3 clinical development of Testosterone MDTS in 2005. We plan to conduct Phase 3 clinical development for Estradiol MDTS in late 2004 for short-term therapy for women experiencing symptoms associated with menopause. However, there are no guarantees that Testosterone MDTS and/or Estradiol MDTS will prove to be safe and effective or receive regulatory approval for any indication. Further, even if we were to receive regulatory approval for these products, there can be no assurance that such products will prove to be commercially successful or profitable.

We are developing avanafil, formerly known as TA-1790, as potential oral and local treatments for male and female sexual dysfunction, and we are developing ALISTA for the potential treatment of female sexual arousal disorder. We are currently conducting pre-clinical safety studies for avanafil and have completed dosing in two efficacy studies in patients with erectile dysfunction. In March 2004, we began a Phase 2 clinical trial for avanafil, the results of which are expected in the first half of 2005. We also completed three Phase 2 ALISTA clinical trials. We intend to initiate additional clinical studies that would be required to obtain regulatory approval for avanafil and ALISTA. However, there are no guarantees that avanafil and/or ALISTA will prove to be safe and effective or receive regulatory approval for any indication. Further, even if we were to receive regulatory approval for these products, there can be no assurance that such products will prove to be commercially successful or profitable.

THE MARKETS IN WHICH WE OPERATE ARE HIGHLY COMPETITIVE AND WE MAY BE UNABLE TO COMPETE SUCCESSFULLY AGAINST NEW ENTRANTS OR ESTABLISHED COMPANIES WITH GREATER RESOURCES.

Competition in the pharmaceutical and medical products industries is intense and is characterized by extensive research efforts and rapid technological progress. The most significant competitive therapy for MUSE is an oral medication marketed by Pfizer 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. Another oral medication under the name Uprima was approved and launched in Europe by Abbott Laboratories and Takeda in May 2001. 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. Cialis was launched in the United States in January 2004. Bayer AG and GlaxoSmithKline plc launched Levitra in the European Union and the United States in March and September 2003, respectively.

Other treatments for erectile dysfunction exist, such as needle injection therapy, vacuum constriction devices and penile implants, and the manufacturers of these products will most likely continue to improve these therapies. Additional competitive products in the erectile dysfunction market include needle injection therapy products from Pfizer (formerly Pharmacia), Schwartz Pharma, Fornier and Senetek.

Several large 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 abilities than VIVUS. 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.

IF WE, OR OUR SUPPLIERS, FAIL TO COMPLY WITH UNITED STATES FOOD AND DRUG ADMINISTRATION AND OTHER GOVERNMENT REGULATIONS, OUR MANUFACTURING OPERATIONS COULD BE INTERRUPTED, AND OUR PRODUCT SALES AND PROFITABILITY COULD SUFFER.

All new drugs, including our products under development, are subject to extensive and rigorous regulation by the United States Food and Drug Administration and comparable foreign authorities. These regulations govern, among other things, the development, pre-clinical and clinical testing, manufacturing, labeling, storage, pre-market approval, advertising, promotion, sale and distribution of our products. To date, MUSE has received marketing approval in more than 40 countries worldwide.

After regulatory approval is obtained, our products are subject to continual regulatory review. Manufacturing, labeling and promotional activities are continually regulated by the United States Food and Drug Administration and equivalent foreign regulatory agencies, and we must also report certain adverse events involving our products to these agencies. Previously unidentified adverse events or an increased frequency of adverse events that occur post-approval could result in labeling modifications of approved products, which could adversely affect future marketing. Finally, approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. 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.

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 marketing and manufacturing of pharmaceutical products are subject to continual United States Food and Drug Administration and other regulatory review, and later discovery of previously unknown problems with a product, manufacturer or facility may result in the United States Food and Drug Administration and/or other regulatory agencies requiring further clinical research or restrictions on the product or the manufacturer, including withdrawal of the product from the market. 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.

Failure of our third-party manufacturers to maintain satisfactory compliance with current Good Manufacturing Practices, or cGMPs, could have a material adverse effect on our ability to continue to market and distribute our products and, in the most serious cases, could result in the issuance of warning letters, seizure or recall of products, civil penalties or closure of our manufacturing facility until such 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 that are required to comply with strict standards established by us. Certain suppliers and service providers are required to follow cGMP requirements and are subject to routine unannounced periodic inspections by the United States Food and Drug Administration and by certain state and foreign regulatory agencies for compliance with cGMP requirements and other applicable regulations. Certain of our suppliers were inspected for cGMP compliance as part of the approval process. However, upon routine re-inspection of these facilities, there can be no assurance that the United States Food and Drug Administration and other regulatory agencies will find the manufacturing process or facilities to be in compliance with cGMP requirements and other regulations.

Failure to achieve satisfactory cGMP compliance as confirmed by routine 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.

WE HAVE LIMITED SALES AND MARKETING CAPABILITIES IN THE UNITED STATES.

We support MUSE sales in the United States through a small sales support group targeting major accounts that include the top prescribers of MUSE. 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 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, and we rely on various third parties to perform this function. 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.

WE RELY ON THIRD PARTIES TO CONDUCT CLINICAL TRIALS FOR OUR PRODUCT CANDIDATES IN DEVELOPMENT AND THOSE THIRD PARTIES MAY NOT PERFORM SATISFACTORILY.

We do not have the ability to independently conduct clinical studies for any of our products currently in development, and we rely on third parties to perform this function. If third parties 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 and may not be able to successfully commercialize these proposed products. If third parties do not perform satisfactorily, we may not be able to locate acceptable replacements or enter into favorable agreements with them, if at all.

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 commencement and rate of completion of clinical trials may be delayed by many factors, including:

- ineffectiveness of the study compound, or perceptions by physicians that the compound is not effective for a particular indication;
- inability to manufacture sufficient quantities of compounds for use in clinical trials;
- failure of the United States Food and Drug Administration to approve our clinical trial protocols;
- slower than expected rate of patient recruitment;
- inability to adequately follow patients after treatment;
- unforeseen safety issues; or
- government or regulatory delays.

The clinical results we have obtained to date 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 United States Food and Drug Administration or physicians, our business, financial condition and results of operations will be materially harmed.

IF WE REQUIRE ADDITIONAL CAPITAL FOR OUR FUTURE OPERATING PLANS, WE MAY NOT BE ABLE TO SECURE THE REQUISITE ADDITIONAL FUNDING ON ACCEPTABLE TERMS, IF AT ALL.

Our capital resources from operating activities are expected to continue to decline over the next several quarters as the result of increased spending for research and development projects, including clinical trials. We expect that our existing capital resources combined with future cash flows will be sufficient to support operating needs for at least the coming year. Financing in future periods will most likely be required to fund development of our research and development pipeline and the possible launch of any future products. Our future capital requirements will depend upon numerous factors, including:

- the progress of our research and development programs;
- the scope, timing and results of pre-clinical testing and 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 the Company.

WE MAY BE SUED FOR INFRINGING ON 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. 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 event, 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.

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 initially receive regulatory approval for suppliers and we obtained our current supply of alprostadil from two approved sources. The first is NeraPharm, formerly Spolana Chemical Works a.s., in Neratovice, Czech Republic. The second is Chinoin Pharmaceutical and Chemical Works Co., Ltd. We have manufacturing agreements with Chinoin and NeraPharm respectively, to produce additional quantities of alprostadil for us. We are currently in the process of assuring the new material meets testing and regulatory specifications. There can be no guarantees the material will pass these requirements and be usable material in our manufacturing process. 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, if at all.

Furthermore, 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 COULD HARM OUR BUSINESS.

We entered into a distribution agreement with Cardinal Health. Under this agreement, Cardinal Health takes the following actions:

- 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.

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. There can be no assurance that such efforts will be successful.

We have an agreement with WRB Communications to handle patient and healthcare professional hotlines for us. WRB Communications maintains a staff of healthcare professionals to answer questions and inquiries about MUSE and ACTIS. These calls 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 Bergen Brunswig Corporation. ICS provides "direct-to-physician" distribution capabilities 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. There can be no assurance that such efforts will be successful.

WE CURRENTLY DEPEND ON A SINGLE SOURCE FOR THE SUPPLY OF PLASTIC APPLICATOR COMPONENTS, AND AN INTERRUPTION TO THIS SUPPLY SOURCE COULD HARM OUR BUSINESS.

We rely on a single injection molding company, Medegen, for our supply of plastic applicator components. In turn, Medegen obtains its supply of resin, a key ingredient of the applicator, from a single source, Huntsman Corporation. There can be no assurance that we will be able to identify and qualify additional sources of plastic components. We are required to initially receive United States Food and Drug Administration approval for 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 development and commercial 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 and results of operations.

ALL OF OUR MANUFACTURING OPERATIONS ARE CURRENTLY CONDUCTED AT A SINGLE LOCATION, AND A PROLONGED INTERRUPTION TO OUR MANUFACTURING OPERATIONS COULD HARM OUR BUSINESS.

We 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 United States Food and Drug Administration and the Medicines and Healthcare products Regulatory Agency, formerly the Medicines Control 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 DEPEND EXCLUSIVELY ON THIRD-PARTY DISTRIBUTORS OUTSIDE OF THE UNITED STATES AND WE HAVE VERY LIMITED CONTROL OVER THEIR ACTIVITIES.

We entered into agreements granting Meda AB exclusive marketing and distribution rights for MUSE and ACTIS in all Member States of the European Union, the Baltic States, the Czech Republic, Hungary, Iceland, Norway, Poland, Switzerland and Turkey. These agreements do not have minimum purchase commitments and we are entirely dependent on Meda AB's efforts to distribute and sell our products effectively in all these markets. There can be no assurance that such efforts will be successful or that Meda AB will continue to support the products.

We entered into an agreement granting Paladin Labs 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.

WE HAVE AN ACCUMULATED DEFICIT OF $116.7 MILLION AT JUNE 30, 2004 AND EXPECT TO CONTINUE TO INCUR SUBSTANTIAL OPERATING LOSSES FOR THE FORESEEABLE FUTURE.

We have generated a cumulative net loss of $116.7 million for the period from our inception through June 30, 2004 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 on a sustained basis. Accordingly, there can be no assurance of our future success.

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 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, 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 and ACTIS are 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 do 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.

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 exposes us to a significant risk of product liability claims due to its availability to a large population of patients. In addition, pharmaceutical products are subject to heightened risk for product liability claims due to inherent side effects. We detail 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.

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;
- our ability to increase demand for our products in the United States;
- 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 Company assessments 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; or
- 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.

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.

Certain 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.

The Financial Accounting Standards Board is considering whether to require all companies to treat the value of stock options granted to employees as an expense. The United States Congress and other governmental and regulatory authorities have also considered requiring companies to expense stock options. If this change were to become mandatory, we and other companies would be required to record a compensation expense equal to the fair market value of each stock option granted. 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. If we were required to expense stock option grants, it would reduce the attractiveness of granting stock options because of the additional expense associated with these grants, which would 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, in the event 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.

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 June 30, 2004, we had drawn $1.2 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. At December 31, 2003 we had no debt outstanding, and therefore no risk exposure associated with increasing interest rates. 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.

(c.) Limitations on the effectiveness of disclosure controls and procedures. Our management, including the Chief Executive Officer and Chief Financial Officer, has designed the internal disclosure controls and procedures to provide only reasonable assurance that such disclosure controls and procedures will meet stated objectives. Even well designed and operated disclosure controls and procedures systems are susceptible to inherent limitations resulting in failures to meet stated objectives. Such inherent limitations include, but are not limited to, faulty assumptions in the design of the controls and procedures, fraud by individuals, and error or mistake by those overseeing the controls and procedures. As a result, no evaluation of the disclosure controls and procedures can provide absolute assurance that such disclosure controls and procedures will meet stated objectives.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

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

The annual meeting of the stockholders of VIVUS, Inc. was held on June 14, 2004 at our principal executive office. Matters voted on at that meeting were: (i) the election of six (6) directors, and (ii) the confirmation of the appointment of KPMG LLP as the Company's independent auditor for the year ending December 31, 2004.

Proposal I. Election of Directors

Tabulations for each individual director were as follows:

DIRECTOR	FOR	WITHHELD
Virgil A. Place, MD	29,471,821	2,194,720
Leland F. Wilson	29,468,336	2,198,205
Mark B. Logan	31,016,885	649,656
Linda M. Dairiki Shortliffe, MD	30,963,534	703,007
Mario M. Rosati	28,447,296	3,219,245
Graham Strachan	31,020,898	645,643

Proposal II. Confirmation of the appointment of KPMG LLP as the Company's independent auditor for the year ending December 31, 2003

Tabulations for the confirmation of the appointment of KPMG LLP as the Company's independent auditor for the year ending December 31, 2004 were as follows:

FOR	AGAINST	ABSTAIN	NO VOTE
31,435,376	119,483	111,682	--

ITEM 5. OTHER INFORMATION

NONE.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) EXHIBITS (IN ACCORDANCE WITH ITEM 601 OF REGULATION S-K)

EXHIBIT NUMBER	DESCRIPTION
3.2(4)	Amended and Restated Certificate of Incorporation of the Company.
3.3(3)	Bylaws of the Registrant, as amended.
3.4(5)	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock.
4.1(4)	Specimen Common Stock Certificate of the Registrant.
4.5(5)	Second Amended and Restated Preferred Shares Rights Agreement, dated as of April 15, 1997 by and between the Registrant and Harris Trust Company of California, including the Certificate of Determination, the form of Rights Certificate and the Summary of Rights attached thereto as Exhibits A, B, and C, respectively.
10.1(1)+	Assignment Agreement by and between Alza Corporation and the Registrant dated December 31, 1993.
10.2(1)+	Memorandum of Understanding by and between Ortho Pharmaceutical Corporation and the Registrant dated February 25, 1992.
10.3(1)+	Assignment Agreement by and between Ortho Pharmaceutical Corporation and the Registrant dated June 9, 1992.
10.4(1)+	License Agreement by and between Gene A. Voss, MD, Allen C. Eichler, MD, and the Registrant dated December 28, 1992.
10.5A(1)+	License Agreement by and between Ortho Pharmaceutical Corporation and Kjell Holmquist AB dated June 23, 1989.
10.5B(1)+	Amendment by and between Kjell Holmquist AB and the Registrant dated July 3, 1992.
10.5C(1)	Amendment by and between Kjell Holmquist AB and the Registrant dated April 22, 1992.
10.5D(1)+	Stock Purchase Agreement by and between Kjell Holmquist AB and the Registrant dated April 22, 1992.
10.6A(1)+	License Agreement by and between Amsu, Ltd., and Ortho Pharmaceutical Corporation dated June 23, 1989.
10.6B(1)+	Amendment by and between Amsu, Ltd., and the Registrant dated July 3, 1992.
10.6C(1)	Amendment by and between Amsu, Ltd., and the Registrant dated April 22, 1992.
10.6D(1)+	Stock Purchase Agreement by and between Amsu, Ltd., and the Registrant dated July 10, 1992.
10.11(3)	Form of Indemnification Agreements by and among the Registrant and the Directors and Officers of the Registrant.
10.12(2)	1991 Incentive Stock Plan and Form of Agreement, as amended.
10.13(1)	1994 Director Option Plan and Form of Agreement.
10.14(1)	Form of 1994 Employee Stock Purchase Plan and Form of Subscription Agreement.
10.17(1)	Letter Agreement between the Registrant and Leland F. Wilson dated June 14, 1991 concerning severance pay.
10.28(4)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates.
10.29(4)	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates.
10.29A(6)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates.
10.29B(6)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates.
10.36(7)	Form of, "Change of Control Agreements," dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company.
10.39(8)	Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999.
10.41(9)+	License and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
10.42(9)+	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and TANABE SEIYAKU CO., LTD.
10.42A	Amendment One to Agreement, dated January 9, 2004 between Registrant and TANABE SEIYAKU CO., LTD.
10.43(10)+	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc. Gary W. Neal and the Registrant.
10.44(11)	2001 Stock Option Plan and Form of Agreement.

EXHIBIT NUMBER	DESCRIPTION
10.45(12)+	Supply Agreement made as of September 3, 2002 between the Registrant and Meda AB.
10.46(13)+	Amendment Three, dated November 21, 2002 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works, Ltd.
10.47(13)	Lease Amendment No. 4 and Settlement Agreement dated October 25, 2000 by and between the Registrant and Airport Associates.
10.48(13)+	Exclusive Distribution Agreement dated October 1, 2002 between the Registrant and Cord Logistics.
10.49(13)+	Distribution and Supply Agreement made as of February 18, 2003 between the Registrant and Meda AB.
10.50(14)++	Testosterone Development and Commercialization Agreement made as of February 7, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.51(14)++	Estradiol Development and Commercialization Agreement made as of February 12, 2004 between the Registrant, Fempharm Pty Ltd. and Acrux DDS Pty Ltd.
10.52(14)++	Note Purchase Agreement, dated January 8, 2004 between Registrant and Tanabe Holding America, Inc.
10.53(14)++	Manufacture and Supply Agreement, dated December 22, 2003 between Registrant and NeraPharm spol., s.r.o. and signed by the Company on January 7, 2004.
31.1	Certification of Chief Executive Officer, dated August 5, 2004, 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 August 5, 2004, pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934, as amended.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\+ Confidential treatment granted.
++ Confidential treatment requested.

(1) Incorporated by reference to the same-numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-75698, as amended.

(2) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-1 No. 33-90390, as amended.

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

(4) 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.

(5) 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.

(6) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997.

(7) 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, 1998.

(8) 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, 1999.

(9) 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, 2000.

(10) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001.

(11) Incorporated by reference to the same numbered exhibit filed with the Registrant's Registration Statement on Form S-8 filed with the Commission on November 15, 2001.

(12) Incorporated by reference to the same numbered exhibit filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended November 30, 2002.

(13) 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, 2002.

(14) Incorporated by reference to the same numbered exhibit filed with the Registrant's Annual Report on Form 10-Q for the quarter ended March, 31, 2004.

(b) Reports on Form 8-K.

On April 29, 2004, we furnished a current report on Form 8-K that disclosed our financial results for the first quarter ended March 31, 2004 and certain other information. The Form 8-K included our unaudited financial statements for the first quarter ended March 31, 2004.

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: August 5, 2004 VIVUS, Inc.

/s/ LARRY J. STRAUSS

Larry J. Strauss
Vice President, Finance and Chief Financial Officer

/s/ LELAND F. WILSON

Leland F. Wilson
President and Chief Executive Officer

VIVUS, INC.

INDEX TO EXHIBITS

EXHIBIT	DESCRIPTION
31.1	Certification of Chief Executive Officer, dated August 5, 2004, 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 August 5, 2004, 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

EXHIBIT 31.1

CERTIFICATION

I, Leland F. Wilson, certify that:

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

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

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

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

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

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

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

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

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

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

Date: August 5, 2004

By: /s/ LELAND F. WILSON

Name: Leland F. Wilson
Title: President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Larry J. Strauss, certify that:

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

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

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

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

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

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

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

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

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

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

Date: August 5, 2004

By: /s/ LARRY J. STRAUSS

Name: Larry J. Strauss
Title: Vice President, Finance and Chief Financial Officer

EXHIBIT 32

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

I, Leland F. Wilson, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ending June 30, 2004 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc.

August 5, 2004 By: /s/ Leland F. Wilson

Leland F. Wilson
President and Chief Executive Officer

I, Larry J. Strauss, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of VIVUS, Inc. on Form 10-Q for the period ending June 30, 2004 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc.

August 5, 2004 By: /s/ Larry J. Strauss

Larry J. Strauss
Vice President, Finance and Chief Financial Officer