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

FORM 10–Q

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2002

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)	(I.R.S. EMPLOYER IDENTIFICATION NUMBER)
1172 CASTRO STREET MOUNTAIN VIEW, CA (ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)	94040 (ZIP CODE)

(650) 934–5200
(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

N/A
(FORMER NAME, FORMER ADDRESS AND FORMER FISCAL YEAR, IF CHANGED SINCE LAST REPORT)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. [X] Yes [ ] No

At August 2, 2002, 32,949,757 shares of common stock were outstanding.

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VIVUS, INC.

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

ASSETS

	JUNE 30, 2002	DECEMBER 31, 2001*
	(UNAUDITED)	
Current assets:		
Cash and cash equivalents	$ 5,526	$ 11,545
Available–for–sale securities	9,536	7,835
Accounts receivable, net	638	2,314
Inventories, net	2,778	3,100
Prepaid expenses and other assets	1,443	780
Total current assets	19,921	25,574
Property and equipment, net	11,309	12,378
Restricted cash	3,324	3,324
Available–for–sale securities, non–current	19,661	17,298
Total assets	$ 54,215	$ 58,574
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,272	$ 1,241
Accrued and other liabilities	9,365	9,435
Total current liabilities	10,637	10,676
Accrued and other long–term liabilities	3,923	3,923
Total liabilities	14,560	14,599
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding — June 30, 2002, 32,950; December 31, 2001, 32,693	33	33
Paid in capital	134,818	133,988
Accumulated other comprehensive income	370	322
Accumulated deficit	(95,566)	(90,368)
Total stockholders' equity	39,655	43,975
Total liabilities and stockholders' equity	$ 54,215	$ 58,574

* The Condensed Consolidated Balance Sheet at December 31, 2001 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, 2002	JUNE 30, 2001	JUNE 30, 2002	JUNE 30, 2001
	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
Revenue				
US product	$ 4,642	$ 5,032	$11,237	$10,269
International product	244	1,633	869	3,051
Returns	(339)	(295)	(1,176)	(591)
Total net revenue	4,547	6,370	10,930	12,729
Cost of goods sold	1,550	3,164	4,904	6,797
Gross profit	2,997	3,206	6,026	5,932
Operating expenses:				
Research and development	3,980	1,937	6,753	7,941
Selling, general and administrative	2,712	2,712	5,400	4,949
Total operating expenses	6,692	4,649	12,153	12,890
Loss from operations	(3,695)	(1,443)	(6,127)	(6,958)
Interest and other income	354	529	661	1,160
Loss before benefit for income taxes	(3,341)	(914)	(5,466)	(5,798)
Benefit for income taxes	—	—	268	—
Net loss	$ (3,341)	$ (914)	$ (5,198)	$ (5,798)
Net loss per share:				
Basic	$ (0.10)	$ (0.03)	$ (0.16)	$ (0.18)
Diluted	$ (0.10)	$ (0.03)	$ (0.16)	$ (0.18)
Shares used in per share computation:				
Basic	32,913	32,530	32,847	32,501
Diluted	32,913	32,530	32,847	32,501

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, 2002	JUNE 30, 2001	JUNE 30, 2002	JUNE 30, 2001
	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
Net loss	$(3,341)	$(914)	$(5,198)	$(5,798)
Other comprehensive income (loss):				
Unrealized gain (loss) on securities	236	(9)	48	(5)
Comprehensive (loss)	$(3,105)	$(923)	$(5,150)	$(5,803)

See accompanying notes to the Condensed Consolidated Financial Statements

VIVUS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	SIX MONTHS ENDED JUNE 30,	
	2002	2001
	(UNAUDITED)	(UNAUDITED)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss)	$ (5,198)	$ (5,798)
Adjustments to reconcile net (loss) to net cash (used for) operating activities:		
Depreciation and amortization	1,138	1,126
Stock compensation costs	52	—
Changes in assets and liabilities:		
Accounts receivable, net	1,676	414
Inventories	322	1,038
Prepaid expenses and other assets	(663)	(152)
Accounts payable	31	(624)
Accrued and other liabilities	(70)	(865)
Net cash (used for) operating activities	(2,712)	(4,861)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Property and equipment purchases	(69)	(259)
Investment purchases	(8,231)	(16,606)
Proceeds from sale/maturity of securities	4,215	12,556
Net cash (used for) investing activities	(4,085)	(4,309)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of common stock options	624	242
Sale of common stock through employee stock purchase plan	154	160
Net cash provided by financing activities	778	402
NET (DECREASE) IN CASH	(6,019)	(8,768)
CASH:		
Beginning of period	11,545	29,236
End of period	$ 5,526	$ 20,468
NON–CASH INVESTING AND FINANCING ACTIVITIES:		
Unrealized gain (loss) on securities	$ 48	$ (5)
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Income taxes paid	$ —	$ 113

See accompanying notes to the Condensed Consolidated Financial Statements

VIVUS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2002

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, 2002 are not necessarily indicative of the results that may be expected for the year ending December 31, 2002. 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, 2001.

2. INVENTORIES

Inventories are recorded net of reserves of $7.5 million as of both June 30, 2002 and December 31, 2001 and consist of (in thousands):

	JUNE 30, 2002	DECEMBER 31, 2001
Raw materials	$ 737	$1,845
Work in process	58	44
Finished goods	1,983	1,211
Inventory, net	$2,778	$3,100

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 currently includes in cost of goods sold the standard cost of raw materials inventory. However, the Company expects that it will begin using its fully reserved raw materials inventory in approximately six months. From that point forward, the fully reserved raw materials will be charged to cost of goods sold at a zero basis, which will have a favorable impact on gross profit.

3. ACCRUED AND OTHER LIABILITIES

Accrued and other liabilities as of June 30, 2002 and December 31, 2001 consist of (in thousands):

	JUNE 30, 2002	DECEMBER 31, 2001
Restructuring	$ 3,315	$ 3,923
Product returns	2,165	1,523
Income taxes	1,657	1,952
Research and clinical expenses	2,078	1,118
Royalties	398	473
Unearned revenue	2,123	2,151
Employee compensation and benefits	959	1,485
Other	593	733
	13,288	13,358
Amount classified as short–term	(9,973)	(9,435)
Amount classified as long–term	$ 3,315	$ 3,923

4. RESTRUCTURING RESERVE

During 1998, VIVUS, Inc. experienced a significant decline in market demand for MUSE® 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, 2001 included in the Company's Annual Report on Form 10–K.) The restructuring reserve balance at June 30, 2002 was $3.3 million, down from $3.9 million at December 31, 2001.

The activity in the restructuring reserve for the six months ended June 30, 2002 is summarized as follows (in thousands):

	INVENTORY AND RELATED COMMITMENTS	PROPERTY AND RELATED COMMITMENTS	TOTAL
Balance at December 31, 2001	$ 902	$3,021	$3,923
Activity in first quarter 2002	—	—	—
Activity in second quarter 2002*	(608)	—	(608)
Balance at June 30, 2002	$ 294	$3,021	$3,315

* During the second quarter of 2002, the Company paid $100 thousand and reversed $508 thousand of the restructuring reserve related to inventory purchase commitments that were not required based on the outcome of negotiations with a supplier.

The Company expects that during the next twelve months it will make cash payments of approximately $294 thousand related to the restructuring, with the remaining $3.0 million in cash payments to occur in later periods.

5. CONCENTRATION OF CUSTOMERS AND SUPPLIERS

During the first six months of 2002 and 2001, sales to significant customers as a percentage of total revenues were as follows:

	2002	2001
Customer A	22%	21%
Customer B	22%	10%
Customer C	19%	15%
Customer D	18%	14%

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

6. STOCK OPTION AND PURCHASE PLANS

The 2001 Stock Option Plan was approved by the stockholders of VIVUS, Inc. at the annual meeting held June 5, 2002.

7. LEGAL MATTERS

On November 3, 1999, the Company filed a demand for arbitration against Janssen Pharmaceutica International ("Janssen") with the American Arbitration Association pursuant to the terms of the Distribution Agreement entered into on January 22, 1997. The Company sought compensation for inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted by Janssen. The Company also sought compensation for forecasts and order shortfalls attributed to Janssen in 1998, pursuant to the terms of the Distribution Agreement. The Company amended its arbitration demand in August 2000 to include claims for lost profits due to Janssen's failure to use the requisite diligence and reasonable efforts to gain regulatory approval for and launch MUSE in China. A full hearing on the merits was conducted before a three–member arbitration panel in Chicago on March 18 – 20, 2002. On July 17, 2002, an Interim Award was issued awarding the Company the purchase price of 332,880 units manufactured for Janssen and lost profits on an additional 421,704 forecasted units. The Panel denied any relief on claims related to diligence in China. The dollar value of the claim will be determined by an audit of VIVUS' cost of goods sold by an independent accountant. This audit is scheduled to begin in mid– August 2002. Also in its Interim Award, the Panel requested further briefing on whether the Company is entitled to interest and attorney's fees as the prevailing party.

This Quarterly Report on Form 10–Q contains forward–looking statements about the potential development and commercialization of pharmaceutical products and reflects management's current beliefs. However, as with any pharmaceutical product under development, there are significant risks related to the development, regulatory approval and commercialization of new products. The Company's actual results could differ from those set forth in such forward–looking statements as a result of certain factors, including those set forth in the Risk Factors section starting on page 11 of this document.

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

OVERVIEW

VIVUS, Inc. ("VIVUS," also referred to herein as "we," "us," and "our") is a pharmaceutical company developing innovative products to improve quality of life disorders in men and women, with a focus on sexual dysfunction. We developed and market in the United States ("U.S.") MUSE® (alprostadil) and ACTIS®, two innovations in the treatment of erectile dysfunction ("ED"), and have entered into a license and supply agreement with Abbott Laboratories ("Abbott") (NYSE:ABT) for the international marketing and distribution of our male transurethral ED products. In Canada, we have entered into a license and supply agreement with Paladin Labs, Inc. ("Paladin") (TSE:PLB) by which Paladin markets and distributes MUSE. We have ongoing research and development ("R&D") programs in male ED, female sexual dysfunction ("FSD"), and premature ejaculation ("PE").

In recent years we have invested in a number of R&D projects. The current status of certain R&D projects is depicted in the chart below.

Indication	Product Candidate	Progress
Erectile Dysfunction	ALIBRA	Regulatory Review
	TA-1790 (oral)	Phase I Efficacy
	TA–1790 (transurethral)	Pre–clinical
Female Sexual Dysfunction	ALISTA (topical PGE1)	Phase II/III
	TA–1790	Pre–clinical
Premature Ejaculation	VI–0134	Phase I

We anticipate that our R&D expenses will continue to increase as we further the development of our current R&D pipeline, target acquisitions of new technologies and pursue the development of patentable uses of known pharmacologic agents for which significant safety data already exists.

Recent progress and current plans in our R&D projects include:

- **ALISTA**™– A proprietary formulation of alprostadil applied locally to the female genitalia to treat female sexual arousal disorder ("FSAD").
  - Our first Phase II clinical study, which was an in–clinic, multi–center trial designed to evaluate the safety of and response to ALISTA in subjects with FSAD, was completed. The study demonstrated a significant increase versus placebo and baseline in sexual response associated with visual sexual stimulation in women with FSAD. ALISTA was associated with a rapid and sustained improvement in sexual response.
  - An expanded Phase II/III study, designed to evaluate the efficacy and safety of ALISTA when used by women with FSAD at–home with their partner, began in the first quarter of 2002. During the second quarter of 2002, we continued recruitment and the study is progressing well.
- **TA–1790** – A relatively fast–acting, highly selective, potent phosphodiesterase type 5 (PDE5) inhibitor for the oral and local treatments of ED and FSD.
  - We successfully filed an Investigational New Drug ("IND") application with the U.S. Food & Drug Administration ("FDA") in December 2001 to initiate a clinical study to evaluate the safety of and erectile response to oral TA–1790 in men with ED. This trial began in the first quarter of 2002. To date, patient enrollment is ongoing and we are on track to conclude the trial by the fourth quarter of 2002.

— We began pre–clinical development work on the local administration of TA–1790, alone and in combination with alprostadil, for the treatment of ED. Our goal for the local administration of TA–1790 is to provide an effective therapy for patients who do not have success with oral treatments.

- **VI–0134** – An on demand, oral treatment for PE.

— During the fourth quarter of 2001, we initiated a clinical trial to evaluate the pharmacokinetic (blood levels in relation to time) profile of our new, oral formulation of VI–0134. This study was completed during the second quarter of 2002. In light of the recently issued patent covering the use of PDE inhibitors for the treatment of PE, we are currently evaluating our strategic options for VI–0134 and our PDE5 inhibitor for this indication. We intend to conduct preliminary studies to evaluate the effects of TA–1790 on ejaculatory latency in the second half of 2002 and further development of VI–0134 would be dependent on the outcome of those studies.

We continue to place significant emphasis on securing global intellectual property rights and we are pursuing new patents to expand upon our foundation for commercializing products in development. In the U.S., patents and patent applications licensed to and developed by VIVUS currently include 22 in ED, 14 in FSD and 7 in PE.

FISCAL 2002 HIGHLIGHTS

FIRST QUARTER

The Company reported a net loss of $1.9 million, for a $0.06 net loss per share. Spending for R&D and lower international product revenue contributed to the loss.

We began our expanded Phase II/III study with ALISTA, which is a trial designed to evaluate the safety and efficacy of the product when used by women with FSAD at–home with their partner.

After successfully filing an IND with the FDA in December 2001, we began a clinical study to evaluate the safety of and erectile response to oral TA-1790 in men with ED.

SECOND QUARTER

The Company reported a net loss of $3.3 million, for a $0.10 net loss per share. Spending for R&D and lower product revenue contributed to the loss.

VIVUS was awarded a new patent by the U.S. Patent & Trademark office for the use of phosphodiesterase inhibitors to treat PE.

RESULTS OF OPERATIONS

Three Months Ended June 30, 2002 and 2001

U.S. net product revenue for the quarter ended June 30, 2002 was $4.3 million, compared to $4.7 million for the quarter ended June 30, 2001.

International product revenue was $244 thousand for the second quarter of 2002, a decrease of $1.4 million compared to the same period last year. Based on projected sales to our international partners, we expect that international revenue will decline further in the remaining quarters of 2002.

Cost of goods sold was $1.6 million for the second quarter of 2002, compared to $3.2 million for the second quarter of 2001. The cost of goods sold for the quarter ended June 30, 2002 was favorably impacted by a $508 thousand reduction against accruals made in 1998 for inventory purchase commitments that were no longer needed based on the outcome of negotiations with a supplier. Adjusting for this item, comparative gross profit margins for the second quarter of 2002 versus the second quarter of 2001 would have been 55% and 50%, respectively. We increased our production of finished goods during the second quarter of 2002, in anticipation of continued growth in revenue as seen in the first quarter of 2002. However, due to lower external demand, sales instead declined. Since manufacturing overheads allocated from cost of sales are capitalized as unit costs of inventory on the balance sheet as of June 30, 2002, the increase in production of inventory led to a significant incremental reduction in cost of goods sold, thus improving the comparative margin for the second quarter of 2002 against the same quarter in 2001.

Research and development expenses for the second quarter of 2002 were $4.0 million, as compared to $1.9 million for the three months ended June 30, 2001. The increase is due primarily to pre–clinical and clinical expenses for our three current R&D projects: ALISTA, TA–1790 and VI–0134.

Selling, general and administrative expenses in the second quarter of 2002 of $2.7 million are comparable to the same period last year.

During the second quarters of 2002 and 2001, we did not record any tax provisions due to the net loss recorded for each of the quarters.

Six Months Ended June 30, 2002 and 2001

U.S. net product revenue for the six months ended June 30, 2002 was $10.1 million compared to $9.7 million for the same period last year.

Product return data through the first quarter of 2002 indicated an increase to the returns provision was warranted. Approximately $403 thousand of the $1.2 million recorded for the returns provision during the first six months of 2002 reflects the required increase to the product returns liability for sales made from January 2000 through December 2001. The charge for actual and anticipated returns has been increased to seven percent (7%) of U.S. gross sales as of January 2002.

For the six months ended June 30, 2002, international product revenue was $869 thousand, a decrease of $2.2 million compared to the same period last year. Based on forecasts from our international partners, we expect that international revenue will decline further in the second half of 2002 as compared to the first six months of 2002.

Cost of goods sold was $4.9 million for the six months ended June 30, 2002 as compared to $6.8 million for the six months ended June 30, 2001. Cost of goods sold for the first six months of 2002 was favorably impacted by a $508 thousand reduction against accruals made in 1998 for inventory purchase commitments that were no longer needed based on the outcome of negotiations with a supplier. Adjusting for this item, comparative gross profit margins for the first six months of 2002 versus the first six months of 2001 would have been 50% and 47%, respectively. The net improvement in margins was largely attributable to the increase in sales within the U.S. in the first quarter of 2002, which carried higher margins than international sales. Comparatively, international sales for the six months ended June 30, 2002 decreased against the six months ended June 30, 2001.

For the six months ended June 30, 2002, R&D expenses were $6.8 million, $1.2 million lower than the same period last year, which included a $5.0 million payment made during the first quarter of 2001 to Tanabe for licensing the proprietary compound TA–1790. If not for this $5.0 million expense, R&D costs in the first half of 2002 would have been $3.9 million higher than the same period last year due to increased expenditures for development of our current pipeline.

Selling, general and administrative expenses were $5.4 million for the six months ended June 30, 2002, $451 thousand higher than the same period last year due to increased investment in U.S. sales and marketing efforts and legal expenses relating to the Janssen arbitration hearing that was held in mid–March 2002 and is discussed on page 19 of this report.

In the first quarter of 2002, we recorded a tax benefit of $268 thousand based on an updated estimate of our net tax liabilities. During the first six months of 2001, VIVUS did not record any tax provisions due to the net loss recorded for the period.

LIQUIDITY AND CAPITAL RESOURCES

Since its inception, the Company has financed operations primarily from the sale of preferred and common stock. Through June 30, 2002, VIVUS raised $155.9 million from financing activities and has an accumulated deficit of $95.6 million.

Unrestricted cash, cash equivalents and available–for–sale securities totaled $34.7 million at June 30, 2002, a decrease of $2.0 million from December 31, 2001. This decrease is due primarily to development expenses for TA–1790, clinical expenses for ALISTA, and development and clinical expenses for VI–0134.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs throughout the next twelve to eighteen months. However, we anticipate that we will be required to obtain additional financing to fund the development of our R&D pipeline in future periods as well as to support the possible launch of any future products. In particular, other substantial payments will be made in accordance with our agreement with Tanabe for licensing TA–1790. These payments are based on certain development, regulatory and sales milestones. In addition, royalty payments are required to be made by the Company to Tanabe on any future product sales.

We expect to evaluate 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 VIVUS' stockholders. Our working capital and additional funding requirements will depend upon numerous factors, including: (i) the progress of our R&D projects; (ii) the timing and results of pre–clinical testing and clinical trials; (iii) results of operations; (iv) demand for MUSE; (v) technological advances; (vi) the level of resources that we devote to our sales and marketing capabilities; and (vii) the activities of competitors. However, there can be no assurance that funding will be available on favorable terms, if at all, when needed.

This Quarterly Report on Form 10–Q contains forward–looking statements that involve risks and uncertainties. The Company's actual results could differ from those set forth in such forward–looking statements as a result of certain factors, including those set forth in the Risk Factors section.

RISK FACTORS

If we are unable to continue to develop, market and obtain regulatory approval for our products, our business would be harmed.

Our future operating results may be adversely affected if we are unable to continue to develop, manufacture and bring to market new drug products in a timely manner. 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 FDA 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 FDA can suspend clinical studies at any time if the agency believes that the subjects participating in such studies are being exposed to unacceptable health risks.

We cannot predict with certainty if or when we might submit for regulatory review those products currently under development. Once we submit our potential products for review, we cannot assure you that the FDA 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 FDA and international regulatory authorities approve a product, we must manufacture sufficient volumes to meet market demand. This is a process that requires accurate forecasting of market demand. There is no guarantee that there will be market demand for any future products or that we will be able to successfully manufacture or adequately support sales of any future products.

We are developing TA–1790 as potential oral and local treatments for male and female sexual dysfunction. In January 2001, we licensed TA–1790, a proprietary phosphodiesterase type 5 (PDE5) inhibitor compound from Tanabe, a Japanese pharmaceutical company. Tanabe completed a Phase I clinical trial evaluating the safety of orally administered TA–1790 for male erectile dysfunction. We are currently conducting additional pre–clinical safety studies as well as an in–clinic efficacy study in patients with erectile dysfunction. Based on the results of these studies, we intend to initiate additional clinical studies that would be required to obtain regulatory approval. However, there are no guarantees that TA–1790 will prove to be safe and effective or receive regulatory approval for any indication. Further, even if we were to receive regulatory approval for a product, there can be no assurance that such a product would prove to be commercially successful or profitable.

We are developing ALISTA for the potential treatment of female sexual dysfunction. We completed dosing for our first Phase II clinical study for topical ALISTA during the third quarter of 2001. Our current ALISTA clinical trial, which is a multi–center, double–blind, at–home efficacy and safety study, began in the first quarter of 2002. There are no guarantees that ALISTA will prove to be safe and effective or receive regulatory approval for the treatment of female sexual dysfunction or any other indication. Even if ALISTA eventually becomes an approved product, there can be no assurance that this treatment for female sexual dysfunction will be successful in the marketplace.

We are developing VI–0134 for the potential treatment of premature ejaculation. We have recently completed a clinical trial to evaluate the pharmacokinetics (blood levels in relation to time) of VI–0134, our re–formulated oral, on–demand treatment for premature ejaculation. However, there can be no assurance that future clinical studies, if performed, will be successful or that a product for the treatment of premature ejaculation, if approved, will prove to be commercially successful.

In December 1999, we submitted a New Drug Application ("NDA") to the FDA to market ALIBRA®, our second–generation product for the treatment of ED, which we subsequently withdrew in October 2000. We met with the FDA in December 2000 and continue to communicate with the agency to determine what additional data is required to obtain marketing clearance for ALIBRA.

There can be no assurance that we will re–file an NDA for ALIBRA. Even if we re–file an NDA for ALIBRA, there can be no assurance that it will be approved or that ALIBRA will be successful in the marketplace.

We rely on third parties to conduct clinical trials for our products 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 products 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 FDA 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 FDA or physicians, our business, financial condition and results of operations will be harmed.

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. Certain treatments for erectile dysfunction exist, such as oral medications, needle injection therapy, vacuum constriction devices and penile implants, and the manufacturers of these products will continue to improve these therapies. The most significant competitive therapy 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 in May 2001.

Additional competitive products in the erectile dysfunction market include needle injection therapy products from Pharmacia and Schwartz Pharma, which were approved by the FDA in July 1995 and June 1997, respectively. Other large pharmaceutical companies are also actively engaged in the development of therapies for the treatment of erectile 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. Lilly ICOS LLC and Bayer AG filed NDAs with the FDA in June and September 2001, respectively, for their oral erectile dysfunction medications. These companies may market commercial products either on their own or through collaborative efforts, such as Bayer AG, which signed a worldwide co–promotion agreement with GlaxoSmithKline plc for its product. 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.

Our success depends in large part on the strength of our current and future patent positions for the treatment of sexual dysfunction.

VIVUS holds various patents and patent applications in three major areas of sexual dysfunction: male erectile dysfunction, female sexual dysfunction and premature ejaculation. We are the exclusive licensee of United States and Canadian patents originally filed in the name of Dr. Gene Voss. These patents claim methods of treating erectile dysfunction with a vasodilator–containing ointment that is administered either topically or transurethrally.

We are also the exclusive licensee of patents and patent applications filed in the name of Dr. Nils G. Kock, in numerous countries. Four United States patents have been issued directed to methods and compositions for treating erectile dysfunction by transurethrally administering an active agent. Patents have also been granted in Australia, Austria, Belgium, Canada, Finland, France, Germany, Great Britain, Greece, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Spain, Sweden and South Africa. Patent applications are pending in Denmark and Romania. The foreign patents and applications, like the United States patents, are directed to the treatment of erectile dysfunction by transurethral administration of certain active substances including alpha–receptor blockers, vasoactive polypeptides, prostaglandins or nitroglycerin dispersed in a hydrophilic vehicle.

VIVUS' license and assignment agreements for the patents and patent applications identified above are royalty bearing and do not expire until the licensed and assigned patents expire. These license and assignment agreements generally provide that we assume responsibility for the maintenance and prosecution of the patents and patent applications and may bring infringement actions.

We are the sole assignee of five United States patents deriving from patent applications originally filed by ALZA Corporation ("ALZA"), covering inventions Dr. Virgil Place made while he was an employee of ALZA. The patents are directed to dosage forms for administering a therapeutic agent to the urethra, methods for treating erectile dysfunction, and specific drug formulations that can be delivered transurethrally for the treatment of erectile dysfunction. With one exception, the patents derive from patent applications that were filed in the United States prior to June 8, 1995, and therefore have a seventeen–year patent term calculated from the date of patent grant. Foreign patents have been granted in Australia, Canada, Europe (including Austria, Belgium, Denmark, France, Germany, Great Britain, Greece, Italy, Luxembourg, the Netherlands, Spain, Sweden and Switzerland), Finland, Ireland, Mexico, New Zealand, Norway, Portugal, South Africa and South Korea, and foreign applications are pending in Canada, Japan and China.

We are the sole assignee of patent applications filed in the name of Dr. Gary W. Neal and AndroSolutions, Inc. in the United States and internationally that are complementary to our patents and applications directed to the treatment of female sexual dysfunction.

In addition to the Voss, Kock, Place and Neal patents and applications identified above, we have numerous issued and pending United States and foreign patents. Many of these patents and applications further address the prevention, treatment and diagnosis of erectile dysfunction, while others are directed to prevention and/or treatment of other types of sexual dysfunction, including premature ejaculation and female sexual dysfunction. One of our issued patents covers VIVUS' venous flow control device, ACTIS.

Our strategy is to expand our existing patent portfolio through internal development of new intellectual property as well as through licensing and acquiring patents and patent applications that would increase our ability to succeed in the fields of erectile dysfunction, female sexual dysfunction and premature ejaculation. Our success will depend in large part on the strength of our current and future patent position for the treatments of these therapeutic indications. Our patent position, like that of other pharmaceutical companies, is highly uncertain and involves complex legal and factual questions. The claims of a United States or foreign patent application may be denied or significantly narrowed, and patents that are ultimately issued may not provide significant commercial protection to us. 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 licensed or assigned inventions. There can be no assurance that our patents will not be successfully challenged or designed around by others.

We were involved in an opposition proceeding that was instigated by the Pharmedic Company against a European patent, inventors Nils G. Kock et al., which is exclusively licensed to VIVUS. As a result of the opposition proceeding, the Opposition Division of the EPO confirmed all claims of the patent with the exception of certain pharmaceutical composition claims. In February 2002, we met with the EPO Appeals Board, which ruled that the pharmaceutical composition claims deemed unpatentable by the Opposition Division were indeed unpatentable. There can be no assurance that further challenges to the European patent that we license will not occur should we try to enforce the patent in the various European courts.

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.

Capital resources from operating activities are expected 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 throughout the next twelve to eighteen months. 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: (i) the progress of our research and development programs; (ii) the scope, timing and results of pre–clinical testing and clinical trials; (iii) the results of operations; (iv) the cost, timing and outcome of regulatory reviews; (v) the rate of technological advances; (vi) ongoing determinations of the potential commercial success of our products under development; (vii) the level of resources devoted to sales and marketing capabilities; and (viii) 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, when needed.

If either of our two 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 Spolana Chemical Works a.s. in Neratovice, Czech Republic (“Spolana”). The second is CHINOIN Pharmaceutical and Chemical Works Co., Ltd. (“Chinoin”). Chinoin is the Hungarian subsidiary of the French pharmaceutical company Sanofi Synthelabo. From July 2000 until March 2002, Spolana was the sole source of supply of alprostadil approved for use in the manufacture of product for distribution in Europe, of which we had a limited supply. Certain restrictions were put in place by the European regulatory authorities that required a variation to be approved before VIVUS could use the Chinoin alprostadil supply for European manufacture. After transferring marketing licenses in Europe to Abbott, Abbott filed a variation on September 26, 2001. The variation was approved in March 2002 and allows us to use a portion of our Chinoin supply of alprostadil for European manufacture. 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 the material 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 CORD Logistics, Inc. (“CORD”), a wholly owned subsidiary of Cardinal Health, Inc. Under this agreement, CORD (i) warehouses our finished goods for United States distribution; (ii) takes customer orders; (iii) picks, packs and ships our products; (iv) invoices customers; and (v) collects related receivables. As a result of this distribution agreement, we are heavily dependent on CORD’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 (“Gibraltar”) performs sterility testing on finished product manufactured by us to ensure that it complies with product specifications. Gibraltar 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 current Good Manufacturing Practice, (“cGMP”) regulations and cleanliness standards. As a result of this testing agreement, we are dependent on Gibraltar 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 (“WRB”) to handle patient and healthcare professional hotlines for us. WRB 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 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 ("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, Porex Medical Products, Inc. ("Porex") (formerly The Kipp Group), for our supply of plastic applicator components. In turn, Porex 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 FDA approval for suppliers. Until we secure and qualify additional sources of plastic components, we are entirely dependent upon Porex. If interruptions in this supply occur for any reason, including a decision by Porex to discontinue manufacturing, political unrest, labor disputes or a failure of Porex 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.

We currently depend on a single source to sterilize MUSE, and an interruption to this source could harm our business.

We rely on a single source, E–Beam Services, Inc. ("E–Beam"), for the sterilization of MUSE. There can be no assurance that we will be able to identify and qualify additional sterilization facilities. We are required to receive prior FDA approval for any sterilization facility. Until we secure and qualify an additional sterilization facility, we are entirely dependent upon E–Beam. If interruptions in these services occur for any reason, including a decision by E–Beam to discontinue manufacturing or services, political unrest, labor disputes or a failure of E–Beam to follow regulations, the development and commercial marketing of MUSE and other potential products could be delayed or prevented. An extended interruption in sterilization services would have a material adverse effect on our business, financial condition and results of operations.

All of our manufacturing operations are currently conducted at a single location, and a prolonged interruption to our manufacturing operations could harm our business.

We lease 90,000 square feet of space in Lakewood, New Jersey, in which we constructed manufacturing, warehousing and testing facilities. The FDA and the Medicines Control Agency, or MCA, 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.

If we, or our suppliers, fail to comply with FDA 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 FDA 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 review. Manufacturing, labeling and promotional activities are continually regulated by the FDA 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. In addition, the marketing and manufacturing of pharmaceutical products are subject to continuing FDA and other regulatory review, and later discovery of previously unknown problems with a product, manufacturer or facility may result in the FDA 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 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 FDA 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 FDA 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 efforts 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. Additionally, telephone marketers focus on additional 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 depend exclusively on third–party distributors outside of the United States and we have very limited control over their activities.

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

We entered into an agreement granting Abbott exclusive marketing and distribution rights for MUSE in all countries outside the United States and Canada. This agreement does not have minimum purchase commitments and we are entirely dependent on Abbott's efforts to distribute and sell our product effectively in all markets except the United States and Canada. There can be no assurance that such efforts will be successful or that Abbott will continue to support the product.

We have an accumulated deficit of $95.6 million at June 30, 2002 and expect to continue to incur substantial operating losses for the foreseeable future.

We have generated a cumulative net loss of $95.6 million for the period from our inception through June 30, 2002 and we anticipate losses for the next several quarters due to increased investment in our research and development programs and limited revenues. We are subject to a number of risks, including our ability to develop and successfully commercialize products in our research and development pipeline, our ability to market, distribute and sell our products in the United States, our reliance on others to market and distribute MUSE in countries other than the United States, intense competition, and our reliance on a single therapeutic approach to erectile dysfunction. 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 therapeutic approach to treat erectile dysfunction.

MUSE, a drug product developed by us to treat erectile dysfunction, relies on a single therapeutic approach, a transurethral system for erection. 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 since MUSE is the only transurethral product we currently produce and sell.

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. We may be required to obtain additional licenses to the patents, patent applications or other proprietary rights of others. There can be no assurance that any such licenses will be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we could encounter delays in product introductions while we attempt to design around such patents, or the development, manufacture or sale of products requiring such licenses could be precluded. We believe there will continue to be significant litigation in the pharmaceutical industry regarding patent and other intellectual property rights.

The rights and measures that we rely upon to protect our intellectual property may not be adequate and could reduce our ability to compete in the market.

We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality agreements and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our patents may be challenged, invalidated or circumvented by third parties. Our patent applications, including those already allowed, may not be issued as patents in a form that will be advantageous to us. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by employees. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Even if our intellectual property rights are adequately protected, litigation may be necessary to enforce our intellectual property rights, which could result in substantial costs to us and result in a substantial diversion of management attention. If our intellectual property is not adequately protected, our competitors could use our intellectual property to enhance their products. This would harm our competitive position, decrease our market share or otherwise harm our business.

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 is currently marketed internationally. Changes in overseas economic and political conditions, 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 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 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 is volatile.

The stock market has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. In addition, the market price of our common stock has been highly 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: (i) announcements of technological innovations or new products by us or our competitors; (ii) our ability to increase demand for our products in the United States; (iii) our ability to successfully sell our products in the United States and internationally; (iv) actual or anticipated fluctuations in our financial results; (v) our ability to obtain needed financing; (vi) economic conditions in the United States and abroad; (vii) comments by or changes in Company assessments or financial estimates by security analysts; (viii) adverse regulatory actions or decisions; (ix) any loss of key management; (x) the results of our clinical trials or those of our competitors; (xi) changing governmental regulations, patents or other proprietary rights; (xii) developments or disputes concerning patents or other proprietary rights; (xiii) product or patent litigation; or (xiv) public concern as to the safety of products developed by us.

Anti–takeover provisions contained in our Charter, Bylaws and Preferred Shares Rights Plan could impair a takeover attempt and could also limit the market price of our stock.

In February 1996, our Board of Directors adopted a Preferred Shares Rights Plan. The Preferred Shares Rights Plan provides for a dividend distribution of one Preferred Shares Purchase Right (a "Right") on each outstanding share of our common stock. The Rights will become exercisable following the tenth day after a person or group announces acquisition of twenty percent (20%) or more of our common stock, or announces commencement of a tender offer, the consummation of which would result in ownership by the person or group of twenty percent (20%) or more of our common stock. We will be entitled to redeem the Rights at $0.01 per Right at any time on or before the tenth day following acquisition by a person or group of twenty percent (20%) or more of our common stock.

The Preferred Shares Rights Plan and certain provisions of our Amended and Restated Certificate of Incorporation and Bylaws contain provisions that could delay or prevent a change in control of our company. Some of these provisions:

- authorize the issuance of preferred stock by the Board of Directors without prior stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of common stock;
- prohibit stockholder actions by written consent;
- specify procedures for director nominations by stockholders and submission of other proposals for consideration at stockholder meetings; and
- eliminate cumulative voting in the election of directors.

In addition, we are governed by the provisions of Section 203 of Delaware General Corporate Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These and other provisions in our Amended and Restated Certificate of Incorporation and Bylaws and under Delaware law 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.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On November 3, 1999, the Company filed a demand for arbitration against Janssen Pharmaceutica International ("Janssen") with the American Arbitration Association pursuant to the terms of the Distribution Agreement entered into on January 22, 1997. The Company sought compensation for inventory manufactured in 1998 in reliance on contractual forecasts and orders submitted by Janssen. The Company also sought compensation for forecasts and order shortfalls attributed to Janssen in 1998, pursuant to the terms of the Distribution Agreement. The Company amended its arbitration demand in August 2000 to include claims for lost profits due to Janssen's failure to use the requisite diligence and reasonable efforts to gain regulatory approval for and launch MUSE in China. A full hearing on the merits was conducted before a three–member arbitration panel in Chicago on March 18 – 20, 2002. On July 17, 2002, an Interim Award was issued awarding the Company the purchase price of 332,880 units manufactured for Janssen and lost profits on an additional 421,704 forecasted units. The Panel denied any relief on claims related to diligence in China. The dollar value of the claim will be determined by an audit of VIVUS' cost of goods sold by an independent accountant. This audit is scheduled to begin in mid–August 2002. Also in its Interim Award, the Panel requested further briefing on whether the Company is entitled to interest and attorney's fees as the prevailing party.

In the normal course of business, the Company receives and makes inquiries regarding patent infringement and other legal matters. The Company believes that it has meritorious claims and defenses and intends to pursue any such matters vigorously. The Company is not aware of any asserted or unasserted claims against it where the resolution would have an adverse material impact on the operations or financial position of the Company.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

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

The annual meeting of the stockholders of VIVUS, Inc. was held on June 5, 2002 at our principal executive office. Matters voted on at that meeting were: (i) the election of six (6) directors, and (ii) the approval of the 2001 Stock Option Plan.

Proposal I. Election of Directors

Tabulations for each individual director were as follows:

DIRECTOR	FOR	WITHHELD
Virgil A. Place, MD	29,201,964	1,858,761
Leland F. Wilson	29,043,043	2,017,682
Mark B. Logan	29,610,530	1,450,195
Linda M. Dairiki Shortliffe, MD	29,709,905	1,350,820
Mario M. Rosati	28,989,154	2,071,571
Graham Strachan	29,661,880	1,398,845

Proposal II. Approval of the 2001 Stock Option Plan

Tabulations for the approval of the 2001 Stock Option Plan were as follows:

FOR	AGAINST	ABSTAIN	NO VOTE
8,170,307	3,502,128	3,318,795	—

ITEM 5. OTHER INFORMATION

On July 8, 2002, VIVUS, Inc. dismissed its independent auditor, Arthur Andersen LLP, and engaged KPMG, LLP as its new independent auditor for the current fiscal year ending December 31, 2002.

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(7)	Amended and Restated Certificate of Incorporation of the Company
3.3(4)	Bylaws of the Registrant, as amended
3.4(8)	Certificate of Designations of Rights, Preferences and Privileges of Series A Participating Preferred Stock
4.1(7)	Specimen Common Stock Certificate of the Registrant
4.2(7)	Registration Rights, as amended
4.4(1)	Form of Preferred Stock Purchase Warrant issued by the Registrant to Invemed Associates, Inc., Frazier Investment Securities, L.P., and Cristina H. Kepner
4.5(8)	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

EXHIBIT NUMBER	DESCRIPTION
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(4)	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
10.21(3)+	Distribution Services Agreement between the Registrant and Synergy Logistics, Inc. (a wholly-owned subsidiary of Cardinal Health, Inc.)+ dated February 9, 1996
10.22(3)+	Manufacturing Agreement between the Registrant and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995
10.22A(11)+	Amendment One, dated as of December 11, 1997, to the Manufacturing Agreement by and between VIVUS and CHINOIN Pharmaceutical and Chemical Works Co., Ltd. dated December 20, 1995
10.23(6)+	Distribution and Services Agreement between the Registrant and Alternate Site Distributors, Inc. dated July 17, 1996
10.24(5)+	Distribution Agreement made as of May 29, 1996 between the Registrant and ASTRAZ AB
10.24A(14)+	Amended Distribution Agreement dated December 22, 1999 between AstraZeneca and the Registrant
10.27(11)+	Distribution Agreement made as of January 22, 1997 between the Registrant and Janssen Pharmaceutica International, a division of Cilag AG International
10.27A(11)+	Amended and Restated Addendum 1091, dated as of October 29, 1997, between VIVUS International Limited and Janssen Pharmaceutica International
10.28(7)	Lease Agreement made as of January 1, 1997 between the Registrant and Airport Associates
10.29(7)	Lease Amendment No. 1 as of February 15, 1997 between Registrant and Airport Associates
10.29A(10)	Lease Amendment No. 2 dated July 24, 1997 by and between the Registrant and Airport Associates
10.29B(10)	Lease Amendment No. 3 dated July 24, 1997 by and between the Registrant and Airport Associates
10.31(9)+	Manufacture and Supply Agreement between Registrant and Spolana Chemical Works, A.S. dated May 30, 1997
10.32A(11)	Agreement between ADP Marshall, Inc. and the Registrant dated December 19, 1997
10.32B(11)	General Conditions of the Contract for Construction
10.32C(11)	Addendum to General Conditions of the Contract for Construction
10.34(12)+	Agreement dated as of June 30, 1998 between Registrant and ALZA Corporation
10.35(12)+	Sales Force Transition Agreement dated July 6, 1998 between Registrant and ALZA Corporation
10.36(13)	Form of, “Change of Control Agreements,” dated July 8, 1998 by and between the Registrant and certain Executive Officers of the Company.
10.30A(13)	Amendment of lease agreement made as of October 19, 1998 by and between Registrant and 605 East Fairchild Associates, L.P.

EXHIBIT NUMBER	DESCRIPTION
10.37(13)	Sublease agreement made as of November 17, 1998 between Caliper Technologies, Inc. and Registrant
10.22B(13)+	Amendment Two, dated as of December 18, 1998 by and between VIVUS, Inc. and CHINOIN Pharmaceutical and Chemical Works Co.
10.31A(13)+	Amendment One, dated as of December 12, 1998 by and between VIVUS, Inc. and Spolana Chemical Works, A.S.
10.38(14)+	License Agreement by and between ASIVI, LLC, AndroSolutions, Inc., and the Registrant dated February 29, 2000
10.38A(14)+	Operating Agreement of ASIVI, LLC, between AndroSolutions, Inc. and the Registrant dated February 29, 2000
10.39(14)	Sublease agreement between KVO Public Relations, Inc. and the Registrant dated December 21, 1999
10.40(15)+	License and Supply Agreement made as of May 23, 2000 between the Registrant and Abbott Laboratories, Inc.
10.41(16)+	License and Supply Agreement made as of November 20, 2000 between the Registrant and Paladin Labs, Inc.
10.42(16)+	Development, License and Supply Agreement made as of January 22, 2001 between the Registrant and TANABE SEIYAKU CO., LTD.
10.43(17)+	Settlement and Modification Agreement made as of July 12, 2001 between ASIVI, LLC, AndroSolutions, Inc. Gary W. Neal and the Registrant.
10.44(18)	2001 Stock Option Plan and Form of Agreement.
99.1	Certification of Chief Executive Officer and Chief Financial Officer.

\+ Confidential treatment granted.

(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 Annual Report on Form 10-K for the year ended December 31, 1995, as amended.
(4) Incorporated by reference to the same numbered exhibit filed with the Registrant's Form 8-B filed with the Commission on June 24, 1996.
(5) Incorporated by reference to the same numbered exhibit filed with the Registrant's Current Report on Form 8-K/A filed with the Commission on June 21, 1996.
(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, 1996.
(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, 1996, as amended.
(8) 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.
(9) 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, 1997.
(10) 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.
(11) 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, 1997.

(12) 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, 1998.
(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, 1998.
(14) 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.
(15) 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, 2000.
(16) 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.
(17) 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.
(18) 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.

(b) REPORTS ON FORM 8-K

None

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 9, 2002

VIVUS, Inc.

/s/ RICHARD WALLISER

Richard Walliser
Vice President and Chief Financial Officer

/s/ LELAND F. WILSON

Leland F. Wilson
President and Chief Executive Officer

VIVUS, INC.
INDEX TO EXHIBITS

EXHIBIT	DESCRIPTION
99.1	Certification of Chief Executive Officer and Chief Financial Officer.

* Exhibits incorporated by reference are set forth in the exhibit listing included in Item 6 of the Quarterly Report on Form 10–Q.

EXHIBIT 99.1

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 quarterly period ended June 30, 2002 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 fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc.

By: /s/ LELAND F. WILSON

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

I, Richard Walliser, 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 quarterly period ended June 30, 2002 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 fairly presents in all material respects the financial condition and results of operations of VIVUS, Inc.

By: /s/ RICHARD WALLISER

Name: Richard Walliser
Title: Vice President and Chief Financial Officer