

ALTEON INC /DE
Form 10-Q
November 08, 2005

Table of Contents

**SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q**

(Mark One)

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

For the quarterly period ended **September 30, 2005**

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 001-16043

ALTEON INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

13-3304550

(I.R.S. Employer Identification No.)

6 Campus Drive, Parsippany, New Jersey 07054

(Address of principal executive offices)

(Zip Code)

(201) 934-5000

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report.)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes No

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

On November 4, 2005, 57,996,711 shares of the registrant's Common Stock were outstanding.

Page 1 of 29 pages
The Exhibit Index is on page 29

**ALTEON INC.
INDEX**

PART I FINANCIAL INFORMATION

Item 1. Condensed Financial Statements (Unaudited)

Condensed Balance Sheets as of September 30, 2005 and December 31, 2004 3

Condensed Statements of Operations for the three and nine months ended September 30, 2005 and 2004 4

Condensed Statement of Changes in Stockholders' Equity for the nine months ended September 30, 2005 5

Condensed Statements of Cash Flows for the nine months ended September 30, 2005 and 2004 6

Notes to Condensed Financial Statements 7

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 10

Item 3. Qualitative and Quantitative Disclosures about Market Risk 25

Item 4. Controls and Procedures 25

PART II OTHER INFORMATION

Item 6. Exhibits 27

SIGNATURES 28

INDEX TO EXHIBITS 29

Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Table of Contents**PART I FINANCIAL INFORMATION****ITEM I. Condensed Financial Statements (Unaudited)****ALTEON INC.
CONDENSED BALANCE SHEETS
(Unaudited)**

	September 30, 2005	December 31, 2004
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 8,183,766	\$ 11,175,762
Other current assets	456,864	159,364
 Total current assets	 8,640,630	 11,335,126
Property and equipment, net	70,880	107,269
Restricted cash	200,000	200,000
 Total assets	 \$ 8,911,510	 \$ 11,642,395

LIABILITIES AND STOCKHOLDERS EQUITY

Current Liabilities:		
Accounts payable	\$ 333,956	\$ 593,094
Accrued expenses	944,811	2,002,381
 Total liabilities	 1,278,767	 2,595,475
 Stockholders Equity:		
Preferred Stock, \$0.01 par value, 1,993,329 shares authorized, and 1,360 and 1,277 shares of Series G and 4,085 and 3,836 shares of Series H issued and outstanding, as of September 30, 2005 and December 31, 2004, respectively. The liquidation value at September 30, 2005, was \$54,447,388	54	51
Common Stock, \$0.01 par value, 300,000,000 shares and 175,000,000 shares authorized, as of September 30, 2005 and December 31, 2004, respectively, and 57,996,711 and 48,472,898 shares issued and outstanding, as of September 30, 2005 and December 31, 2004, respectively	579,967	484,729
Additional paid-in capital	227,059,931	214,274,790

Edgar Filing: ALTEON INC /DE - Form 10-Q

Accumulated deficit	(220,007,209)	(205,712,650)
Total stockholders' equity	7,632,743	9,046,920
Total liabilities and stockholders' equity	\$ 8,911,510	\$ 11,642,395

The accompanying notes are an integral part of these unaudited condensed financial statements.

3

Table of Contents

ALTEON INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Income:				
Investment income	\$ 87,235	\$ 55,198	\$ 286,789	\$ 121,614
Other income			100,000	151,822
Total income	\$ 87,235	\$ 55,198	\$ 386,789	\$ 273,436
Expenses:				
Research and development	1,981,136	2,131,879	8,115,615	7,261,576
General and administrative	1,062,503	933,414	3,245,946	3,258,749
Total expenses	3,043,639	3,065,293	11,361,561	10,520,325
Net loss	(2,956,404)	(3,010,095)	(10,974,772)	(10,246,889)
Preferred stock dividends	1,142,016	1,049,920	3,319,787	3,062,731
Net loss applicable to common stockholders	\$ (4,098,420)	\$ (4,060,015)	\$ (14,294,559)	\$ (13,309,620)
Basic/diluted net loss per share applicable to common stockholders	\$ (0.07)	\$ (0.08)	\$ (0.25)	\$ (0.31)
Weighted average common shares used in computing basic/diluted net loss per share	57,996,711	48,298,985	57,518,794	43,100,121

The accompanying notes are an integral part of these unaudited condensed financial statements.

Table of Contents

ALTEON INC.
CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS EQUITY
(Unaudited)

	Preferred Stock		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Stockholders Equity
Balance, December 31, 2004	5,113	\$ 51	48,472,898	\$ 484,729	\$ 214,274,790	\$ (205,712,650)	\$ 9,046,920
Net loss						(10,974,772)	(10,974,772)
Issuance of Series G and H preferred stock dividends	332	3			3,319,784	(3,319,787)	
Public offerings of common stock			9,523,813	95,238	9,437,057		9,532,295
Deferred compensation expense in connection with the issuance of non-qualified stock options granted to non-employees					28,300		28,300
Balance, September 30, 2005	5,445	\$ 54	57,996,711	\$ 579,967	\$ 227,059,931	\$ (220,007,209)	\$ 7,632,743

The accompanying notes are an integral part of these unaudited condensed financial statements.

Table of Contents

ALTEON INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2005	2004
Cash Flows from Operating Activities:		
Net loss	\$ (10,974,772)	\$ (10,246,889)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	49,497	56,548
Stock Compensation Expense	28,300	15,138
Changes in operating assets and liabilities:		
Other assets	(297,500)	(207,953)
Accounts payable and accrued expenses	(1,316,708)	323,485
Net cash used in operating activities	(12,511,183)	(10,059,671)
Cash Flows from Investing Activities:		
Capital expenditures	(13,108)	(80,646)
Net cash used in investing activities	(13,108)	(80,646)
Cash Flows from Financing Activities:		
Net proceeds from issuance of common stock	9,532,295	7,581,318
Net proceeds from exercise of employee stock options		5,085
Net cash provided by financing activities	9,532,295	7,586,403
Net decrease in cash and cash equivalents	(2,991,996)	(2,553,914)
Cash and cash equivalents, beginning of period	11,175,762	16,678,582
Cash and cash equivalents, end of period	\$ 8,183,766	\$ 14,124,668

The accompanying notes are an integral part of these unaudited condensed financial statements.

Table of Contents

**ALTEON INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)**

Note 1 Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2005, are not necessarily indicative of the results that may be expected for the year ending December 31, 2005. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K and Form 10-K/A for the year ended December 31, 2004, as filed with the Securities and Exchange Commission.

Note 2 Liquidity

The Company has devoted substantially all of its resources to research, drug discovery and development programs. To date, it has not generated any revenues from the sale of products and does not expect to generate any such revenues for a number of years, if at all. As a result, Alteon has incurred net losses since inception, has an accumulated deficit of \$220,007,209 as of September 30, 2005, and expects to incur net losses, potentially greater than losses in prior years, for a number of years.

The Company has financed its operations through proceeds from the sale of common and preferred equity securities, revenue from former collaborative relationships, reimbursement of certain of our research and development expenses by collaborative partners, investment income earned on cash and cash equivalent balances and short-term investments and the sale of a portion of the Company's New Jersey state net operating loss carryforwards and research and development tax credit carryforwards.

As of September 30, 2005, the Company had working capital of \$7,361,863, including \$8,183,766 of cash and cash equivalents. In January 2005, the Company completed the sale of 9,523,813 shares of common stock, which provided net proceeds of \$9,532,295 (see Note 5). The Company's net cash used in operating activities for the nine months ended September 30, 2005 was \$12,511,183 and for the year ended December 31, 2004 was \$13,109,869.

The Company expects to utilize cash and cash equivalents to fund its operating activities, including any continued development of our lead compound, alagebrium. As a result of the discontinuation of the SPECTRA trial, Alteon has begun curtailment actions and expects to have reduced expenses in the fourth quarter of 2005 and the first half of 2006. These actions include evaluating clinical strategies before resuming clinical trials, increased selectivity in pre-clinical programs and reduced headcount. The Company has the ability to quickly and significantly further reduce its cash burn rate, if necessary, as it has limited fixed commitments. Alteon has engaged third parties to assist in developing and identifying options designed to diversify its portfolio of product candidates and to enhance its ability to raise financing in the future. Such potential transactions include the acquisition of technologies and product programs, licensing opportunities, the sale to or merger of the Company into another company, and debt and equity financing. If we are unable to secure additional financing on reasonable terms, unable to generate sufficient new sources of revenue through collaborative arrangements or if the level of cash and cash equivalents falls below anticipated levels, Alteon will be forced to take substantial restructuring actions, which may include further reduction or curtailment of its research and product development activities and other operations. The Company expects to have sufficient cash and cash equivalents to satisfy its working capital requirements into the second half of 2006, either by future fund-raising or, if needed, curtailment actions. If the Company is unable to raise additional funds, the Company will have to take additional curtailment actions and will not have the ability to continue as a going concern after mid-2006. As part of the exploration of its strategic options, Alteon is considering various transactions that could result in the payment of certain obligations of approximately \$3 million, including severance, lease, insurance, and other contractual and regulatory requirements.

The amount and timing of the Company's future capital requirements will depend on numerous factors, including the timing of resuming its research and development programs, if at all, the number and characteristics of product candidates that it pursues, the conduct of pre-clinical tests and clinical studies, the status and timelines of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the ability to complete strategic collaborations and the availability of third-party funding, if any.

The Company will require substantial new funding to pursue development and commercialization of alagebrium and its other product candidates and to continue its operations. Alteon believes that satisfying these

Table of Contents

capital requirements over the long term will require successful commercialization of its product candidates, particularly alagebrium. However, it is highly uncertain whether alagebrium or any other products will be approved or will be commercially successful.

Selling securities to satisfy the Company's short-term and long-term capital requirements may have the effect of materially diluting the current holders of its outstanding stock. Alteon may also seek additional funding through corporate collaborations and other financing vehicles. There can be no assurance that such funding will be available at all or on terms acceptable to the Company. Potential financing sources for Alteon may be dissuaded from investing in Alteon in light of the fact that Genentech, Inc., as the sole holder of the outstanding shares of our Series G and Series H Preferred Stock, currently has a significant liquidation preference and voting position, on an as-converted to common stock basis, in Alteon. If adequate funds are not available, the Company may be required to curtail significantly one or all of its research and development programs. If funds are obtained through arrangements with collaborative partners or others, the Company may be required to relinquish rights to certain of its technologies or product candidates. If Alteon is unable to obtain necessary funding, it may need to cease operations.

The Company is actively pursuing opportunities designed to diversify its product portfolio and to enhance its ability to raise future financing. There can be no assurance that any such transaction will be completed in the near term, if at all. Several factors may make it difficult for the Company to complete a merger, including the current uncertain state of the Company's regulatory pathway for alagebrium and the Genentech preferred stock position. Even if the Company does complete a merger, there can be no assurance that the products or technologies acquired in such transaction will result in revenues to the combined company.

Note 3 Stock-Based Compensation

The Company accounts for employee stock-based compensation and awards issued to non-employee directors using the intrinsic value method under Accounting Principles Board, or APB, Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations, under which no compensation cost (excluding those options granted below fair market value) has been recognized. Stock option awards issued to consultants and contractors are accounted for in accordance with Statement of Financial Accounting Standards, or SFAS, No. 123, Accounting for Stock-Based Compensation, SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure and Emerging Issues Task Force Issue No. 96-18, Accounting for Equity Instruments that are Issued To Other Than Employees for Acquiring or In Conjunction with Selling Goods or Services. In March 2000, the Financial Accounting Standards Board, or the FASB, released Interpretation No. 44, or FIN No. 44, Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB Opinion No. 25. The interpretation became effective on July 1, 2000, but in some circumstances applies to transactions that occurred prior to the effective date. Under the interpretation, stock options that are repriced must be accounted for as variable-plan arrangements until the options are exercised, forfeited or expire. This requirement applies to any options repriced after December 15, 1998.

On February 2, 1999, the Company repriced certain stock options. There was no non-cash stock compensation expense resulting from the 1999 repricing for the three and nine months ended September 30, 2005 and 2004, respectively. As of September 30, 2005, there were 383,759 repriced options outstanding, which expire on various dates through January 2008.

If the Company had applied the fair value recognition provisions of SFAS No. 123 to its employee and director option grants, the Company's pro forma net loss and net loss per share applicable to common stockholders for the three and nine months ended September 30, 2005 and 2004, would be as follows:

Table of Contents

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net loss, as reported	\$ (2,956,404)	\$ (3,010,095)	\$ (10,974,772)	\$ (10,246,889)
Less: Total stock-based employee and director compensation expense determined under fair value method	(231,914)	125,580	(943,493)	(604,087)
Pro forma net loss	(3,188,318)	(2,884,515)	(11,918,265)	(10,850,976)
Preferred stock dividends	1,142,016	1,049,920	3,319,787	3,062,731
Pro forma net loss applicable to common stockholders	\$ (4,330,334)	\$ (3,934,435)	\$ (15,238,052)	\$ (13,913,707)
Earnings per share applicable to common stockholders:				
Basic/diluted, as reported	\$ (0.07)	\$ (0.08)	\$ (0.25)	\$ (0.31)
Basic/diluted, pro forma	\$ (0.07)	\$ (0.08)	\$ (0.26)	\$ (0.32)

In December 2004, the FASB issued SFAS No. 123 (revised 2004) (SFAS 123(R)), Share-Based Payment, which is a revision of SFAS 123 and supersedes APB 25 and its related implementation guidance. Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS 123. However, SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values at the date of grant. As a result of the issuance of SFAS No. 123(R), the Company will be required to expense the fair value of employee stock options over the service period, beginning no later than with its fiscal quarter ending March 31, 2006.

Note 4 Net Loss Per Share Applicable to Common Stockholders

Basic net loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares outstanding during the period. Diluted net loss per share is the same as basic net loss per share applicable to common stockholders, since the assumed exercise of stock options and warrants and the conversion of preferred stock would be antidilutive. The amount of potentially dilutive securities excluded from the calculation as of September 30, 2005 and 2004, was 188,203,378 and 59,061,487 shares, respectively.

Note 5 Stockholders Equity

In January 2005, Alteon completed a public offering of 9,523,813 shares of common stock at \$1.05 per share, which provided net proceeds of \$9,532,295. In connection with this offering, the Company issued to its placement agent in the offering a five-year warrant to purchase 312,381 shares of common stock at \$1.37 per share.

Series G Preferred Stock and Series H Preferred Stock dividends are payable quarterly in shares of preferred stock at a rate of 8.5% of the accumulated balance. Each share of Series G Preferred Stock and Series H Preferred Stock is convertible, upon 70 days prior written notice, into the number of shares of common stock determined by dividing \$10,000 by the average of the closing sales price of the common stock, as reported on the American Stock Exchange, for the 20 business days immediately preceding the date of conversion. For the three months ended September 30, 2005 and 2004, preferred stock dividends of \$1,142,016 and \$1,049,920, respectively, were recorded. On September 30, 2005, the Series G and Series H Preferred Stock would have been convertible into 44,963,636 common stock shares and 135,028,099 common stock shares, respectively, and such shares of preferred stock had a total liquidation value of \$54,447,388. The Series G and Series H Preferred Stock have no voting rights.

Table of Contents**ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations
Overview**

We are a product-based biopharmaceutical company engaged in the development of small molecule drugs to reverse or slow down diseases of aging and complications of diabetes. Our product portfolio represents novel approaches to large pharmaceutical markets. Our lead compound, alagebrium (formerly ALT-711), is being developed for the treatment of cardiovascular diseases and disorders relating to complications of diabetes and is being evaluated for other indications in a number of pre-clinical studies. We have identified several other promising drug candidates for future development, although none of these other candidates is currently in active clinical development. Our pharmaceutical portfolio was developed as a result of our research on the Advanced Glycation End-Product, or A.G.E., pathway, a fundamental pathological process and inevitable consequence of aging that causes or contributes to many medical disorders.

We initiated several Phase 2 studies of alagebrium during 2004 and 2005, although as noted below we are not currently enrolling subjects in these studies: PEDESTAL (**P**atients with Impaired Ejection Fraction and **D**iaстolic Dysfunction: **E**fficacy and **S**afety **T**rial of **A**lagebrium), a Phase 2a study in heart failure; EMERALD (**E**fficacy and **S**afety of **A**lagebrium in **E**rectile Dysfunction in **M**ale **D**iabetics), a Phase 2a study in erectile dysfunction, or ED; and a Phase 2a study in endothelial dysfunction. Data from PEDESTAL and the endothelial-dysfunction study are scheduled to be presented at the American Heart Association meeting in November 2005. In June 2005, SPECTRA (**S**ystolic **P**ressure **E**fficacy and **S**afety **T**rial of **A**lagebrium), a Phase 2b trial in systolic hypertension, was discontinued after an interim analysis found that the data did not indicate a treatment effect of alagebrium and we have ceased development of alagebrium for this indication.

Of the approximately 1,300 subjects who have participated in the Phase 1 and Phase 2 clinical studies of alagebrium to date, approximately 1,000 subjects have received alagebrium and approximately 300 subjects have received placebo. The compound has demonstrated an excellent safety profile in all human clinical testing to date.

In December 2004, we announced that findings of a routine two-year rodent toxicity study indicated that male Sprague Dawley rats exposed to high doses of alagebrium over their natural lifetime developed dose-related increases in liver cell alterations and tumors, and that the liver tumor rate was slightly over the expected background rate in this gender and species of rat. In February 2005, based on the initial results from one of the follow-on pre-clinical toxicity experiments, we voluntarily and temporarily suspended enrollment of new subjects into each of the ongoing clinical studies pending receipt of additional pre-clinical data. Since our investigational new drug applications, or INDs, for alagebrium are under the oversight of two divisions of the U.S. Food and Drug Administration, or FDA, the Cardio-Renal Division and the Reproductive and Urologic Division, we simultaneously submitted the conclusions from the pre-clinical toxicity data on alagebrium to both divisions. Our clinical protocols under the oversight of the Cardio-Renal Division were allowed to proceed. However, the EMERALD study in ED was placed and remains on clinical hold by the Reproductive and Urologic Division. We have been corresponding with the FDA on these matters in an effort to resolve this issue.

Our current priorities are to resume the clinical development of alagebrium in heart failure and other indications, and to ensure that we have the funding and personnel necessary to accomplish this goal. However, we are actively exploring a spectrum of strategic options not only to secure funding and other support for the continuation of our programs, but also to diversify our product candidate portfolio. Such strategic options include debt and equity financing, research and development collaborations, out-licensing of our technology and development programs or a possible sale of our business to, or merger into, another entity. We have engaged third parties to assist us in developing, identifying and executing strategic options. We cannot predict at this time when enrollment in our EMERALD study will resume, if ever.

We continue to evaluate potential pre-clinical and clinical trials in other therapeutic indications in which A.G.E. Crosslink Breaker compounds may address significant unmet needs. In addition to our clinical studies in ED and heart failure, our pre-clinical research has focused on: atherosclerosis; erectile dysfunction; diastolic heart failure; Alzheimer's disease; eye diseases, including age-related macular degeneration, or AMD, glaucoma; and diabetic complications, including renal diseases, among others.

Since our inception in October 1986, we have devoted substantially all of our resources to research, drug discovery and development programs. To date, we have not generated any revenues from the sale of products and do not expect to generate any such revenues for a number of years, if at all. We have incurred an accumulated deficit of \$220,007,209 as of September 30, 2005, and expect to incur net losses, potentially greater than losses in prior years, for a number of years.

Table of Contents**ITEM 2. Management s
Discussion and
Analysis of
Financial
Condition and
Results of
Operations
(Continued)**

We have financed our operations through proceeds from public offerings of common stock, private placements of common and preferred equity securities, revenue from former collaborative relationships, reimbursement of certain of our research and development expenses by our collaborative partners, investment income earned on cash and cash equivalent balances and short-term investments and the sale of a portion of our New Jersey State net operating loss carryforwards and research and development tax credit carryforwards.

Our business is subject to significant risks including, but not limited to, (1) our ability to continue our clinical studies of alagebrium, including our ability to resume enrollment in our ED study and other studies, (2) our ability to obtain funding, (3) the risks inherent in our research and development efforts, including clinical trials and the length, expense and uncertainty of the process of seeking regulatory approvals for our product candidates, (4) our reliance on alagebrium, which is our only significant drug candidate, (5) uncertainties associated with obtaining and enforcing our patents and with the patent rights of others, (6) uncertainties regarding government healthcare reforms and product pricing and reimbursement levels, (7) technological change and competition, (8) manufacturing uncertainties, (9) dependence on collaborative partners and other third parties, and (10) our ability to execute a strategic transaction, such as a sale or merger of the Company, if we elect to do so, in a timely manner. Even if our product candidates appear promising at an early stage of development, they may not reach the market for numerous reasons. These reasons include the possibilities that the products will prove ineffective or unsafe during pre-clinical or clinical studies, will fail to receive necessary regulatory approvals, will be difficult to manufacture on a large scale, will be uneconomical to market or will be precluded from commercialization by proprietary rights of third parties. These risks and others are discussed under the heading **Forward-Looking Statements and Cautionary Statements** .

Results of Operations**Three Months ended September 30, 2005 and 2004**

Total income for the three months ended September 30, 2005 and 2004, was \$87,235 and \$55,198, respectively. The income consisted of interest earned on cash and cash equivalents. The increase was attributed to increased interest rates offset by lower investment balances.

Our total expenses were \$3,043,639 for the three months ended September 30, 2005, compared to \$3,065,293 for the three months ended September 30, 2004, and in each period consisted primarily of research and development expenses. Research and development expenses included third-party expenses associated with pre-clinical and clinical studies, manufacturing costs, including the development and preparation of clinical supplies, personnel and personnel-related expenses and facility expenses. Research and development expenses were \$1,981,136 for the three months ended September 30, 2005 as compared to \$2,131,879 for the same period in 2004, a decrease of \$150,743 or 7.1%. The decrease was primarily attributed to decreased clinical trial costs due to the termination of the SPECTRA trial offset by higher pre-clinical costs associated with additional toxicity studies. In 2005, of the total amount spent on research and development expenses, we incurred \$893,333 in personnel and personnel-related expenses, \$472,276 in pre-clinical expenses, \$220,934 in clinical trial expenses, and \$88,061 related to manufacturing (packaging and distribution). In 2004, we primarily incurred \$978,054 in personnel and personnel-related expenses, \$787,433 in clinical trial expenses, primarily related to SPECTRA, and \$206,034 in pre-clinical expenses, including the completion of a two-year carcinogenicity study.

General and administrative expenses increased 13.8% to \$1,062,503 for the three months ended September 30, 2005, as compared to \$933,414 for the same period in 2004. The increase is primarily related to higher corporate expenses including third-party consulting, increased Board of Director expenses, accounting and legal expenses associated with Sarbanes-Oxley compliance, and the ongoing evaluation of our strategic options, offset by decreased

patent expense.

Our net loss applicable to common stockholders increased 0.9% to \$4,098,420 for the three months ended September 30, 2005 as compared to \$4,060,015 for the three months ended September 30, 2004. Included in the net loss applicable to common stockholders are preferred stock dividends of \$1,142,016 and \$1,049,920, respectively.

Nine Months Ended September 30, 2005 and 2004

Total income for the nine months ended September 30, 2005 and 2004 was \$386,789 and \$273,436, respectively. The income consisted of interest earned on cash and cash equivalents and other income. Interest income increased to \$286,789 in the nine months ended September 30, 2005 as compared to \$121,614 in the same period of the prior year due to an increase in short-term interest rates. In 2005, other income included \$100,000 received from a licensing agreement with Avon Products, Inc. In 2004, other income included \$51,822 derived from

Table of Contents**ITEM 2. Management's
Discussion and
Analysis of
Financial
Condition and
Results of
Operations
(Continued)**

the sale of fully depreciated laboratory equipment and supplies, and a reimbursement of \$100,000 for improvements made to our former Ramsey facility.

Our total expenses were \$11,361,561 for the nine months ended September 30, 2005 compared to \$10,520,325 for the nine months ended September 30, 2004, and in each year consisted primarily of research and development expenses. Research and development expenses for the nine months ended September 30, 2005 were \$8,115,615, an increase of \$854,039 or 11.8% as compared to the nine months ended September 30, 2004. The increase was primarily attributed to increased pre-clinical costs due to additional toxicity studies, and increased personnel and personnel related costs, offset by lower manufacturing costs. In 2005, research and development expenses included \$3,087,654 in personnel and personnel related expenses, \$2,217,790 in clinical trial expenses, \$1,307,373 in pre-clinical expenses primarily related to additional toxicity studies, \$541,657 in manufacturing (packaging and on-going stability studies), \$353,076 in third-party consulting fees, and \$281,664 of facility and other overhead related costs. Research and development expenses for the nine months ended September 30, 2004 were \$7,261,576, and included \$2,767,114 in personnel and personnel related expenses, \$2,268,038 in clinical trial expenses, of which \$2,000,000 related to SPECTRA, \$925,966 related to manufacturing (tableting and packaging), \$360,110 in pre-clinical expenses, consisting of the completion of a carcinogenicity study, \$361,955 of facility and other overhead related costs and \$269,810 in third-party consulting fees.

General and administrative expenses decreased to \$3,245,946 for the nine months ended September 30, 2005 as compared to \$3,258,749 for the same period in 2004. This decrease is primarily attributed to lower business development and marketing costs offset by higher accounting and legal fees associated with Sarbanes-Oxley compliance and the ongoing evaluation of our strategic options.

Our net loss applicable to common stockholders increased to \$14,294,559 for the nine months ended September 30, 2005 as compared to \$13,309,620 for the same period in 2004, an increase of 7.4%, due to increased research and development expenses. Included in the net loss applicable to common stockholders are preferred stock dividends of \$3,319,787 and \$3,062,731, respectively.

Liquidity and Capital Resources

We have devoted substantially all of our resources to research, drug discovery and development programs. To date, we have not generated any revenues from the sale of products and do not expect to generate any such revenues for a number of years, if at all. As a result, we have incurred net losses since inception, have an accumulated deficit of \$220,007,209 as of September 30, 2005, and expect to incur net losses, potentially greater than losses in prior years, for a number of years.

We have financed our operations through proceeds from the sale of common and preferred equity securities, revenue from former collaborative relationships, reimbursement of certain of our research and development expenses by collaborative partners, investment income earned on cash and cash equivalent balances and short-term investments and the sale of a portion of our New Jersey state net operating loss carryforwards and research and development tax credit carryforwards.

As of September 30, 2005, we had working capital of \$7,361,863, including \$8,183,766 of cash and cash equivalents. In January 2005, we completed the sale of 9,523,813 shares of common stock, which provided net proceeds of \$9,532,295 (see Note 5). Our net cash used in operating activities for the nine months ended September 30, 2005 was \$12,511,183 and for the year ended December 31, 2004 was \$13,109,869.

We expect to utilize cash and cash equivalents to fund our operating activities, including any continued development of our lead compound, alagebrium. As a result of the discontinuation of the SPECTRA trial, we have

begun curtailment actions and expect to have reduced expenses in the fourth quarter of 2005 and the first half of 2006. These actions include evaluating clinical strategies before resuming clinical trials, increased selectivity in pre-clinical programs and reduced headcount. We have the ability to quickly and significantly further reduce our cash burn rate, if necessary, as we have limited fixed commitments. We have engaged third parties to assist in developing and identifying options designed to diversify our portfolio of product candidates and to enhance our ability to raise financing in the future. Such potential transactions include the acquisition of technologies and product programs, licensing opportunities, the sale to, or merger into, another company, and debt and equity financing. If we are unable to secure additional financing on reasonable terms, unable to generate sufficient new sources of revenue through collaborative arrangements or if the level of cash and cash equivalents falls below anticipated levels, we will be forced to take substantial restructuring actions, which may include further reduction or curtailment of our research and product development activities and other operations. We expect to have sufficient cash and cash equivalents to satisfy our working capital requirements into the second half of 2006, either by future fund-raising or, if needed, curtailment actions. If we are unable to raise additional funds, we will have to take additional curtailment actions and

Table of Contents**ITEM 2. Management s
Discussion and
Analysis of
Financial
Condition and
Results of
Operations
(Continued)**

will not have the ability to continue as a going concern after mid-2006. As part of the exploration of our strategic options, we are considering various transactions that could result in the payment of certain obligations of approximately \$3 million, including severance, lease, insurance, and other contractual and regulatory requirements.

The amount and timing of our future capital requirements will depend on numerous factors, including the timing of resuming our research and development programs, if at all, the number and characteristics of product candidates that we pursue, the conduct of pre-clinical tests and clinical studies, the status and timelines of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the ability to complete strategic collaborations and the availability of third-party funding, if any.

We will require substantial new funding to pursue development and commercialization of alagebrium and our other product candidates and to continue our operations. We believe that satisfying these capital requirements over the long term will require successful commercialization of our product candidates, particularly alagebrium. However, it is highly uncertain whether alagebrium or any other products will be approved or will be commercially successful.

Selling securities to satisfy our short-term and long-term capital requirements may have the effect of materially diluting the current holders of our outstanding stock. We may also seek additional funding through corporate collaborations and other financing vehicles. There can be no assurance that such funding will be available at all or on terms acceptable to us. Potential financing sources may be dissuaded from investing in us in light of the fact that Genentech, Inc., as the sole holder of the outstanding shares of our Series G and Series H Preferred Stock, currently has a significant liquidation preference and voting position, on an as-converted to common stock basis. If adequate funds are not available, the Company may be required to curtail significantly one or all of its research and development programs. If funds are obtained through arrangements with collaborative partners or others, we may be required to relinquish rights to certain of its technologies or product candidates. If we are unable to obtain necessary funding, we may need to cease operations.

We are actively pursuing opportunities designed to diversify our product portfolio and to enhance our ability to raise future financing. There can be no assurance that any such transaction will be completed in the near term, if at all. Several factors may make it difficult for us to complete a merger, including the current uncertain state of our regulatory pathway for alagebrium and the Genentech preferred stock position. Even if we complete a merger, there can be no assurance that the products or technologies acquired in such transaction will result in revenues to the combined company.

Critical Accounting Policies

In December 2001, the SEC issued a statement concerning certain views of the SEC regarding the appropriate amount of disclosure by publicly held companies with respect to their critical accounting policies. In particular, the SEC expressed its view that in order to enhance investor understanding of financial statements, companies should explain the effects of critical accounting policies as they are applied, the judgments made in the application of these policies and the likelihood of materially different reported results if different assumptions or conditions were to prevail. We have since carefully reviewed the disclosures included in our filings with the SEC, including, without limitation, this Quarterly Report on Form 10-Q and accompanying unaudited financial statements and related notes thereto. We believe the effect of the following accounting policy is significant to our results of operations and financial condition.

We account for options granted to employees and directors using the intrinsic value method in accordance with APB Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. As such, compensation expense is recorded on fixed stock grants only if the current fair value of the underlying stock exceeds the exercise

price of the option at the date of grant and it is recognized on a straight-line basis over the vesting period. Based on the performance of our stock, we repriced certain employee stock options on February 2, 1999. As a result of this repricing, options to purchase 1.06 million shares of stock were repriced and certain vesting periods related to these options were modified or extended. FIN No. 44, Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB Opinion No. 25 requires us to record compensation expense or benefit, which is adjusted every quarter, for increases or decreases in the fair value of the repriced options based on changes in our stock price from the value at July 1, 2000. As a result, net loss applicable to common stockholders and net loss per share applicable to common stockholders may be subject to volatility. Had we accounted for repricing of stock option grants in accordance with SFAS No. 123, Accounting for Stock-Based Compensation, the expense related to the vested options would have been recorded at the repricing date, and the expense related to non-vested options would have been recorded over the vesting period.

Table of Contents

**ITEM 2. Management s
Discussion and
Analysis of
Financial
Condition and
Results of
Operations
(Continued)**

In December 2004, the FASB issued SFAS No. 123 (revised 2004), Share-Based Payment, or SFAS No. 123(R), which replaces FASB Statement No. 123 and will be effective for us beginning no later than with our fiscal quarter ending March 31, 2006. This Statement requires that the costs of employee share-based payments be measured at fair value on the awards grant date using an option-pricing model and recognized in the financial statements over the requisite service period.

SFAS No. 123(R) allows for two alternative transition methods. The first method is the modified prospective application whereby compensation cost for the portion of awards for which the requisite service has not yet been rendered that are outstanding as of the adoption date will be recognized over the remaining service period. The compensation cost for that portion of awards will be based on the grant date fair value of those awards as calculated for pro forma disclosures under SFAS No. 123, as originally issued. All new awards and awards that are modified, repurchased or cancelled after the option date will be accounted for under the provisions of SFAS No. 123(R). The second method is the modified retrospective application, which requires that we restate prior period financial statements. We have determined to use the modified prospective application as our transition method, and believe it may have a material effect on our results of operations.

Table of Contents***Forward-Looking Statements and Cautionary Statements***

Statements in this Form 10-Q that are not statements or descriptions of historical facts are forward-looking statements under Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and are subject to numerous risks and uncertainties. These forward-looking statements and other forward-looking statements made by us or our representatives are based on a number of assumptions. The words believe, expect, anticipate, intend, estimate or other expressions, which are predictions of or indicate future events and trends and which do not relate to historical matters, identify forward-looking statements. The forward-looking statements represent our judgments and expectations as of the date of this Report. We assume no obligation to update any such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, as they involve risks and uncertainties, and actual results could differ materially from those currently anticipated due to a number of factors, including those set forth in this section and elsewhere in this Form 10-Q. These factors include, but are not limited to, the risks set forth below.

If we do not obtain sufficient additional funding to meet our needs, we may have to curtail or discontinue the research, product development, pre-clinical testing and clinical trials of some or all of our product candidates, and cease operations.

As of September 30, 2005, we had working capital of \$7,361,863, including \$8,183,766 of cash and cash equivalents. Our net cash used in operating activities for the nine months ended September 30, 2005 was \$12,511,183.

We initiated several Phase 2 studies of alagebrium during 2004 and 2005, although as noted below we are not currently enrolling subjects in these studies: PEDESTAL (Patients with Impaired Ejection Fraction and Diastolic Dysfunction: Efficacy and Safety Trial of Alagebrium), a Phase 2a study in heart failure; EMERALD (Efficacy and Safety of Alagebrium in Erectile Dysfunction in Male Diabetics), a Phase 2a study in erectile dysfunction, or ED; and a Phase 2a study in endothelial dysfunction. Data from PEDESTAL and the endothelial-dysfunction study are scheduled to be presented at the American Heart Association meeting in November 2005. In June 2005, SPECTRA (Systolic Pressure Efficacy and Safety Trial of Alagebrium), a Phase 2b trial in systolic hypertension, was discontinued after an interim analysis found that the data did not indicate a treatment effect of alagebrium and we have ceased development of alagebrium for this indication. Also in June 2005, the EMERALD study was placed on clinical hold by the Reproductive and Urologic Division of the FDA pending the satisfactory completion of certain pre-clinical toxicity testing. We cannot predict at this time if these efforts will be successful or when enrollment in our EMERALD clinical study, or any other clinical study, will resume, if ever. Our current priorities are to continue the clinical development of alagebrium in heart failure and other indications, and ensure that we have the funding and personnel necessary to accomplish this objective. We are actively exploring a spectrum of strategic options to enable us to secure funding for our programs and have engaged third parties to assist in developing, identifying and executing strategic options for the Company. Such strategic options include debt and equity financing, research and development collaborations, out-licensing of our technology and development programs or a possible sale of our business to, or merger into, another entity.

We expect to utilize cash and cash equivalents to fund our operating activities, including any continued development of our lead compound, alagebrium. As a result of the discontinuation of the SPECTRA trial, we have begun curtailment actions and expect to have reduced expenses in the fourth quarter of 2005 and the first half of 2006. These actions include evaluating clinical strategies before resuming clinical trials, increased selectivity in pre-clinical programs and reduced headcount. We have the ability to quickly and significantly further reduce our cash burn rate, if necessary, as we have limited fixed commitments. We have engaged third parties to assist in developing and identifying options designed to diversify our portfolio of product candidates and to enhance our ability to raise financing in the future. Such potential transactions include the acquisition of technologies and product programs, licensing opportunities, the sale to or merger into another company, and debt and equity financing. If we are unable to secure additional financing on reasonable terms, unable to generate sufficient new sources of revenue through collaborative arrangements or if the level of cash and cash equivalents falls below anticipated levels, we will be forced to take substantial restructuring actions, which may include further reduction or curtailment of our research and product development activities and other operations. We expect to have sufficient cash and cash equivalents to satisfy our working capital requirements into the second half of 2006, either by future fund-raising or, if needed, curtailment

actions. If we are unable to raise additional funds, we will have to take additional curtailment actions and will not have the ability to continue as a going concern after mid-2006. As part of the exploration of our strategic options, we are considering various transactions that could result in the payment of certain obligations of approximately \$3 million, including severance, lease, insurance, and other contractual and regulatory requirements.

The amount and timing of our future capital requirements will depend on numerous factors, including the timing of resuming our research and development programs, if at all, the number and characteristics of product candidates that we pursue, the conduct of pre-clinical tests and clinical studies, the status and timelines of regulatory

Table of Contents

submissions, the costs associated with protecting patents and other proprietary rights, the ability to complete strategic collaborations and the availability of third-party funding, if any.

We will require substantial new funding to pursue development and commercialization of alagebrium and our other product candidates and to continue our operations. We believe that satisfying these capital requirements over the long term will require successful commercialization of our product candidates, particularly alagebrium. However, it is highly uncertain whether alagebrium or any other products will be approved or will be commercially successful.

Selling securities to satisfy our short-term and long-term capital requirements may have the effect of materially diluting the current holders of its outstanding stock. We may also seek additional funding through corporate collaborations and other financing vehicles. There can be no assurance that such funding will be available at all or on terms acceptable to us. Potential financing sources may be dissuaded from investing in us in light of the fact that Genentech, Inc., as the sole holder of the outstanding shares of our Series G and Series H Preferred Stock, currently has a significant liquidation preference and voting position, on an as-converted to common stock basis. If adequate funds are not available, the Company may be required to curtail significantly one or all of its research and development programs. If funds are obtained through arrangements with collaborative partners or others, we may be required to relinquish rights to certain of its technologies or product candidates. If we are unable to obtain necessary funding, we may need to cease operations.

We are actively pursuing opportunities designed to diversify our product portfolio and to enhance our ability to raise future financing. There can be no assurance that any such transaction will be completed in the near term, if at all. Several factors may make it difficult for us to complete a merger, including the current uncertain state of our regulatory pathway for alagebrium and the Genentech preferred stock position. Even if we complete a merger, there can be no assurance that the products or technologies acquired in such transaction will result in revenues to the combined company.

If we are unable to renegotiate our preferred stock agreement with Genentech, we may not be able to secure future equity financing or merge with a third party.

In December 1997, we entered into an agreement with Genentech relating to the development of pimagedine, an A.G.E. formation inhibitor, for the treatment of diabetic nephropathy. As part of this agreement, Genentech purchased shares of Alteon Series G Preferred Stock and Series H Preferred Stock, the proceeds of which were used to fund the pimagedine development program. Both the Series G Preferred Stock and Series H Preferred Stock have dividends which are payable quarterly in shares of preferred stock at a rate of 8.5% of the accumulated balance. The Series G and Series H Preferred Stock each carry a liquidation preference, which means that the value of that preferred stock would be required to be paid to the holders of the Series G and Series H Preferred Stock upon a sale or liquidation before any proceeds from such sale or liquidation are paid to any other holders of equity securities, including the common stock. As of September 30, 2005, holders of the outstanding shares of Series G and Series H Preferred Stock, including shares issued pursuant to the dividend obligation, were entitled to a liquidation preference of \$54,447,388. Our total market capitalization as of that date was \$17,399,013. As a result, unless we are successful in renegotiating our preferred stock terms with Genentech, holders of our common stock will not realize any value upon our sale or liquidation at a valuation of less than \$54,447,388. The Series G and Series H Preferred Stock have no voting rights. Each share of Series G Preferred Stock and Series H Preferred Stock is convertible, upon 70 days prior written notice, into the number of shares of common stock determined by dividing \$10,000 by the average of the closing prices of our common stock, as reported on the American Stock Exchange, for the 20 business days immediately preceding the date of conversion. On September 30, 2005, the Series G and Series H Preferred Stock would have been convertible into 44,963,636 and 135,028,099 shares of common stock, respectively, representing, in aggregate, approximately 76% of our common stock outstanding on an as-converted basis as of that date.

While the terms of the Series G and Series H Preferred Stock generally restrict Genentech's ownership position in us upon conversion to 40% of our outstanding common stock, any conversion of shares of Series G and/or Series H Preferred Stock into common stock would represent a substantial dilution to existing common shareholders. Potential financing sources for us may be dissuaded from investing in us in light of the presence of a significant holder of securities having a sizable liquidation preference and/or voting position. This could also discourage any potential acquirer from pursuing a transaction with us at a valuation that does not result in sufficient proceeds to pay the full

liquidation preference due to Genentech. Although we have been in negotiations with Genentech to restructure Genentech's preferred stock position, we have not been successful to date in making an agreement. Our ability to effect a merger transaction with a third party in order to diversify our product portfolio and enhance our ability to raise additional capital will be severely compromised unless we can restructure the Genentech preferred stock terms.

Table of Contents***If we are unable to form the collaborative relationships that our business strategy requires, then our programs will suffer and we may not be able to develop products.***

Our strategy for developing and deriving revenues from our products depends, in large part, upon entering into arrangements with research collaborators, corporate partners and others. The potential market, pre-clinical and clinical study results and safety profile of our product candidates may not be attractive to potential corporate partners. As noted above, a two-year toxicity study found that male rats exposed to high doses of alagebrium over their natural lifetime developed dose-related increases in liver cell alterations including hepatocarcinomas, and that the alteration rate was slightly over the expected background rate in this gender and species of rat. Also, as noted above, the EMERALD study in erectile dysfunction was placed on clinical hold by the Reproductive and Urologic Division which may adversely affect our ability to enter into research and development collaborations with respect to alagebrium. We face significant competition in seeking appropriate collaborators and these collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

If we are unable to attract and retain the key personnel on whom our success depends, our product development, marketing and commercialization plans could suffer.

We depend heavily on the principal members of our management and scientific staff to realize our strategic goals and operating objectives. Over the past few months, due to the reduction in our clinical trial activities, the number of our employees has decreased from 30 as of June 30, 2005 to 22 as of September 30, 2005. The loss of services in the near term of any of our principal members of management and scientific staff could impede the achievement of our development priorities. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future will also be critical to our success, and there is significant competition among companies in our industry for such personnel. We have established retention programs for our current key employees, and we may be required to provide additional retention and severance benefits to our employees as we curtail operations or prepare to effect a strategic transaction such as a sale or merger with another company. However, we cannot assure you that we will be able to attract and retain personnel on acceptable terms given the competition between pharmaceutical and healthcare companies, universities and non-profit research institutions for experienced managers and scientists, and given the recent clinical and regulatory setbacks that we have experienced. In addition, we rely on consultants to assist us in formulating our research and development strategy. All of our consultants are employed by other entities and may have commitments to or consulting or advisory contracts with those other entities that may limit their availability to us.

Clinical studies required for our product candidates are time-consuming, and their outcome is uncertain.

Before obtaining regulatory approvals for the commercial sale of any of our products under development, we must demonstrate through pre-clinical and clinical studies that the product is safe and effective for use in each target indication. Success in pre-clinical studies of a product candidate may not be predictive of similar results in humans during clinical trials. None of our products has been approved for commercialization in the United States or elsewhere. In December 2004, we announced that findings of a routine two-year rodent toxicity study indicated that male Sprague Dawley rats exposed to high doses of alagebrium over their natural lifetime developed dose-related increases in liver cell alterations and tumors, and that the liver tumor rate was slightly over the expected background rate in this gender and species of rat. In February 2005, based on the initial results from one of the follow-on pre-clinical toxicity experiments, we voluntarily and temporarily suspended enrollment of new subjects into each of the ongoing clinical studies pending receipt of additional pre-clinical data. Since our INDs for alagebrium are under the oversight of two divisions of the FDA, the Cardio-Renal Division and the Reproductive and Urologic Division, we simultaneously submitted the conclusions from the pre-clinical toxicity data on alagebrium to both divisions. Our

clinical protocols under the oversight of the Cardio-Renal Division were allowed to proceed. However, the EMERALD study in ED was placed and remains on clinical hold by the Reproductive and Urologic Division. We have been corresponding with the FDA on these matters in an effort to resolve this issue.

In June 2005, the Phase 2b SPECTRA trial in systolic hypertension was discontinued after an interim analysis found that the data did not indicate a treatment effect of alagebrium and we have ceased development of alagebrium for this indication.

Table of Contents

We cannot predict at this time when enrollment in our EMERALD clinical study or any other clinical study, will resume, if ever. If we are unable to resume enrollment in our clinical studies in a timely manner, or at all, our business will be materially adversely affected.

If we do not prove in clinical trials that our product candidates are safe and effective, we will not obtain marketing approvals from the FDA and other applicable regulatory authorities. In particular, one or more of our product candidates may not exhibit the expected medical benefits in humans, may cause harmful side effects, may not be effective to treat the targeted indication or may have other unexpected characteristics that preclude regulatory approval for any or all indications of use or limit commercial use if approved.

The length of time necessary to complete clinical trials varies significantly and is difficult to predict. Factors that can cause delay or termination of our clinical trials include:

- slower than expected patient enrollment due to the nature of the protocol, the proximity of subjects to clinical sites, the eligibility criteria for the study, competition with clinical trials for other drug candidates or other factors;

- adverse results in pre-clinical safety or toxicity studies;

- lower than expected retention rates of subjects in a clinical trial;

Even if we obtain positive results from pre-clinical or clinical studies for a particular product, we may not achieve the same success in future studies of that product. Data obtained from pre-clinical and clinical studies are susceptible to varying interpretations that could delay, limit or prevent regulatory approval. In addition, we may encounter delays or rejections based upon changes in FDA policy for drug approval during the period of product development and FDA regulatory review of each submitted new drug application, or NDA. We may encounter similar delays in foreign countries. Moreover, regulatory approval may entail limitations on the indicated uses of the drug. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude our licensees or marketing partners from marketing our products or limit the commercial use of such products and will have a material adverse effect on our business, financial condition and results of operations.

In addition, some or all of the clinical trials we undertake may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals, which could prevent or delay the creation of marketable products. Our product development costs will increase if we have delays in testing or approvals, if we need to perform more, larger or different clinical or pre-clinical trials than planned or if our trials are not successful. Delays in our clinical trials may harm our financial results and the commercial prospects for our products.

Before a clinical trial may commence in the United States, we must submit an IND, containing pre-clinical studies, chemistry, manufacturing, control and other information and a study protocol to the FDA. If the FDA does not object within 30 days after submission of the IND, then the trial may commence. If commenced, the FDA may delay, limit, suspend or terminate clinical trials at any time, or may delay, condition or reject approval of any of our product candidates, for many reasons. For example:

- ongoing pre-clinical or clinical study results may indicate that the product candidate is not safe or effective;

- the FDA may interpret our pre-clinical or clinical study results to indicate that the product candidate is not safe or effective, even if we interpret the results differently; or

Table of Contents

the FDA may deem the processes and facilities that our collaborative partners, our third-party manufacturers or we propose to use in connection with the manufacture of the product candidate to be unacceptable.

If we do not successfully develop any products, or are unable to derive revenues from product sales, we will never be profitable.

Virtually all of our revenues to date have been generated from collaborative research agreements and interest income. We have not received any revenues from product sales. We may not realize product revenues on a timely basis, if at all, and there can be no assurance that we will ever be profitable.

At September 30, 2005, we had an accumulated deficit of \$220,007,209. We anticipate that we will incur substantial, potentially greater, losses in the future as we continue our research, development and clinical studies. We have not yet requested or received regulatory approval for any product from the FDA or any other regulatory body. All of our product candidates, including our lead candidate, alagebrium, are still in research, pre-clinical or clinical development. We may not succeed in the development and marketing of any therapeutic or diagnostic product. We do not have any product other than alagebrium in active clinical development, and there can be no assurance that we will be able to bring any other compound into clinical development. Adverse results of any pre-clinical or clinical study could cause us to materially modify our clinical development programs, resulting in delays and increased expenditures, or cease development for all or part of our ongoing studies of alagebrium.

In June 2005, SPECTRA (Systolic Pressure Efficacy and Safety Trial of Alagebrium), a Phase 2b trial in systolic hypertension, was discontinued after an interim analysis found that the data did not indicate a treatment effect of alagebrium and we have ceased development of alagebrium for this indication.

In December 2004, we announced that findings of a routine two-year rodent toxicity study indicated that male Sprague Dawley rats exposed to high doses of alagebrium over their natural lifetime developed dose-related increases in liver cell alterations and tumors, and that the liver tumor rate was slightly over the expected background rate in this gender and species of rat. In February 2005, based on the initial results from one of the follow-on pre-clinical toxicity experiments, we voluntarily and temporarily suspended enrollment of new subjects into each of the ongoing clinical studies pending receipt of additional pre-clinical data. Since our INDs for alagebrium are under the oversight of two divisions of the FDA, the Cardio-Renal Division and the Reproductive and Urologic Division, we simultaneously submitted the conclusions from the pre-clinical toxicity data on alagebrium to both divisions. The Company's clinical protocols under the oversight of the Cardio-Renal Division were allowed to proceed. However, the EMERALD study in ED was placed and remains on clinical hold by the Reproductive and Urologic Division. We have been corresponding with the FDA on these matters in an effort to resolve this issue.

To achieve profitable operations, we must, alone or with others, successfully identify, develop, introduce and market proprietary products. Such products will require significant additional investment, development and pre-clinical and clinical testing prior to potential regulatory approval and commercialization. The development of new pharmaceutical products is highly uncertain and expensive and subject to a number of significant risks. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. Potential products may be found ineffective or cause harmful side effects during pre-clinical testing or clinical studies, fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical, fail to achieve market acceptance or be precluded from commercialization by proprietary rights of third parties. We may not be able to undertake additional clinical studies. In addition, our product development efforts may not be successfully completed, we may not have the funds to complete any ongoing clinical trials, we may not obtain regulatory approvals, and our products, if introduced, may not be successfully marketed or achieve customer acceptance. We do not expect any of our products, including alagebrium, to be commercially available for a number of years, if at all.

Failure to remediate the material weaknesses in our internal controls and to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and stock price.

During the preparation of our Form 10-Q for the quarter ended June 30, 2005, our independent registered public accounting firm identified a material weakness, as of June 30, 2005, in the review process for the financial statement recording and disclosures of stock options that we have granted to non-employee consultants in accordance with Emerging Issues Task Force (EITF) 96-18. As defined by the Public Company Accounting Oversight Board Auditing

Standard No. 2, a material weakness is a significant control deficiency or a combination of significant control deficiencies, that results in there being more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. This material weakness did not result in the restatement of any previously reported financial statements or any other related financial disclosure. Stock options that we had granted to non-employee consultants should have been accounted for under variable accounting

Table of Contents

and we have corrected the accounting for these stock options as of the second quarter of 2005. The changes that would have resulted in the financial statements for the first quarter of 2005 were deemed immaterial. We have instituted additional procedures in the review process for the financial statement recording and disclosures of options in order to remediate this issue.

On April 22, 2005, we filed an amendment to our Annual Report on Form 10-K for the fiscal year ended December 31, 2004 (the 10-K Amendment), in which we reported that, as of December 31, 2004, and as required by Section 404 of the Sarbanes-Oxley Act of 2002, management, with the participation of our principal executive officer and principal financial officer, had assessed the effectiveness of our internal control over financial reporting based on the framework established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Management’s assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Management reviewed the results of its assessment with the Audit Committee of our Board of Directors, and based on this assessment, management determined that as of December 31, 2004, there were three material weaknesses in our internal control over financial reporting. In light of these material weaknesses, management concluded that, as of December 31, 2004, we did not maintain effective internal control over financial reporting.

The three material weaknesses identified were in the areas of audit committee oversight of the internal control review process, information technology controls and process controls, and control over cash disbursements. With respect to each of these matters, as set forth in the Form 10-K Amendment, management either has implemented, or is in the process of implementing, remedial measures or procedures to address these matters. However, we cannot currently assure you that the remedial measures that are currently being implemented will be sufficient to result in a conclusion that our internal controls no longer contain any material weaknesses, and that our internal controls are effective. In addition, we cannot assure you that, even if we are able to achieve effective internal control over financial reporting, our internal controls will remain effective for any period of time.

If we are able to form collaborative relationships, but are unable to maintain them, our product development may be delayed and disputes over rights to technology may result.

We may form collaborative relationships that, in some cases, will make us dependent upon outside partners to conduct pre-clinical testing and clinical studies and to provide adequate funding for our development programs.

In general, collaborations involving our product candidates pose the following risks to us:

collaborators may fail to adequately perform the scientific and pre-clinical studies called for under our agreements with them;

collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

collaborators may not pursue further development and commercialization of our product candidates or may elect not to continue or renew research and development programs based on pre-clinical or clinical study results, changes in their strategic focus or available funding or external factors, such as an acquisition that diverts resources or creates competing priorities;

collaborators may delay clinical trials, provide insufficient funding for a clinical program, stop a clinical study or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive; collaborators with marketing and distribution rights to one or more products may not commit enough resources to their marketing and distribution;

collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

disputes may arise between us and the collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and

Table of Contents

collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development of the applicable product candidates.

In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development program could be delayed, diminished or terminated.

Our product candidates will remain subject to ongoing regulatory review even if they receive marketing approval. If we fail to comply with continuing regulations, we could lose these approvals and the sale of our products could be suspended.

Even if we receive regulatory approval to market a particular product candidate, the approval could be granted with the condition that we conduct additional costly post-approval studies or that we limit the indicated uses included in our labeling. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us to withdraw it from the market or impede or delay our ability to obtain regulatory approvals in additional countries. In addition, the manufacturer of the product and its facilities will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product will remain subject to extensive regulatory requirements. We may be slow to adapt, or we may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements.

If we fail to comply with the regulatory requirements of the FDA and other applicable United States and foreign regulatory authorities or if previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

restrictions on the products, manufacturers or manufacturing processes;

warning letters;

civil or criminal penalties;

finest;

injunctions;

product seizures or detentions;

import bans;

voluntary or mandatory product recalls and publicity requirements;

suspension or withdrawal of regulatory approvals;

total or partial suspension of production; and

refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

If we cannot successfully develop a marketing and sales force or maintain suitable arrangements with third parties to market and sell our products, our ability to deliver products to the market may be impaired.

We currently have no experience in marketing or selling pharmaceutical products. In order to achieve commercial success for any approved product, we must either develop a marketing and sales force ourselves, or, where appropriate and permissible, enter into arrangements with third parties to market and sell our products. We might not be successful in developing marketing and sales capabilities. Further, we may not be able to enter into marketing and

sales agreements with others on acceptable terms, and any such arrangements, if entered into, may be terminated. If we develop our own marketing and sales capability, we will compete with other companies that currently have experienced, well funded and larger marketing and sales operations. To the extent that we enter into co-promotion or other sales and marketing arrangements with other companies, our revenues will depend on the efforts of others, which may not be successful.

Table of Contents

If we cannot successfully form and maintain suitable arrangements with third parties for the manufacturing of the products we may develop, our ability to develop or deliver products may be impaired.

We have no experience in manufacturing products and do not have manufacturing facilities. Consequently, we are dependent on contract manufacturers for the production of products for development and commercial purposes. The manufacture of our products for clinical trials and commercial purposes is subject to current cGMP regulations promulgated by the FDA. In the event that we are unable to obtain or retain third-party manufacturing capabilities for our products, we will not be able to commercialize our products as planned. Our reliance on third-party manufacturers will expose us to risks that could delay or prevent the initiation or completion of our clinical trials, the submission of applications for regulatory approvals, the approval of our products by the FDA or the commercialization of our products or result in higher costs or lost product revenues. In particular, contract manufacturers:

could encounter difficulties in achieving volume production, quality control and quality assurance and suffer shortages of qualified personnel, which could result in their inability to manufacture sufficient quantities of drugs to meet our clinical schedules or to commercialize our product candidates;

could terminate or choose not to renew the manufacturing agreement, based on their own business priorities, at a time that is costly or inconvenient for us;

could fail to establish and follow FDA-mandated cGMPs, as required for FDA approval of our product candidates, or fail to document their adherence to cGMPs, either of which could lead to significant delays in the availability of material for clinical study and delay or prevent filing or approval of marketing applications for our product candidates; and

could breach, or fail to perform as agreed, under the manufacturing agreement.

Changing any manufacturer that we engage for a particular product or product candidate may be difficult, as the number of potential manufacturers is limited, and we will have to compete with third parties for access to those manufacturing facilities. cGMP processes and procedures typically must be reviewed and approved by the FDA, and changing manufacturers may require re-validation of any new facility for cGMP compliance, which would likely be costly and time-consuming. We may not be able to engage replacement manufacturers on acceptable terms quickly or at all. In addition, contract manufacturers located in foreign countries may be subject to import limitations or bans. As a result, if any of our contract manufacturers is unable, for whatever reason, to supply the contracted amounts of our products that we successfully bring to market, a shortage would result which would have a negative impact on our revenues.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Agency and corresponding state and foreign agencies to ensure strict compliance with cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit the performance of third-party contractors, we do not have control over our third-party manufacturers' compliance with these regulations and standards. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions. Our current dependence upon others for the manufacture of our products may adversely affect our profit margin, if any, on the sale of future products and our ability to develop and deliver such products on a timely and competitive basis.

If we are not able to protect the proprietary rights that are critical to our success, the development and any possible sales of our product candidates could suffer and competitors could force our products completely out of the market.

Our success will depend on our ability to obtain patent protection for our products, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others, both in the United States and abroad.

The degree of patent protection afforded to pharmaceutical inventions is uncertain and our potential products are subject to this uncertainty. Competitors may develop competitive products outside the protection that may be afforded

by the claims of our patents. We are aware that other parties have been issued patents and have filed patent applications in the United States and foreign countries with respect to other agents that have an effect on A.G.E.s., or the formation of A.G.E. crosslinks. In addition, although we have several patent applications pending to protect proprietary technology and potential products, these patents may not be issued, and the claims of any patents

Table of Contents

that do issue, may not provide significant protection of our technology or products. In addition, we may not enjoy any patent protection beyond the expiration dates of our currently issued patents.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to maintain, develop and expand our competitive position, which we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and certain, but not all, corporate partners and consultants. Relevant inventions may be developed by a person not bound by an invention assignment agreement. Binding agreements may be breached, and we may not have adequate remedies for such breach. In addition, our trade secrets may become known to or be independently discovered by competitors.

The effect of accounting rules relating to our equity compensation arrangements may have an adverse effect on our stock price and financial condition.

Based on the performance of our stock and in order to bolster employee retention, we repriced certain employee stock options on February 2, 1999. As a result of this repricing, options to purchase 1.06 million shares of stock were repriced and certain vesting periods related to these options were modified or extended. This repricing may have a material adverse impact on future financial performance based on the Financial Accounting Standards Board, or the FASB, Interpretation No. 44, or FIN No. 44, Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of Accounting Principles Board, or APB Opinion No. 25. This interpretation requires us to record compensation expense or benefit, which is adjusted every quarter, for increases or decreases in the fair value of the repriced options based on changes in our stock price from the value at July 1, 2000. The options expire at various dates through January 2008.

In December 2004, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), Share-Based Payment, or SFAS No. 123(R), which replaces FASB Statement No. 123 and will be effective for us beginning no later than with our fiscal quarter ending March 31, 2006. This Statement requires that the costs of employee share-based payments be measured at fair value on the awards grant date using an option-pricing model and recognized in the financial statements over the requisite service period. We have determined to use the modified prospective application as our transition method and we believe it may have a material effect on our results of operations.

If we are not able to compete successfully with other companies in the development and marketing of cures and therapies for cardiovascular diseases, diabetes, erectile dysfunction and the other conditions for which we seek to develop products, we may not be able to continue our operations.

We are engaged in pharmaceutical fields characterized by extensive research efforts and rapid technological progress. Many established pharmaceutical and biotechnology companies with financial, technical and human resources greater than ours are attempting to develop, or have developed, products that would be competitive with our products. Many of these companies have extensive experience in pre-clinical and human clinical studies. Other companies may succeed in developing products that are safer, more efficacious or less costly than any we may develop and may also be more successful than us in production and marketing. Rapid technological development by others may result in our products becoming obsolete before we recover a significant portion of the research, development or commercialization expenses incurred with respect to those products.

Certain technologies under development by other pharmaceutical companies could result in better treatments for cardiovascular disease, diabetes and its related complications or ED. Several large companies have initiated or expanded research, development and licensing efforts to build pharmaceutical franchises focusing on these medical conditions, and some companies already have products approved and available for commercial sale to treat these indications. It is possible that one or more of these initiatives may reduce or eliminate the market for some of our products. In addition, other companies have initiated research in the inhibition or crosslink breaking of A.G.E.s.

If governments and third-party payers continue their efforts to contain or decrease the costs of healthcare, we may not be able to commercialize our products successfully.

In certain foreign markets, pricing and/or profitability of prescription pharmaceuticals are subject to government control. In the United States, we expect that there will continue to be federal and state initiatives to control and/or reduce pharmaceutical expenditures. In addition, increasing emphasis on managed care in the United States will

continue to put pressure on pharmaceutical pricing. Cost control initiatives could decrease the price that we receive for any products for which we may receive regulatory approval to develop and sell in the future and could have a material adverse effect on our business, financial condition and results of operations. Further, to the extent that cost control initiatives have a material adverse effect on our corporate partners, our ability to commercialize our

Table of Contents

products may be adversely affected. Our ability to commercialize pharmaceutical products may depend, in part, on the extent to which reimbursement for the products will be available from government health administration authorities, private health insurers and other third-party payers. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and third-party payers, including Medicare, frequently challenge the prices charged for medical products and services. In addition, third-party insurance coverage may not be available to subjects for any products developed by us. Government and other third-party payers are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing in some cases to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. If government and other third-party payers for our products do not provide adequate coverage and reimbursement levels, the market acceptance of these products would be adversely affected.

If the users of the products that we are developing claim that our products have harmed them, we may be subject to costly and damaging product liability litigation, which could have a material adverse effect on our business, financial condition and results of operations.

The use of any of our potential products in clinical studies and the sale of any approved products, including the testing and commercialization of alagebrium or other compounds, may expose us to liability claims resulting from the use of products or product candidates. Claims could be made directly by participants in our clinical studies, consumers, pharmaceutical companies or others. We maintain product liability insurance coverage for claims arising from the use of our products in clinical studies. However, coverage is becoming increasingly expensive, and we may not be able to maintain or acquire insurance at a reasonable cost or in sufficient amounts to protect us against losses due to liability that could have a material adverse effect on our business, financial condition and results of operations. We may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future, and insurance coverage and our resources may not be sufficient to satisfy any liability resulting from product liability claims. A successful product liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

Table of Contents**ITEM 3. Qualitative and Quantitative Disclosures about Market Risk**

Our cash and cash equivalents are invested primarily in money market accounts. We do not use derivative financial instruments. Accordingly, we believe we have limited exposure to market risk for changes in interest rates.

ITEM 4. Controls and Procedures

a) Evaluation of Disclosure Controls and Procedures. Our management has evaluated, with the participation of our Chief Executive Officer and our Director of Finance and Financial Reporting, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of the end of the fiscal quarter covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, the Chief Executive Officer and the Director of Finance and Financial Reporting have concluded that as of the end of such fiscal quarter, our current disclosure controls and procedures were not effective, because of the material weaknesses in internal control over financial reporting described below. We have taken, and are continuing to take, steps to address these weaknesses as described below. With the exception of such weaknesses, however, the Chief Executive Officer and the Director of Finance and Financial Reporting believe that our current disclosure controls and procedures are adequate to ensure that information required to be disclosed in the reports we file under the Exchange Act is recorded, processed, summarized and reported on a timely basis.

b) Material Weaknesses and Changes in Internal Controls. During the preparation of our Form 10-Q for the quarter ended June 30, 2005, our independent registered public accounting firm identified a material weakness, as of June 30, 2005, in the review process for the financial statement recording and disclosures of stock options that we have granted to non-employee consultants in accordance with Emerging Issues Task Force (EITF) 96-18. As defined by the Public Company Accounting Oversight Board Auditing Standard No. 2, a material weakness is a significant control deficiency or a combination of significant control deficiencies, that results in there being more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. This material weakness did not result in the restatement of any previously reported financial statements or any other related financial disclosure. Stock options that we had granted to non-employee consultants should have been accounted for under variable accounting and we have corrected the accounting for these stock options as of the second quarter of 2005. The changes that would have resulted in the financial statements for the first quarter of 2005 were deemed immaterial. We have instituted additional procedures in the review process for the financial statement recording and disclosures of options in order to remediate this issue. We have engaged a consultant to review our stock option activity specifically concentrating on this issue and any new grants issued for the period. Therefore, we anticipate that this material weakness will be remedied by December 31, 2005.

As described in the 10-K Amendment, management concluded that, as of December 31, 2004, we had three material weaknesses in our internal control over financial reporting. Since December 31, 2004, we have made the following changes in our internal control over financial reporting in order to address these material weaknesses:

1. INTERNAL CONTROL REVIEW AUDIT COMMITTEE EFFECTIVENESS. As noted in the 10-K Amendment, the Audit Committee of our Board of Directors and management initially underestimated the complexity and depth of work that would be required to comply with the internal control review required under Section 404 of the Sarbanes-Oxley Act of 2002, as well as the comprehensive nature of the internal control assessment. As a result, this process was begun later than appropriate and certain remediation efforts were not completed or tested until after December 31, 2004.

Since December 31, 2004, management and the Audit Committee have implemented remedial measures to address these matters, including establishment of a Disclosure Committee, more rigorous and documented internal sub-certification procedures, and commitment of additional resources to document and monitor ongoing changes to our internal control over financial reporting, and to document Audit Committee involvement with all of the foregoing.

2. INFORMATION TECHNOLOGY CONTROLS AND PROCESS CONTROLS. As noted in the 10-K Amendment, management has determined that, as of December 31, 2004, we did not adequately document and implement certain controls over information technology. These areas include certain change management and vendor management procedures. In addition, certain financial computer program application controls and related access controls relating to information security were not adequately implemented. Back-up and recovery processes were not adequately documented, and testing of recovery procedures was not implemented. As of September 30, 2005, the implementation

of these controls has been completed and will be tested in the fourth quarter of 2005.

3. CONTROLS OVER CASH DISBURSEMENTS. As noted in the 10-K Amendment, management has determined that, as of December 31, 2004, inadequate internal controls existed over our processing of cash disbursements. Specifically, during the fiscal year ended December 31, 2004, a number of checks, which we believe to be not greater than nine, were issued from our account without signature, and a number of checks, in amounts greater than \$7,500, which we believe to be not greater than eight, were issued from our account with only one signature, when our internal policy requires that checks greater than that amount be issued with two signatures. In all instances reviewed

Table of Contents

by us, the disbursements had been appropriately authorized and were valid disbursements. Since December 31, 2004, we have implemented remedial controls to address this matter, involving a review of checks prior to issuance to ensure their signature.

c) Except for the changes in controls described above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II OTHER INFORMATION

ITEM 6. Exhibits

Exhibits

See Exhibit Index on page 29 for Exhibits filed with this Quarterly Report on Form 10-Q.

27

Table of Contents

SIGNATURES

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

Date: November 9, 2005

ALTEON INC.

By: /s/ Kenneth I. Moch
Kenneth I. Moch
President and Chief Executive Officer
(principal executive officer)

By: /s/ Mary T. Phelan
Mary T. Phelan
Director of Finance and Financial
Reporting
(principal accounting officer)

Table of Contents

INDEX TO EXHIBITS

Exhibit

No.	Description of Exhibit
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.