ALTEON INC /DE
Form 10-Q
May 10, 2005

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SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2005

OR

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

For the transition period from _____ to _____

Commission file number 001-16043

ALTEON INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-3304550**
(State or other jurisdiction of incorporation or organization)	(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 þ No o

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

On May 2, 2005, 57,996,711 shares of the registrant s Common Stock were outstanding.

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PART I FINANCIAL INFORMATION

ITEM l. Condensed Financial Statements (Unaudited)

ALTEON INC.

CONDENSED BALANCE SHEETS
(Unaudited)

	March 31, 2005	December 31, 2004
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 15,415,788	$ 11,175,762
Other current assets	491,558	159,364
Total current assets	15,907,346	11,335,126
Property and equipment, net	90,760	107,269
Restricted cash	200,000	200,000
Total assets	$ 16,198,106	$ 11,642,395
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 683,117	$ 593,094
Accrued expenses	1,512,366	2,002,381
Total liabilities	2,195,483	2,595,475
Stockholders Equity:		
Preferred Stock, $0.01 par value, 1,993,329 shares authorized, and 1,304 and 1,277 shares of Series G and 3,916 and 3,836 shares of Series H issued and outstanding, as of March 31, 2005 and December 31, 2004, respectively. The liquidation value at March 31, 2005, was $52,199,146	52	51
Common Stock, $0.01 par value, 175,000,000 shares authorized, and 57,996,711 and 48,472,898 shares issued and outstanding, as of March 31, 2005 and December 31, 2004, respectively	579,967	484,729

Additional paid-in capital	224,849,131	214,274,790
Accumulated deficit	(211,426,527)	(205,712,650)
Total stockholders equity	14,002,623	9,046,920
Total liabilities and stockholders equity	$ 16,198,106	$ 11,642,395

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

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ALTEON INC.

CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2005	2004
Income:		
Investment income	$ 99,149	$ 37,366
Other Income		51,821
Total income	99,149	89,187
Expenses:		
Research and development	3,641,100	2,684,135
General and administrative	1,100,348	1,140,045
Total expenses	4,741,448	3,824,180
Net loss	(4,642,299)	(3,734,993)
Preferred stock dividends	1,071,578	995,853
Net loss applicable to common stockholders	$ (5,713,877)	$ (4,730,846)
Basic/diluted net loss per share applicable to common stockholders	$ (0.10)	$ (0.12)
Weighted average common shares used in computing basic/diluted net loss per share applicable to common stockholders	56,547,028	40,471,349

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

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ALTEON INC.

CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2005	2004
Cash flows from operating activities:		
Net loss	$ (4,642,299)	$ (3,734,993)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	17,269	19,934
Stock compensation expense	65,707	3,059
Changes in operating assets and liabilities:		
Other current assets	(332,194)	(210,449)
Accounts payable and accrued expenses	(399,992)	430,290
Net cash used in operating activities	(5,291,509)	(3,492,159)
Cash flows from investing activities:		
Capital expenditures	(760)	(76,316)
Net cash used in investing activities	(760)	(76,316)
Cash flows from financing activities:		
Net proceeds from issuance of common stock	9,532,295	
Net proceeds from exercise of employee stock options		5,085
Net cash provided by financing activities	9,532,295	5,085
Net increase/(decrease) in cash and cash equivalents	4,240,026	(3,563,390)
Cash and cash equivalents, beginning of period	11,175,762	16,678,582
Cash and cash equivalents, end of period	$ 15,415,788	$ 13,115,192

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

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ALTEON INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

Note 1 Basis of Presentation

The accompanying unaudited 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 months ended March 31, 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 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 $211,426,527 as of March 31, 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.

In February 2005, Alteon voluntarily and temporarily suspended enrollment of new patients into its ongoing clinical studies of alagebrium pending receipt of additional pre-clinical toxicity data. However, patients currently enrolled in these clinical studies are permitted to continue treatment. In May 2005, the Company reported encouraging interim results from these ongoing toxicity tests. The Company also announced its intention to perform an interim analysis of the data from the ongoing Phase 2b SPECTRA trial of alagebrium in patients with uncontrolled systolic hypertension. The results of both the pre-clinical data and the interim analysis are expected approximately mid-year 2005. The Company expects that decisions regarding resumption of enrollment in these clinical trials will be made at that time.

As of March 31, 2005, the Company had working capital of $13,711,863, including $15,415,788 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 three months ended March 31, 2005 was $5,291,509 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 the ongoing Phase 2 studies of our lead compound, alagebrium. The Company will actively continue to pursue fund-raising possibilities through the sale of its equity securities. If the Company is unsuccessful in its efforts to raise additional funds through the sale of additional equity securities or if the level of cash and cash equivalents falls below anticipated

levels, Alteon will be required to significantly reduce or curtail its research and product development activities, including the number of patients enrolled in the studies and other operations. The Company has the ability to quickly and significantly reduce its cash burn rate, if necessary, as it has limited fixed commitments. The Company expects to have sufficient cash and cash equivalents to satisfy its working capital requirements at least into the first quarter of 2006, either by future fund-raising or, if needed, curtailment actions.

The amount and timing of the Company s future capital requirements will depend on numerous factors, including the progress of its research and development programs, 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 development of marketing and sales capabilities, the ability to complete strategic collaborations and the availability of third-party funding.

The Company will require, over the long term, 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 capital requirements over the long term will require successful commercialization of its product

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candidates, particularly alagebrium. However, it is uncertain whether any 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. If adequate funds are not available, the Company may be required to curtail significantly one or more 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 the necessary funding, it may need to cease operations.

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 months ended March 31, 2005 and 2004, respectively. As of March 31, 2005, there were 388,759 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 months ended March 31, 2005 and 2004, would be as follows:

	Three Months Ended March 31,	
	2005	2004
Net loss, as reported	$ (4,642,299)	$ (3,734,993)
Less: Total stock-based employee and director compensation expense determined under fair value method	(464,128)	(373,436)
Pro forma net loss	(5,106,427)	(4,108,429)
Preferred stock dividends	1,071,578	995,853
Pro forma net loss applicable to common stockholders	$ (6,178,005)	$ (5,104,282)

Net loss per share applicable to common stockholders:				
Basic/diluted, as reported	$	(0.10)	$	(0.12)
Basic/diluted, pro forma	$	(0.11)	$	(0.13)

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 vesting period, beginning no later than with its fiscal quarter ending March 31, 2006.

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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 common stock equivalents excluded from the calculation as of March 31, 2005 and 2004, was 87,780,852 and 32,182,486 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 March 31, 2005 and 2004, preferred stock dividends of $1,071,578 and $995,853, respectively, were recorded. On March 31, 2005, the Series G and Series H Preferred Stock would have been convertible into 19,892,906 common stock shares and 59,739,588 common stock shares, respectively, and had a total liquidation value of $52,199,146. The Series G and Series H Preferred Stock have no voting rights.

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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 discovery and development of small molecule drugs to reverse or slow down diseases of aging and complications of diabetes. Our product candidates represent novel approaches to some of the largest pharmaceutical markets. Our lead compound, alagebrium (formerly ALT-711), is in Phase 2 clinical development for systolic hypertension, diastolic dysfunction in heart failure, or DHF, and erectile dysfunction, or ED. We have identified several other promising drug candidates for future development; none of these other candidates is currently in active clinical development. Our pharmaceutical candidates were 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.

Alagebrium is our lead product candidate and we believe it to be the only A.G.E. Crosslink Breaker in advanced human clinical testing. We initiated several Phase 2 studies of alagebrium during 2004: the SPECTRA (**S**ystolic **P**ressure **E**ffica**c**y and Safety **Tr**ial of **A**lagebrium) trial in systolic hypertension and the PEDESTAL (**P**atients with Impaired **E**jection Fraction and **D**iastolic Dysfunction: **E**fficacy and **S**afety **T**rial of **Al**agebrium) study in heart failure, as well as a study in endothelial dysfunction. We initiated a Phase 2a study in ED, EMERALD (**E**fficacy and Safety of Alagebriu**m** in **Er**ectile Dysfunction in M**al**e **D**iabetics), in January 2005. Several Phase 2 clinical studies have been completed: the DIAMOND (**D**istensibility **I**mprovement **a**nd Re**mo**deli**n**g in **D**iastolic Heart Failure) study in DHF, the SAPPHIRE/SILVER (**S**ystolic **A**nd **P**ulse **P**ressure **H**emodynamic **I**mprovement by **R**estoring **E**lasticity/**S**ystolic Hypertension **I**nteraction with **L**eft **VE**ntricular **R**emodeling) trial in systolic hypertension and a study in cardiovascular compliance. Of the approximately 1,300 patients who have participated in the Phase 1 and Phase 2 clinical studies of alagebrium to date, approximately 1,000 patients have received alagebrium and approximately 300 patients 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 two-year 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 including hepatocarcinomas, and that the alteration rate was slightly over the expected background rate in this gender and species of rat. The relevance of these findings to humans is unknown. Our Data Monitoring Committee, or DMC, has reviewed the cumulative human safety data and previous pre-clinical experience of alagebrium and found that the data did not demonstrate an association with the lifetime carcinogenicity study in rats. We have previously completed four genotoxicity studies of alagebrium to help determine potential toxicities in humans, and these studies have not indicated any potential human risk. Earlier pre-clinical toxicity studies found no mutagenic or carcinogenic activity in either rats or mice. We also announced in December 2004 our intent to conduct a series of pre-clinical experiments to explore the mechanism by which the liver alterations developed and the relevance of such alterations to human exposure. In February 2005, we voluntarily and temporarily suspended enrollment of new patients into our ongoing clinical studies of alagebrium pending receipt of additional pre-clinical data. However, patients currently enrolled in these clinical studies are permitted to continue treatment. In May 2005, we announced that the interim results from the pre-clinical toxicity tests announced in December 2004 appear to be encouraging, but that we expect that decisions regarding resumption of enrollment in our clinical trials will be made when the tests are completed, which is expected to be by mid-year 2005. Prior to resuming enrollment into any of our clinical studies of alagebrium, we intend to review all relevant findings with appropriate oversight entities, including our DMC, Investigational Review Boards, or IRBs, and the U.S. Food and Drug Administration, or FDA.

In May 2005, we also announced our intention to perform an interim analysis of the data from the ongoing Phase 2b SPECTRA trial of alagebrium in patients with uncontrolled systolic hypertension. The results of this

analysis, expected to be done approximately mid-year, will also help guide us in determining the appropriateness of continuing our development of alagebrium for uncontrolled systolic hypertension.

We cannot predict at this time when enrollment in our clinical studies will resume, if ever. If we do not resume enrollment in one or more of our clinical studies we will evaluate moving into more focused clinical trials in different indications or returning to our pre-clinical library of compounds to identify new compounds to bring forward for further evaluation. Should we be unable to resume enrollment in our clinical studies, in a timely manner, or at all, our business will be materially adversely affected.

Our primary priorities are to continue the clinical development of alagebrium in systolic hypertension, diastolic dysfunction in heart failure and ED, and to ensure that we have the funding and personnel necessary to accomplish this objective.

As we continue clinical development of alagebrium, we will determine if it is appropriate to retain development and marketing rights for one or several indications in North America, while at the same time continuing to evaluate potential corporate partnerships for the further development and ultimate marketing of the compound in other territories throughout the world. We believe that alagebrium may address the cardiovascular, diabetes, urology and primary care physician markets.

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

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 systolic hypertension, heart failure, endothelial dysfunction and ED, we have early research studies focused on atherosclerosis; Alzheimer s disease; photoaging of the skin; eye diseases, including age-related macular degeneration, or AMD, and glaucoma; and diabetic complications, including renal diseases.

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 $211,427,000 as of March 31, 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 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 resume enrollment in our clinical studies of alagebrium, (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, and (9) dependence on collaborative partners and other third parties. 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 March 31, 2005 and 2004

Total income for the three months ended March 31, 2005 and 2004, was $99,000 and $89,000, respectively. Investment income for the three months ended March 31, 2005 and 2004 was $99,000 and $37,000, respectively. This increase was attributed to higher investment balances and interest rates. In 2004, income also included approximately $52,000 in other income derived from the sale of fully depreciated laboratory equipment and supplies.

Our total expenses were $4,741,000 for the three months ended March 31, 2005, compared to $3,824,000 for the three months ended March 31, 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.

In 2005, we continued the clinical development of alagebrium. In January, we announced the initiation of a Phase 2a study of alagebrium in ED. EMERALD will assess the ability of alagebrium to restore erectile function in diabetic patients with moderate to severe ED who are insufficiently responsive to current treatment with Phosphodiesterase Type 5, or PDE5 inhibitors, the first class of orally-active compounds marketed for ED. In February 2005, we voluntarily and temporarily suspended enrollment of new patients into EMERALD pending receipt of additional pre-clinical toxicity data. We expect that decisions regarding resumption of enrollment will be made following completion of the pre-clinical tests. Prior to resuming enrollment in EMERALD, we intend to review all relevant findings with appropriate oversight entities, including our DMC, IRBs and the FDA.

In March 2004, we initiated SPECTRA, a Phase 2b clinical trial in patients with systolic hypertension. The trial is being conducted at over 70 clinical sites throughout the United States. In April 2004, we initiated PEDESTAL, a Phase 2a study being conducted at Baylor Heart Clinic in Houston. PEDESTAL is designed to evaluate the effect of alagebrium on diastolic dysfunction and left ventricular mass in patients with significant heart failure. In December 2004, we announced preliminary data from the initial 14 (of planned 20) patients in the study. In February 2005, we voluntarily and temporarily suspended enrollment of new patients into both SPECTRA and PEDESTAL pending receipt of additional pre-clinical data. We expect that decisions regarding resumption of enrollment will be made following completion of the pre-clinical

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

tests. Prior to resuming enrollment in any of our clinical studies of alagebrium, we intend to review all relevant findings with appropriate oversight entities, including our DMC, IRBs and the FDA.

In May 2005, the Company announced that interim results from the pre-clinical toxicity tests announced in December 2004 appear encouraging. These toxicity tests are ongoing and are expected to be completed by mid-year 2005. Decisions regarding resumption of enrollment of patients into each of the Phase 2 trials will be made at that time.

In May 2005, the Company also announced that it intends to perform an interim analysis of the ongoing Phase 2b SPECTRA trial. The results of this analysis, together with the results of the pre-clinical toxicity tests under way, will help guide Alteon in determining the next steps for continuing our development of alagebrium for uncontrolled systolic hypertension and resuming enrollment in SPECTRA.

Research and development expenses were $3,641,000 for the three months ended March 31, 2005, as compared to $2,684,000 for the same period in 2004, an increase of $957,000, or 35.7%. This increase was primarily attributed to higher clinical costs and personnel and personnel-related expenses associated with SPECTRA, and increased pre-clinical expenses related to the additional toxicity studies referenced above. In 2005, of the total amount spent on research and development expenses, we incurred $1,275,000 in clinical trial expenses primarily related to SPECTRA, $1,252,000 in personnel and personnel-related expenses, $441,000 in pre-clinical expenses and $284,000 related to manufacturing (packaging and distribution). Research and development expenses for the three months ended March 31, 2004, primarily consisted of $821,000 in personnel and personnel-related expenses, $760,000 in clinical trial expenses related to the initiation of SPECTRA, $534,000 related to manufacturing (tableting and packaging) and $152,000 in pre-clinical expenses.

General and administrative expenses were $1,100,000 for the three months ended March 31, 2005, as compared to $1,140,000 for the same period in 2004. Although general and administrative expenses remained relatively flat, 2005 includes approximately $200,000 in Sarbanes-Oxley compliance fees which offset lower business development and patent fees.

Our net loss applicable to common stockholders was $5,714,000 for the three months ended March 31, 2005, compared to $4,731,000 in the same period in 2004, an increase of 20.8%, primarily related to higher clinical trial expenses associated with SPECTRA and additional toxicity studies. Included in the net loss applicable to common stockholders are preferred stock dividends of $1,072,000 and $996,000 for the three months ended March 31, 2005 and 2004 respectively.

Liquidity and Capital Resources

We had cash and cash equivalents at March 31, 2005, of $15,416,000, compared to $11,176,000 at December 31, 2004. The increase is attributable to $9,532,000 of net cash provided by financing activities offset by $5,292,000 of net cash used in operating activities, consisting primarily of research and development expenses, personnel-related costs and facility expenses. At March 31, 2005, we had working capital of $13,712,000.

In January 2005, we completed a public offering of 9,523,813 shares of common stock at $1.05 per share, which provided net proceeds of $9,532,000 (see Note 5).

In 2004, we sold $3,456,000 of our gross state net operating loss carryforwards and $123,000 of our state research and development tax credit carryforwards under the State of New Jersey s Technology Business Tax Certificate Transfer Program, referred to as the Program. The Program allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of net operating loss carryforwards and defined research and development tax credits for cash. Due to the uncertainty at any time as to our ability to effectuate the sale of our available New Jersey state net operating losses, and since we have no control or influence over the Program, the benefits are recorded once the agreement with the counterparty is signed and the sale is approved by the State. The proceeds from the sales in 2004 were $386,000 and were recorded as a tax benefit in the December 31, 2004 statements of operations. As of December 31, 2004, we had state net loss carryforwards and state research and development tax credit carryforwards available for sale of $81,730,000. We cannot be certain if we will be able to sell any or all of these carryforwards under the Program.

We do not have any approved products and currently derive cash from sales of our securities, sales of our New Jersey state net operating loss carryforwards and interest on cash and cash equivalents. We are highly susceptible to conditions in the global financial markets and in the pharmaceutical industry. Positive and negative movement in those markets will continue to pose opportunities and challenges to us. Previous downturns in the market valuations of biotechnology companies and of the equity markets more generally have restricted our ability to raise additional capital on favorable terms.

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

We expect to utilize cash and cash equivalents to fund our operating activities, including the ongoing Phase 2 studies of our lead compound, alagebrium. The first two of these Phase 2 studies, the SPECTRA trial and the PEDESTAL study, were initiated in 2004, and the EMERALD study was initiated in 2005. In February 2005, Alteon voluntarily and temporarily suspended enrollment of new patients into its ongoing clinical studies of alagebrium pending receipt of additional pre-clinical toxicity data. In May 2005, the Company reported encouraging interim results from these ongoing toxicity tests. The Company also announced its intention to perform an interim analysis of the data from the ongoing Phase 2b SPECTRA trial of alagebrium in patients with uncontrolled systolic hypertension. The results of both the pre-clinical data and the interim analysis are expected by mid-year 2005. The Company expects that decisions regarding resumption of enrollment in these clinical trials will be made at that time. Clinical studies of alagebrium are ongoing and patients currently enrolled in these clinical studies are continuing treatment.

Assuming enrollment is resumed in all our ongoing trials by mid-year 2005, the remaining cost of these studies, exclusive of our internal cost, is estimated to be $7.5 million. The cost includes executed, but cancelable, agreements with outside organizations. The estimated cost includes additional expenses for SPECTRA as a result of our decision to increase the number of clinical sites and to engage a clinical research organization. If enrollment does not resume in one or more of our clinical trials, Alteon s cash required for operations may be reduced. In January 2005, we completed a sale of common stock, which provided net proceeds of approximately $9.5 million. We intend to continue to pursue fund-raising possibilities through the sale of our equity securities actively. If we are unsuccessful in our efforts to raise additional funds through the sale of additional equity securities, we will be required to significantly reduce or curtail our research and product development activities, including the number of patients enrolled in our studies, and other operations if our level of cash and cash equivalents falls below anticipated levels. We have the intent and ability to quickly and significantly reduce the cash burn rate, if necessary, as we have limited fixed commitments. We expect to have sufficient cash and cash equivalents to satisfy our working capital requirements at least into the first quarter of 2006, either by future fund-raising or, if needed, curtailment actions.

The amount and timing of our future capital requirements will depend on numerous factors, including the progress of our research and development programs, 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 development of marketing and sales capabilities, our ability to complete strategic collaborations and the availability of third-party funding.

Our current priorities and the focus of our resources are the evaluation and continued development of alagebrium and determining the optimal course for the development of other compounds in our patent estate. As we continue clinical development of alagebrium, we will determine if it is appropriate to retain development and marketing rights for one or several indications in North America, while at the same time, continuing to evaluate potential corporate partnerships for the further development and ultimate marketing of the compound throughout the world.

We will require, over the long term, substantial additional 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 uncertain whether alagebrium or any product candidate 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. If adequate funds are not available, we may be required to curtail significantly one or more of our research and development programs. If we obtain funds through arrangements with collaborative partners or others, we may be required to relinquish rights to certain of our technologies or product candidates. If we are unable to obtain the necessary funding, we may need to cease operations.

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.

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

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, until adoption of newly issued accounting rules on January 1, 2006 described below. 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.

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 are currently determining which transition method we will adopt and are evaluating the impact SFAS No. 123(R) will have on our financial position and results of operations. However, we believe it may have a material effect on our results of operations.

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 futu events and trends and which do not relate to historical matters, identify 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.

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.

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.

As of March 31, 2005, we had working capital of $13,712,000, including $15,416,000 of cash and cash equivalents. Our cash used in operating activities for the three months ended March 31, 2005 was $5,292,000.

Alagebrium is our lead product candidate and we believe it to be the only A.G.E. Crosslink Breaker in advanced human clinical testing. We initiated several Phase 2 studies of alagebrium during 2004: the SPECTRA trial in systolic hypertension, the PEDESTAL study in heart failure and a study in endothelial dysfunction. A Phase 2a study in ED, EMERALD, was initiated in January 2005. Several Phase 2 clinical studies have been completed: the DIAMOND study in DHF, the SAPPHIRE/SILVER trial in systolic hypertension and a study in cardiovascular compliance. In February 2005, Alteon voluntarily and temporarily suspended enrollment of new patients into its ongoing clinical studies of alagebrium pending receipt of additional pre-clinical toxicity data. However, patients currently enrolled in these clinical studies are permitted to continue treatment. In May 2005, the Company reported encouraging interim results from these ongoing toxicity tests. The Company also announced its intention to perform an interim analysis of the data from the ongoing Phase 2b SPECTRA trial of alagebrium in patients with uncontrolled

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

systolic hypertension. The results of both, the pre-clinical data and the interim analysis are expected by mid-year 2005. The Company expects that decisions regarding resumption of enrollment in these clinical trials will be made at that time. Prior to resuming enrollment in any of our clinical studies of alagebrium, we intend to review all relevant findings with appropriate oversight entities, including our DMC, IRBs and the FDA. We cannot predict at this time when enrollment in our clinical studies 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.

We expect to utilize cash and cash equivalents to fund our operating activities, including the ongoing Phase 2 studies. In January 2005, we completed a sale of common stock that provided net proceeds of approximately $9.5 million. We will actively continue to pursue fund-raising possibilities through the sale of our equity securities. If we are unsuccessful in our efforts to raise additional funds through the sale of additional equity securities or if our level of cash and cash equivalents falls below anticipated levels, we will be required to significantly reduce or curtail our research and product development activities, including the number of patients enrolled in our studies and other operations. We have the ability to quickly and significantly reduce the cash burn rate, if necessary, as we have limited fixed commitments. We expect to have sufficient cash and cash equivalents to satisfy our working capital requirements at least into the first quarter of 2006, either by future fund-raising or, if needed, curtailment actions.

The amount and timing of our future capital requirements will depend on numerous factors, including the progress of our research and development programs, 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 development of marketing and sales capabilities, our ability to complete strategic collaborations and the availability of third-party funding.

We will require, over the long term, 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 uncertain whether any 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. If adequate funds are not available, we may be required to curtail significantly one or more of our research and development programs. If we obtain funds through arrangements with collaborative partners or others, we may be required to relinquish rights to certain of our technologies or product candidates. If we are unable to obtain the necessary funding, we may need to cease operations.

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.

As we announced in December 2004, findings of a two-year 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 including hepatocarcinomas, and that the alteration rate was slightly over the expected background rate in this gender and species of rat. The relevance of these findings to humans is unknown. As we further announced in February 2005, we have voluntarily and temporarily suspended enrollment of patients into our active clinical studies of alagebrium, pending receipt of additional pre-clinical toxicity data. In May 2005, we also announced our intention to perform an interim analysis of the data from the ongoing Phase 2b SPECTRA trial of alagebrium in patients with uncontrolled systolic hypertension. The results of both, the pre-clinical data and the interim analysis are expected by mid-year 2005. The Company expects that decisions regarding resumption of enrollment in these clinical trials will be made at that time. Prior to resuming enrollment in any of our clinical studies of alagebrium, we intend to review all relevant findings with appropriate oversight entities, including the DMC, IRBs and the FDA. We cannot predict at this time that enrollment in our clinical studies will resume. 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.

Before a clinical trial may commence in the United States, we must submit an investigational new drug application, or 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:

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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

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 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 patients 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 patients in a clinical trial;

inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials;

delays in approvals from a study site s review board, or other required approvals;

longer treatment time required to demonstrate effectiveness or determine the appropriate product dose;

lack of sufficient supplies of the product candidate;

adverse medical events or side effects in treated patients;

lack of effectiveness of the product candidate being tested; and

regulatory changes.

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.

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.

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At March 31, 2005, we had an accumulated deficit of $211,427,000. 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. As we announced in December 2004, findings of a two-year 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 including hepatocarcinomas, and that the alteration rate was slightly over the expected background rate in this gender and species of rat. The relevance of these findings to humans is unknown. As we further announced, we have voluntarily and temporarily suspended enrollment of patients into our ongoing clinical studies of alagebrium, pending receipt of additional pre-clinical data. However, patients currently enrolled in these clinical studies are permitted to continue treatment. In May 2005, Alteon announced that the interim results from the pre-clinical toxicity tests announced in December 2004 appear to be encouraging, but that decisions regarding resumption of enrollment in our clinical trials will be made when the tests are completed, which is expected to be by mid-year 2005. Prior to resuming enrollment into any of our clinical studies of alagebrium, we intend to review all relevant findings with appropriate oversight entities, including our DMC, IRBs and the FDA.

In May 2005, we also announced that we are preparing to perform an interim analysis of the data from the ongoing Phase 2b SPECTRA trial of alagebrium in patients with uncontrolled systolic hypertension. The results of this analysis will also help guide us in determining the appropriateness of continuing our development of alagebrium for uncontrolled systolic hypertension.

We cannot predict at this time that enrollment in our clinical studies will resume. 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. We have discussed the findings from the two-year toxicity study announced in December 2004 with the FDA and intend to conduct additional studies to explore the mechanism by which the liver alterations developed and will provide that information to the agency. We cannot yet determine what effect, if any, these preliminary results will have on our ability to complete clinical development of alagebrium in a timely manner, or at all.

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 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 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.

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. We intend to enter into these arrangements, especially in target indications in which our potential collaborator has particular therapeutic expertise or that involve a market that must be served by large sales and marketing organizations. 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 recent preliminary report of 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, in February 2005, we voluntarily and temporarily suspended enrollment into our ongoing clinical studies of alagebrium pending receipt of additional pre-clinical data. Such results could 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 its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or

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

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.

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.

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, Alteon 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;

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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

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;

fines;

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

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

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.

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

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

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 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, until the adoption of newly issued accounting rules on January 1, 2006 described below. 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 are currently determining which transition method we will adopt and are evaluating the impact SFAS No. 123(R) will have on our financial position and results of operations. However, 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

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

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 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 patients 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 .

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 on the principal members of our management and scientific staff. The loss of services of any of these personnel could impede the achievement of our development objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future will also be critical to our success. We may not 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. 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.

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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 Vice President, Finance, 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 Vice President, Finance, 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. With the exception of such weaknesses, however, the Chief Executive Officer and the Vice President, Finance, 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. As described in the 10-K Amendment, management has 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. The Company has drafted, and is in the process of implementing remedial procedures to address these matters.

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 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.

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PART II OTHER INFORMATION

ITEM 6. Exhibits

Exhibits

See the Exhibit Index on page 25 for exhibits required to be filed with this Quarterly Report on Form 10-Q.

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SIGNATURES

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

Date: May 10, 2005

ALTEON INC.

By: /s/Kenneth I. Moch

Kenneth I. Moch
President and Chief Executive Officer
(principal executive officer)

By: /s/Elizabeth A. O Dell

Elizabeth A. O Dell
Vice President, Finance
Secretary and Treasurer
(principal financial officer)

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EXHIBIT INDEX

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.