ALTEON INC /DE
Form 10-Q
November 09, 2004

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2004

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission file number 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 [X] No [ ]

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

Yes [X] No [ ]

On November 2, 2004, 48,472,898 shares of the registrant's Common Stock were outstanding.

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ALTEON INC.

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PART I - FINANCIAL INFORMATION

ITEM I. CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

ALTEON INC.
CONDENSED BALANCE SHEETS
(UNAUDITED)

	September 30, 2004
ASSETS	
Current Assets:	
Cash and cash equivalents	$ 14,124,668
Other current assets	433,392
Total current assets	14,558,060
Property and equipment, net	125,062
Restricted cash	250,000
Total assets	$ 14,933,122
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current Liabilities:	
Accounts payable	$ 416,058
Accrued expenses	1,777,980
Total current liabilities	2,194,038
Stockholders' Equity:	
Preferred Stock, $0.01 par value, 1,993,329 shares authorized, and 1,250 and 1,174 shares of Series G and 3,755 and 3,525 shares of Series H issued and outstanding, as of September 30, 2004 and December 31, 2003, respectively	50
Common Stock, $0.01 par value, 175,000,000 shares authorized, and 48,472,898 and 40,467,148 shares issued and outstanding, as of September 30, 2004 and December 31, 2003, respectively	484,729
Additional paid-in capital	213,182,784
Accumulated deficit	(200,928,479)
Total stockholders' equity	12,739,084
Total liabilities and stockholders' equity	$ 14,933,122

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

ALTEON INC.
CONDENSED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months Ended September 30,		
	2004	2003	
Income:			
Investment income	$ 55,198	$ 35,623	$
Other income	--	--	
Total income	$ 55,198	$ 35,623	$
Expenses:			
Research and development (which includes non-cash variable stock compensation expense/(benefit) of $0 and $(63,620) for the three months ended September 30, 2004 and 2003, respectively, and $0 and $20,019, for the nine months ended September 30, 2004 and 2003, respectively)	2,131,879	2,165,182	
General and administrative (which includes non-cash variable stock compensation expense/(benefit) of $0 and $(1,475,917) for the three months ended September 30, 2004 and 2003, respectively)	933,414	(422,294)	
Total expenses	3,065,293	1,742,888	1
Net loss	(3,010,095)	(1,707,265)	(1
Preferred stock dividends	1,049,920	965,004	
Net loss applicable to common stockholders	$ (4,060,015)	$(2,672,269)	$(1
Basic/diluted net loss per share applicable to common stockholders	$ (0.08)	$ (0.07)	$
Weighted average common shares used in computing basic/diluted net loss per share applicable to common stockholders	48,298,985	35,961,899	4

The accompanying notes are an integral part of these unaudited condensed

financial statements.

ALTEON INC.
CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Nine Ended S
	2004
Cash Flows from Operating Activities:	
Net loss	$(10,246,889
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation and amortization	56,548
Amortization of deferred compensation	15,138
Non-cash compensation expense related to variable plan employee stock options	--
Changes in operating assets and liabilities:	
Other assets	(207,953
Accounts payable and accrued expenses	323,485
Net cash used in operating activities	(10,059,671
Cash Flows from Investing Activities:	
Capital expenditures	(80,646
Purchases of marketable securities	--
Maturities of marketable securities	--
Net cash used in investing activities	(80,646
Cash Flows from Financing Activities:	
Net proceeds from issuance of common stock	7,581,318
Net proceeds from exercise of employee stock options	5,085
Net cash provided by financing activities	7,586,403
Net decrease in cash and cash equivalents	(2,553,914
Cash and cash equivalents, beginning of period	16,678,582
Cash and cash equivalents, end of period	$ 14,124,668

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

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 and nine months ended September 30, 2004, are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2003, 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 an accumulated deficit of $200,928,479 as of September 30, 2004, and expects to incur operating 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 collaborative relationships, reimbursement of certain of its research and development expenses by its collaborative partners, investment income earned on cash balances and short-term investments and the sale of a portion of its New Jersey net operating loss carryforwards.

As of September 30, 2004, the Company had working capital of $12,364,022, including $14,124,668 of cash and cash equivalents. The Company's net cash used in operations for the nine months ended September 30, 2004, was $10,059,671, and for the year ended December 31, 2003 was $15,906,230.

In July 2004, Alteon completed a public offering of 8,000,000 shares of common stock at $1.00 per share, which provided net proceeds of $7,581,318. The Stock Purchase Agreement provides that the Company will sell a total of 3,200,000 additional shares of common stock at $1.50 per share for $4,800,000 in gross proceeds to the investors who elect to purchase shares by no later than December 31, 2004. The investors are not obligated and at their discretion may elect not to purchase additional shares.

The Company expects to utilize cash and cash equivalents to fund its operations, including the Phase 2 SPECTRA (Systolic Pressure EffiCacy and Safety TRial of Alagebrium) and PEDESTAL (Patients with Impaired Ejection Fraction and Diastolic Dysfunction: Efficacy and Safety Trial of ALagebrium) trials. Based on the projected spending levels for the Company, including these trials, which are expected to continue into 2005, the Company does not currently have adequate cash and cash equivalents to complete the trials and therefore will require additional funding. The Company believes that its existing cash and cash equivalents will be adequate to satisfy its working capital requirements for its

current operations into the second quarter of 2005. As a result, the Company will monitor its liquidity position and the status of its clinical trials and will continue actively 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 its equity securities, Alteon will be required to significantly reduce or curtail its research and product development activities, including the number of patients enrolled in the trials, and other operations if its level of cash and cash equivalents falls below pre-determined levels. The Company has the intent and ability to quickly and significantly reduce the cash burn rate, if necessary, as it has limited fixed commitments. The Company believes that such curtailment actions, if needed, will enable Alteon to fund its operations beyond early 2005.

The Company will require, over the long term, substantial new funding to pursue development and commercialization of alagebrium and its other product candidates and continue its operations. The Company believes that satisfying these capital requirements over the long term will require successful commercialization of its product candidates. However, it is uncertain whether any products will be approved or will be commercially successful. The amount 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 we pursue, the conduct of pre-clinical tests and clinical trials, the development of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the development of marketing and sales capabilities and the availability of third-party funding.

Selling securities to satisfy Alteon's short-term and long-term capital requirements may have the effect of materially diluting the current holders of the Company's outstanding common stock. The Company 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 Alteon. If Alteon obtains funds through arrangements with collaborative partners or others, the Company may be required to relinquish rights to certain of its technologies or product candidates. If the Company 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 under Accounting Principles Board Opinion No. 25 ("APB Opinion No. 25"), "Accounting for Stock Issued to Employees," and related interpretations, under which no compensation cost (excluding those options granted below fair value) has been recognized. Stock option awards issued to consultants and contractors are accounted for in accordance with Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation" 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 ("FASB") released Interpretation No. 44 ("FIN 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/(benefit) in 2004. The total non-cash stock compensation (benefit)/expense resulting from the 1999 repricing for the three months ended September 30, 2003 was $(1,539,537), and for the nine months ended September 30, 2003 was $20,019. As of September 30, 2004, there were 545,484 repriced options outstanding, which expire on various dates through January 2008.

If the Company had applied the fair value recognition provisions of SFAS No. 123 to its employee and director option grants, the Company's pro forma net loss and net loss per share applicable to common stockholders for the three and nine months ended September 30, 2004 and 2003, would be as follows:

	Three Months Ended September 30,		Nine Mont
	2004	2003	2004
Net loss, as reported	$ (3,010,095)	$ (1,707,265)	$ (10,246
Add: Variable non-cash employee and director stock compensation (benefit)/expense recognized in the Statements of Operations	--	(1,539,537)	
Less: Total stock-based employee and director compensation benefit/(expense) determined under fair value method	125,580	(305,775)	(604
Pro forma net loss	(2,884,515)	(3,552,577)	(10,850
Preferred stock dividends	1,049,920	965,004	3,062
Pro forma net loss applicable to common stockholders	$ (3,934,435)	$ (4,517,581)	$ (13,913
Earnings per share applicable to common stockholders:			
Basic/diluted, as reported	$ (0.08)	$ (0.07)	$ (
Basic/diluted, pro forma	$ (0.08)	$ (0.13)	$ (

NOTE 4 - CASH AND CASH EQUIVALENTS

Cash and cash equivalents include cash and highly liquid investments, which have a maturity of less than three months at the time of purchase.

NOTE 5 - 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 due to the Company's losses. The amount of potentially issuable shares of common stock excluded from the calculation as of September 30, 2004 and 2003, was 59,061,487 and 28,218,949, respectively.

NOTE 6 - COMPREHENSIVE LOSS

The following sets forth comprehensive loss for the three and nine months ended September 30, 2004 and 2003:

	Three Months Ended September 30,	
	2004	2003
Net Loss	$(3,010,095)	$(1,707,265)
Net Unrealized Loss on Short-Term Investments	--	(1,642)
Comprehensive Loss	$(3,010,095)	$(1,708,907)

NOTE 7 - STOCKHOLDERS' EQUITY

A Special Meeting of the Stockholders of the Company was held on September 15, 2004. The stockholders voted to amend the Company's Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 100,000,000 to 175,000,000.

In July 2004, Alteon completed a public offering of 8,000,000 shares of common stock at $1.00 per share, which provided net proceeds of $7,581,318, and issued warrants to purchase 400,000 shares of common stock at an exercise price of $1.30 per share. The Stock Purchase Agreement provides that the Company will sell a total of 3,200,000 additional shares of common stock at $1.50 per share for $4,800,000 in gross proceeds to the investors who elect to purchase shares by no later than December 31, 2004. The investors are not obligated and at their discretion may elect not to purchase additional shares. In connection with this offering, certain previously issued warrants were repriced to $1.00 per share pursuant to antidilution provisions connected to the warrants.

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 prices of the common stock, as reported on the American Stock Exchange, for the 20 business days immediately preceding the date of conversion. For the three months ended September 30, 2004 and 2003, preferred stock dividends were $1,049,920 and $965,004, respectively, and for the nine months ended September 30, 2004 and 2003, preferred stock dividends were $3,062,731 and $2,805,168, respectively.

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 is in clinical development; several others are in earlier development stages. These pharmaceutical candidates were developed as a result of our research on the Advanced Glycation End-Products ("A.G.E.") pathway, a fundamental pathological process and inevitable consequence of aging that causes or contributes to many medical disorders, including cardiovascular, kidney and eye diseases.

Alagebrium chloride (formerly ALT-711) is our lead product candidate and we believe it to be the only A.G.E. Crosslink Breaker in advanced human clinical testing. In February 2004, the United States Adopted Name (USAN) Council approved alagebrium chloride as the generic name of the chemical compound formerly known as ALT-711.

We believe that alagebrium works through a unique mechanism of action that directly reverses the stiffening of the vasculature that leads to systolic hypertension and heart failure, two cardiovascular indications for which there are clear, unmet medical needs. Several Phase 2 clinical trials of alagebrium have been completed in heart failure and systolic hypertension: the DIAMOND (Distensibility Improvement And ReMOdeliNg in Diastolic Heart Failure) trial in diastolic heart failure ("DHF"); the SAPPHIRE (Systolic And Pulse Pressure Hemodynamic Improvement by Restoring Elasticity) and SILVER (Systolic Hypertension Interaction with Left VEntricular Remodeling) trial in uncontrolled systolic hypertension; and a trial in cardiovascular compliance.

Based on evidence of alagebrium's demonstrated efficacy and biological activity in these Phase 2 clinical trials, as well as the compound's safety profile in humans, Alteon is proceeding with further Phase 2 development of alagebrium in systolic hypertension and heart failure. SPECTRA (Systolic Pressure EffiCacy and Safety TRial of Alagebrium), a Phase 2 trial, was initiated in March 2004, and PEDESTAL (Patients with Impaired Ejection Fraction and Diastolic Dysfunction: Efficacy and Safety Trial of ALagebrium), a Phase 2 trial, was initiated in April 2004. We are conducting a Phase 2 trial of alagebrium in endothelial dysfunction at Johns Hopkins University School of Medicine under grants from the National Heart, Lung and Blood Institute and the Society of Geriatric Cardiology.

Our primary priorities are to continue the clinical development of alagebrium in systolic hypertension and in heart failure 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 and primary care physician markets.

We plan to continue to explore the use of alagebrium and other A.G.E. Crosslink Breakers in additional indications where A.G.E.s and A.G.E. crosslinking contribute to disease. Recent pre-clinical evidence has demonstrated the beneficial effects of alagebrium on erectile dysfunction, kidney disease, atherosclerosis and other disorders.

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 $200,928,479 as of September 30, 2004, and expect to incur operating losses, potentially greater than losses in prior years, for a number of years.

We have financed our operations through proceeds from an initial public offering of common stock in 1991, subsequent public offerings of common stock, private placements of common and preferred equity securities, revenue from collaborative relationships, reimbursement of certain of our research and development expenses by our collaborative partners, investment income earned on cash balances and short-term investments and the sale of a portion of our New Jersey net operating loss carryforwards.

Our business is subject to significant risks, which are described in this Report, including those under the heading "Forward-Looking Statements and Cautionary Statements."

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

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

Total income for the three months ended September 30, 2004 and 2003, was $55,198 and $35,623, respectively. Income consisted of interest earned on cash and cash equivalents, which increased in the three months ended September 30, 2004, compared to the same period in the prior year, due to higher investment balances and an increase in short-term interest rates.

Our total expenses were $3,065,293 for the three months ended September 30, 2004, compared to $1,742,888 for the three months ended September 30, 2003, and in each period consisted primarily of research and development expenses.

Research and development expenses were relatively flat as compared to the three months ended September 30, 2003. They included higher clinical trial costs associated with SPECTRA and PEDESTAL, offset by lower manufacturing costs. Research and development expenses included third-party expenses associated with pre-clinical and clinical studies, manufacturing costs, including the development and preparation of clinical supplies, personnel and personnel-related expenses and facility expenses. Research and development expenses were $2,131,879 for the three months ended September 30, 2004, as compared to $2,165,182 for the same period in 2003. In 2004, they consisted of $978,054 in personnel and personnel-related expenses, $787,433 in clinical trial expenses, primarily related to SPECTRA, and $206,034 in pre-clinical expenses, including the completion of a two-year carcinogenicity study. In 2003, they primarily consisted of $1,023,128 in personnel and personnel-related expenses, $350,848 in clinical trial expenses, including $240,113 related to the Phase 2 SAPPHIRE/SILVER trial, $151,090 related to process development and drug stability studies and $145,516 in pre-clinical expenses.

General and administrative expenses increased to $933,414 for the three months ended September 30, 2004, compared to $(422,294) for the same period in 2003, which included a non-cash variable stock compensation benefit of $(1,475,917). Non-cash variable stock compensation expense/(benefit) is directly related to changes in our stock price (see Note 3). Excluding the non-cash variable stock compensation, general and administrative expenses were $933,414 and $1,053,623 in 2004 and 2003, respectively, and in 2003 included increased facility expenses related to the termination of our lease in Ramsey, New Jersey.

Our net loss applicable to common stockholders was $4,060,015 for the three months ended September 30, 2004, compared to $2,672,269 in the same period in 2003, an increase of 51.9%, primarily related to non-cash variable stock compensation and the effect of expense/(benefit) relating thereto. Included in

the net loss applicable to common stockholders are preferred stock dividends of $1,049,920 and $965,004 for the three months ended September 30, 2004 and 2003, respectively.

NINE MONTHS ENDED SEPTEMBER 30, 2004 AND 2003

Total income for the nine months ended September 30, 2004 and 2003 was $273,436 and $139,521, respectively. The income consisted of interest earned on cash and cash equivalents, which decreased in the nine months ended September 30, 2004, compared to the same period in the prior year due to lower investment balances. In 2004, income also included approximately $52,000 in other income derived from the sale of fully depreciated laboratory equipment and supplies, and a reimbursement of $100,000 for improvements made to our former Ramsey facility.

Our total expenses were $10,520,325 for the nine months ended September 30, 2004, compared to $12,131,317 for the nine months ended September 30, 2003, and in each year consisted primarily of research and development expenses. Research and development expenses for the nine months ended September 30, 2004 were $7,261,576, and included $2,767,114 in personnel and personnel-related expenses, $2,268,038 in clinical trial expenses, of which approximately $2,000,000 related to SPECTRA, $925,966 related to manufacturing (packaging and tableting), $360,110 in pre-clinical expenses, consisting of the completion of a carcinogenicity study, $361,955 of facility and other overhead related costs and $269,810 in third-party consulting. Research and development expenses for the nine months ended September 30, 2003 were $8,330,120 and included $3,352,234 in personnel and personnel-related expenses, $2,022,375 in clinical trial expenses, of which $1,637,197 related to the Phase 2 SAPPHIRE/SILVER trial, $628,574 in pre-clinical expenses (including toxicity and range-finding studies), manufacturing costs of $583,697, primarily related to tablet manufacturing and drug stability studies, $350,747 in third-party consulting, a non-cash variable stock compensation expense of $20,019 and $1,039,362 of facility and other overhead related costs.

Research and development expenses for the nine months ended September 30, 2004 decreased by $1,068,544 or 12.8%, as compared to the nine months ended September 30, 2003. The decrease was primarily attributed to lower personnel and personnel-related expenses and lower facility expenses in the nine months ended September 30, 2004, offset by higher clinical trial and manufacturing costs associated with SPECTRA and PEDESTAL.

General and administrative expenses decreased to $3,258,749 for the nine months ended September 30, 2004, compared to $3,801,197 for the same period in 2003. General and administrative expenses in 2003 included higher business development and marketing research costs associated with the unblinding of the SAPPHIRE/SILVER trial and higher facility costs related to the termination of our lease in Ramsey, New Jersey.

Our net loss applicable to common stockholders decreased to $13,309,620 for the nine months ended September 30, 2004, compared to $14,796,964 in the same period in 2003, a decrease of 10.0%. Included in the net loss applicable to common stockholders are preferred stock dividends of $3,062,731 and $2,805,168 for the nine months ended September 30, 2004 and 2003, respectively.

LIQUIDITY AND CAPITAL RESOURCES

We had cash and cash equivalents at September 30, 2004, of $14,124,668, compared to $16,678,582 at December 31, 2003. This is a decrease in cash and cash equivalents of $2,553,914 and is attributed to $10,059,671 of cash used in operations consisting primarily of research and development expenses, personnel related costs and facility expenses, $80,646 of capital expenditures and $7,586,403 of cash provided by financing. At September 30, 2004, we had working capital of $12,364,022.

In July 2004, Alteon completed a public offering of 8,000,000 shares of common stock at $1.00 per share, which provided net proceeds of $7,581,318. The Stock Purchase Agreement provides that the Company will sell a total of 3,200,000 additional shares of common stock at $1.50 per share for $4,800,000 in gross proceeds to the investors who elect to purchase shares by no later than December 31, 2004. The investors are not obligated and at their discretion may elect not to purchase additional shares.

We do not have any approved products and currently derive cash from sales of our equity securities, sales of our New Jersey 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.

We expect to utilize cash and cash equivalents to fund our operations, including the ongoing Phase 2 trials. The remaining cost of these trials, exclusive of our internal cost, is currently estimated to be approximately $7,700,000 for both the systolic hypertension trial and the first phase of the heart failure trial. This cost is higher than previously estimated as a result of our decision to increase the number of clinical sites for SPECTRA to facilitate our ability to meet projected timelines. The cost includes executed, but cancelable agreements with outside organizations. Based on the projected spending levels for the Company, including these trials which are expected to continue into 2005, we do not currently have adequate cash and cash equivalents to complete the trials and therefore will require additional funding. We believe that our existing cash and cash equivalents will be adequate to satisfy our working capital requirements for our current operations into the second quarter of 2005. As a result, we will monitor our liquidity position and the status of our clinical trials and will continue actively 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, we will be required to significantly reduce or curtail our research and product development activities, including the number of patients enrolled in the trials, and other operations if our level of cash and cash equivalents falls below pre-determined levels. We have the intent and ability to quickly and significantly reduce the cash burn rate, if necessary, as we have limited fixed commitments, which include executed, but cancelable, agreements with outside organizations for the newly initiated trials. We believe that such curtailment actions, if needed, will enable us to fund our operations beyond early 2005.

We will require, over the long term, substantial new funding to pursue development and commercialization of alagebrium and our other product candidates and continue our operations. We believe that satisfying these capital requirements over the long term will require successful commercialization of our product candidates. However, it is uncertain whether any products will be approved or will be commercially successful. The amount 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 candidate that we pursue, the conduct of pre-clinical tests and clinical trials, the development of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the development of marketing and sales

capabilities and the availability of third-party funding.

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

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 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.

Our current priorities and the focus of our resources are the evaluation and continued development of alagebrium (in systolic hypertension and in heart failure) 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. As described above, we believe that additional development of this compound and other product candidates will require us to obtain additional funding.

CRITICAL ACCOUNTING POLICIES

In December 2001, the United States Securities and Exchange Commission issued a statement concerning certain views of the Commission regarding the appropriate amount of disclosure by publicly held companies with respect to their critical accounting policies. In particular, the Commission 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 Commission, including, without limitation, our Annual Report on Form 10-K for the year ended December 31, 2003, and the accompanying audited financial statements and related notes thereto. We believe the effect of the following accounting policy is critical to our results of operations and financial condition.

We account for options granted to employees and directors in accordance with APB Opinion No. 25, 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. Interpretation 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 the repriced options are exercised, forfeited or expire. As a result, net loss applicable to common stockholders and net loss per share to common stockholders may be subject to volatility. Had we accounted for repricing

of stock option grants in accordance with SFAS No. 123, 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. As of September 30, 2004, there were 545,484 repriced options outstanding, which expire on various dates through January 2008.

FORWARD-LOOKING STATEMENTS AND CAUTIONARY STATEMENTS

Statements in this Form 10-Q that are not statements or descriptions of historical facts are "forward-looking" statements under Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and are subject to numerous risks and uncertainties. These forward-looking statements and other forward-looking statements made by us or our representatives are based on a number of assumptions. The words "believe," "expect," "anticipate," "intend," "estimate" or other expressions, which are predictions of or indicate future events and trends and which do not relate to historical matters, identify forward-looking statements. 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 judgment and expectations as of the date of this Report. We assume no obligation to update any such forward-looking statements.

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

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 September 30, 2004, we had working capital of $12,364,022, including $14,124,668 of cash and cash equivalents. Our cash used in operations for the nine months ended September 30, 2004 was $10,059,671. We believe that our lead compound, alagebrium chloride (formerly ALT-711), is the only A.G.E. Crosslink Breaker in advanced human testing. Several Phase 2 clinical trials have been completed: the DIAMOND trial in diastolic dysfunction in heart failure, the SAPPHIRE/SILVER trial in systolic hypertension and a trial in cardiovascular compliance. Based on evidence of alagebrium's demonstrated efficacy and biological activity in these Phase 2 trials, as well as the compound's safety profile, we are proceeding with Phase 2 development of alagebrium in two major cardiovascular indications, systolic hypertension and heart failure.

We expect to utilize cash and cash equivalents to fund our operations, including the ongoing Phase 2 trials of our lead compound, alagebrium chloride. The first of these Phase 2 trials, SPECTRA, was initiated in March 2004, and the second, PEDESTAL, was initiated in April 2004. Based on our projected spending levels, including these trials which are expected to continue into 2005, we do not currently have adequate cash and cash equivalents to complete the trials and therefore will require additional funding. We believe that our existing cash and cash equivalents will be adequate to satisfy our working capital requirements for our current operations into the second quarter of 2005. As a result, we will monitor our liquidity position and the status of our clinical trials and will continue actively 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, we will be required to significantly reduce or curtail our research and product development activities, including the number of patients enrolled in our trials, and other operations if our level of cash and cash equivalents falls below pre-determined 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 believe that such curtailment actions, if needed, will enable us to fund our operations beyond early 2005.

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 trials, 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.

IF WE DO NOT SUCCESSFULLY DEVELOP ANY PRODUCTS, OR ARE UNABLE TO DERIVE REVENUES FROM PRODUCT SALES, WE WILL NEVER BE PROFITABLE.

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

At September 30, 2004, we had an accumulated deficit of $200,928,479. We anticipate that we will incur substantial, potentially greater, losses in the future as we continue our research, development and clinical trials. We have not yet requested or received regulatory approval for any product from the United States Food and Drug Administration ("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

OF OPERATIONS (CONTINUED)

expenditures, or cease development for all or part of our ongoing programs of alagebrium. 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 trials, 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 trials. 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.

CLINICAL TRIALS 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 studies and clinical trials 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. Before a clinical trial may commence in the United States, we must submit an investigational new drug application ("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, we, the FDA, other applicable regulatory authorities or institutional review boards may delay, suspend or terminate clinical trials of a product candidate at any time if, among other reasons, we or they believe the subjects or patients participating in the clinical trials are being exposed to unacceptable health risks or for other reasons.

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 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 may be difficult to predict. Factors which 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;

- 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;

- 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 trials for a particular product, we may not achieve the same success in future trials of that product. 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 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 or larger 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 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 trial results and safety profile of our product candidates may not be attractive to potential corporate partners. 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 commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

IF WE ARE 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 trials and to provide adequate funding for our development programs.

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

- 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 trial 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 trial program, stop a clinical trial 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;

- a collaborator with marketing and distribution rights to one or more products may not commit enough resources to their marketing and distribution;

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

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

- 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 recent 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.

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 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 or, where appropriate or 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, it will compete with other companies that currently have experienced, well funded and larger marketing and sales operations. To the extent that we enter into co-promotion or other sales and marketing arrangements with other companies, 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 Good Manufacturing Practice ("cGMP") regulations promulgated by the FDA. In the event that we are unable to obtain or retain third-party manufacturing for our products, we will not be able to commercialize such 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 current good manufacturing practices, or cGMPs, 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 manufacturing 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, our 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 United States 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.

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

IF WE ARE NOT ABLE TO PROTECT THE PROPRIETARY RIGHTS THAT ARE CRITICAL TO OUR SUCCESS, THE DEVELOPMENT AND ANY POSSIBLE SALES OF OUR PRODUCT CANDIDATES COULD SUFFER AND COMPETITORS COULD FORCE OUR PRODUCTS COMPLETELY OUT OF THE MARKET.

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

The degree of patent protection afforded to pharmaceutical inventions is uncertain and our potential products are subject to this uncertainty. Competitors may develop competitive products outside the protection that may be afforded by the claims of our patents. We are aware that other parties have been issued patents and have filed patent applications in the United States and foreign countries with respect to other agents that have an effect on A.G.E.s. or the formation of A.G.E. crosslinks. In addition, although we have several patent applications pending to protect proprietary technology and potential products, these patents may not be issued, and the claims of any patents which 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.

IF WE FAIL TO OBTAIN REGULATORY APPROVALS FOR OUR PRODUCTS, THE COMMERCIAL USE OF OUR PRODUCTS WILL BE LIMITED.

Our research, pre-clinical testing and clinical trials of our product candidates are, and the manufacturing and marketing of our products will be,

subject to extensive and rigorous regulation by numerous governmental authorities in the United States and in other countries where we intend to test and market our product candidates.

Prior to marketing, any product we develop must undergo an extensive regulatory approval process. This regulatory process, which includes pre-clinical testing and clinical trials and may include post-marketing surveillance of each compound to establish its safety and efficacy, can take many years and can require the expenditure of substantial resources.

The FDA may delay, limit or deny approval of any of our product candidates for many reasons. For example:

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

- the FDA may interpret our pre-clinical or clinical trial 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 we, our collaborative partners or our third-party manufacturers propose to use in connection with the manufacture of the product candidate to be unacceptable.

Data obtained from pre-clinical and clinical activities is 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 ("NDA"). We may encounter similar delays in foreign countries. We may not obtain regulatory approval for the drugs we develop. Moreover, regulatory approval may entail limitations on the indicated uses of the drug. Further, even if we obtain regulatory approval, a marketed drug and its manufacturer are subject to continuing review and discovery of previously unknown problems with a product or manufacturer which may have adverse effects on our business, financial condition and results of operations, including withdrawal of the product from the market. Violations of regulatory requirements at any stage, including pre-clinical testing, clinical trials, the approval process or post-approval, may result in various adverse consequences, including the FDA's delay in approving, or its refusal to approve a product, withdrawal of an approved product from the market and the imposition of criminal penalties against the manufacturer and NDA holder. None of our products has been approved for commercialization in the United States or elsewhere. We may not be able to obtain FDA approval for any products. 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.

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

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 conditioned on us conducting additional costly

post-approval studies or could 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 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.

PRIOR STOCK OPTION REPRICING MAY HAVE AN ADVERSE EFFECT ON OUR FUTURE FINANCIAL PERFORMANCE.

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 ("FASB") Interpretation No. 44 ("FIN 44"), "Accounting for Certain Transactions Involving Stock Compensation, An Interpretation of 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 repriced options are exercised, forfeited or expire. The options expire at various dates through January 2008.

IF WE ARE NOT ABLE TO COMPETE SUCCESSFULLY WITH OTHER COMPANIES IN THE DEVELOPMENT AND MARKETING OF CURES AND THERAPIES FOR CARDIOVASCULAR DISEASES, DIABETES 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 resources greater than ours are attempting to develop products that would be competitive with our products. 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, or diabetes and its related complications. Several large companies have initiated or expanded research, development and licensing efforts to build pharmaceutical franchises focusing on these medical conditions. It is possible that one or more of these initiatives may reduce or eliminate the market for some of our products. In addition, other companies have initiated research in the inhibition or crosslink breaking of A.G.E.s.

IF GOVERNMENTS AND THIRD-PARTY PAYERS CONTINUE THEIR EFFORTS TO CONTAIN OR DECREASE THE COSTS OF HEALTHCARE, WE MAY NOT BE ABLE TO COMMERCIALIZE OUR PRODUCTS SUCCESSFULLY.

In certain foreign markets, pricing and/or profitability of prescription pharmaceuticals are subject to government control. In the United States, we expect that there will continue to be federal and state initiatives to control and/or reduce pharmaceutical expenditures. In addition, increasing emphasis on managed care in the United States will continue to put pressure on pharmaceutical pricing. Cost control initiatives could decrease the price that we receive for any products we may develop and sell in the future and 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, are increasingly challenging the prices charged for medical products and services. 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 adequate coverage and reimbursement levels are not provided by government and other third-party payers for our products, the market acceptance of these products would be adversely affected.

IF THE USERS OF THE PRODUCTS WE DEVELOP 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 CONDITIONS AND RESULTS OF OPERATIONS.

The use of any of our potential products in clinical trials and the sale of any approved products, including the testing and commercialization of alagebrium or other compounds, expose us to liability claims resulting from the use of products or product candidates. Claims could be made directly by participants in our clinical trials, consumers, pharmaceutical companies or others. We maintain product liability insurance coverage for claims arising from the use of our products in clinical trials. 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 conditions 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 are highly dependent 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 scientists. In addition, we rely on consultants to assist us in formulating our research and development strategy. All of our consultants are employed outside of us and may have commitments to or consulting or advisory contracts with other entities that may limit their availability to us.

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 Chief Executive Officer and our Vice President, Finance, evaluated 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 are adequate and effective 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) Changes in Internal Controls. There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation of such internal control that occurred during the fiscal quarter covered by this Quarterly Report

on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

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

A Special Meeting of Stockholders of Alteon (the "Meeting") was held on September 15, 2004. stockholders voted upon a proposal to amend our Restated Certificate of Incorporation to increase the number of authorized shares of Common Stock from 100,000,000 to 175,000,000.

The number of votes cast for, against and abstaining from the proposal to amend our Restated Certificate of Incorporation, was as follows:

Votes For	Votes Against	Abstentions
41,680,732	1,447,730	79,812

ITEM 6. EXHIBITS

Exhibits

See Exhibit Index on page 22 for Exhibits 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: November 9, 2004

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 accounting officer)

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INDEX TO EXHIBITS

Exhibit No.	Description of Exhibit
3.1	Certificate of Amendment to Restated Certificate of Incorporation of Alteon Inc., d
3.2	Amended Certificate of Designations of Series G Preferred Stock of Alteon Inc., dat
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.