

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

ALTEON INC /DE  
Form 10-Q  
May 10, 2004

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 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  No

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

Yes  No

On May 6, 2004, 40,472,898 shares of the registrant's Common Stock were outstanding.

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

Page 1 of 21 pages  
The Exhibit Index is on page 20

ALTEON INC.

INDEX

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

Balance Sheets as of March 31, 2004 and  
December 31, 2003.....

Statements of Operations for the three months  
ended March 31, 2004 and 2003.....

Statements of Cash Flows for the three months  
ended March 31, 2004 and 2003.....

Notes to Financial Statements.....

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

Item 4. Controls and Procedures.....

PART II - OTHER INFORMATION

Item 6. Reports on Form 8-K and Exhibits.....

SIGNATURES .....

INDEX TO EXHIBITS .....

PART I - FINANCIAL INFORMATION

ITEM I. FINANCIAL STATEMENTS (UNAUDITED)

ALTEON INC.  
BALANCE SHEETS  
(UNAUDITED)

March 31,  
2004  
-----

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

ASSETS

Current Assets:

Cash and cash equivalents.....	\$	13,115,192	\$
Other current assets.....		435,888	
		-----	
Total current assets.....		13,551,080	
Property and equipment, net.....		157,346	
Restricted cash.....		250,000	
		-----	
Total assets.....	\$	13,958,426	\$
		=====	

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities:

Accounts payable.....	\$	895,232	\$
Accrued expenses.....		1,405,611	
		-----	
Total current liabilities.....		2,300,843	
		-----	

Stockholders' Equity:

Preferred Stock, \$0.01 par value, 1,993,329 shares authorized, and 1,199 and 1,174 shares of Series G and 3,600 and 3,525 shares of Series H issued and outstanding, as of March 31, 2004 and December 31, 2003, respectively.....		48	
Common Stock, \$0.01 par value, 80,000,000 shares authorized, and 40,472,898 and 40,467,148 shares issued and outstanding, as of March 31, 2004 and December 31, 2003, respectively.....		404,729	
Additional paid-in capital .....		203,602,511	
Accumulated deficit.....		(192,349,705)	
		-----	
Total stockholders' equity.....		11,657,583	
		-----	
Total liabilities and stockholders' equity.....	\$	13,958,426	\$
		=====	

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

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

STATEMENTS OF OPERATIONS  
(UNAUDITED)

	Three Months Ended March 2004	2003
	-----	-----
Income:		
Investment income.....	\$ 37,366	\$
Other Income .....	51,821	
	-----	-----
Total income.....	\$ 89,187	\$
Expenses:		
Research and development (which includes non-cash variable stock compensation expense of \$0 and \$61,970 for the three months ended March 31, 2004 and 2003, respectively).....	2,684,135	2
General and administrative (which includes non-cash variable stock compensation expense of \$0 and \$965,929 for the three months ended March 31, 2004 and 2003, respectively).....	1,140,045	2
	-----	-----
Total expenses.....	3,824,180	5
	-----	-----
Net loss.....	\$ (3,734,993)	\$ (5
Preferred stock dividends.....	995,853	
	-----	-----
Net loss applicable to common stockholders.....	\$ (4,730,846)	\$ (6
	=====	=====
Basic/diluted net loss per share applicable to common stockholders.....	\$ (0.12)	\$
	=====	=====
Weighted average common shares used in computing basic/diluted net loss per share.....	40,471,349	33
	=====	=====

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

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

	Three Mo Ended Mar
	----- 2004 -----
Cash Flows from Operating Activities:	
Net loss.....	\$ (3,734,993)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation and amortization.....	19,934
Amortization of deferred compensation.....	3,059
Non-cash compensation expense related to variable plan employee stock options.....	---
Changes in operating assets and liabilities:	
Other assets.....	(210,449)
Accounts payable and accrued expenses.....	430,290
	-----
Net cash used in operating activities.....	(3,492,159)
	-----
Cash Flows from Investing Activities:	
Capital expenditures.....	(76,316)
Purchases of marketable securities.....	---
	-----
Net cash used in investing activities.....	(76,316)
	-----
Cash Flows from Financing Activities:	
Net proceeds from issuance of common stock.....	---
Net proceeds from exercise of employee stock options.....	5,085
	-----
Net cash provided by financing activities.....	5,085
	-----
Net (decrease)/increase in cash and cash equivalents.....	(3,563,390)
Cash and cash equivalents, beginning of period.....	16,678,582
	-----
Cash and cash equivalents, end of period.....	\$13,115,192
	=====

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

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

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 accruals) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 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 \$192,349,705 as of March 31, 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 March 31, 2004, the Company had working capital of \$11,250,237, including \$13,115,192 of cash and cash equivalents. The Company's net cash used in operations for the three months ended March 31, 2004, was \$3,492,159 and for the year ended December 31, 2003 was \$15,906,230

Alagebrium chloride (formerly ALT-711) is the Company's lead product candidate and Alteon believes the only A.G.E. Crosslink Breaker in advanced human 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.

The Company believes 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 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 a strong and consistent safety profile, 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), the first of these Phase 2 trials, was initiated in March 2004, and the second, PEDESTAL (Patients with Impaired Ejection Fraction and Diastolic Dysfunction: Efficacy and Safety Trial of ALagebrium), was initiated in April 2004.

The Company expects to utilize cash and cash equivalents to fund its

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

operations, including the new Phase 2 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 or complete the 2004 fiscal year; and therefore will require additional funding. As a result, throughout 2004, the Company will monitor its liquidity position and the status of its clinical trials. The Company is actively pursuing fund-raising possibilities through the sale of its equity securities at the current time. If the Company is unsuccessful in its efforts to raise additional funds through the sale of additional 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, which include executed, but cancelable, agreements with outside organizations for the newly initiated trials. The Company believes that such curtailment actions, if needed, will enable Alteon to fund its operations into early 2005.

6

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 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.

Because of Alteon's short-term and long-term capital requirements, the Company, as stated above, may seek access to the public or private equity markets. This may have the effect of materially diluting the current holders of the Company's outstanding stock. The Company may also seek additional funding through corporate collaborations and other financing vehicles, potentially including off-balance sheet financing through limited partnerships or corporations. 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

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

("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. The total non-cash stock compensation expense resulting from the 1999 repricing for the three months ended March 31, 2004 and 2003, is \$0 and \$1,027,899, respectively. As of March 31, 2004, there were 548,409 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, 2004 and 2003, would be as follows:

	Three Months Ended March 31 2004	2003
	-----	-----
Net loss, as reported.....	\$ (3,734,993)	\$ (5,223,000)
Add: Variable non-cash employee and director stock compensation expense/(benefit)/ recognized in the Statements of Operations.....	--	1,027,899
Less: Total stock-based employee and director stock compensation expense determined under fair value method.....	(373,436)	(329,200)
	-----	-----
Pro forma net loss.....	\$ (4,108,429)	\$ (4,524,300)
Preferred stock dividends.....	995,853	905,400
	-----	-----
Pro forma net loss applicable to common stockholders.....	\$ (5,104,282)	\$ (5,429,800)
	=====	=====
 Net loss per share applicable to common stockholders:		
Basic/diluted, as reported.....	\$ (0.12)	\$ (0.12)
Basic/diluted, pro forma.....	\$ (0.13)	\$ (0.13)

7

#### 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. The



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

amount of common stock equivalents excluded from the calculation as of March 31, 2004 and 2003, was 32,182,486 and 18,041,617 shares, respectively.

### NOTE 6 - COMPREHENSIVE LOSS

The following sets forth comprehensive loss for the three months ended March 31, 2004 and 2003:

	Three Months Ended March 31	
	2004	2003
Net Loss.....	\$ (3,734,993)	\$ (5,223,0
Net Unrealized Loss on Short-Term Investments.....	--	(7
Comprehensive Loss.....	\$ (3,734,993)	\$ (5,223,8

### NOTE 7 - STOCKHOLDERS' EQUITY

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, 2004 and 2003, preferred stock dividends of \$995,853 and \$905,458, respectively, were recorded.

8

## 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 the only A.G.E. Crosslink Breaker in advanced human 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

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

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 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 a strong and consistent safety profile, 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), the first of these Phase 2 trials, was initiated in March 2004, and the second, PEDESTAL (Patients with Impaired Ejection Fraction and Diastolic Dysfunction: Efficacy and Safety Trial of ALagebrium), was initiated in April 2004.

Our primary priorities are to continue the clinical development of alagebrium in systolic hypertension and diastolic dysfunction 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 topical A.G.E. Crosslink Breakers in skin and photoaging, as a result of our recent evaluation of ALT-744. We will focus efforts on bringing forward other crosslink breaker compounds with more attractive formulation characteristics than those of ALT-744 to address the pharmaceutical market for skin and photoaging.

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 \$192,349,705 as of March 31, 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 under the heading "Forward-Looking Statements and Cautionary Statements."

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

### RESULTS OF OPERATIONS

#### THREE MONTHS ENDED MARCH 31, 2004 AND 2003

Total income for the three months ended March 31, 2004 and 2003, was \$89,000 and \$49,000, respectively. In 2004, income included approximately \$52,000 in other income derived from the sale of fully depreciated laboratory equipment and supplies. Income was also derived from interest earned on cash and cash equivalents.

Our total expenses were \$3,824,000 for the three months ended March 31, 2004, compared to \$5,272,000 for the three months ended March 31, 2003, and in each period consisted primarily of research and development expenses. Research and development expenses included third-party expenses associated with pre-clinical and clinical studies, manufacturing costs, including the development and preparation of clinical supplies, personnel and personnel-related expenses and facility expenses. Research and development expenses were \$2,684,000 for the three months ended March 31, 2004, as compared to \$2,905,000 for the same period in 2003. In 2004, they primarily consisted of \$821,000 in personnel and personnel-related expenses, \$764,000 in clinical trial expenses, primarily related to the start-up of SPECTRA, \$534,000 related to manufacturing (tableting and packaging) and \$152,000 in pre-clinical expenses. Research and development expenses for the three months ended March 31, 2003, primarily consisted of \$1,100,000 in personnel and personnel-related expenses, \$811,000 in clinical trial expenses related to the Phase 2b SAPPHIRE and SILVER trial, \$307,000 in pre-clinical expenses, \$144,000 related to manufacturing (assay validation and development) and drug stability studies, and non-cash variable stock compensation expense of \$62,000.

Research and development expenses decreased by \$221,000, or 7.6%, as compared to the three months ended March 31, 2003. The decrease was primarily attributed to lower clinical costs and personnel and personnel-related expenses associated with the completion of the SAPPHIRE and SILVER trial in 2003 as compared to the start-up of SPECTRA in 2004, partially offset by higher manufacturing costs for tableting and packaging in preparation for SPECTRA.

General and administrative expenses decreased to \$1,140,000 for the three months March 31, 2004, compared to \$2,367,000 for the same period in 2003 and included a non-cash variable stock compensation expense of \$966,000 in 2003. Non-cash variable stock compensation expense/(benefit) is directly related to changes in our stock price (see Note 3). Exclusive of the 2003 non-cash variable stock compensation expense, general and administrative expenses were \$1,401,000 for the three months ended March 31, 2003. The remaining decrease of \$261,000 is primarily related to personnel and personnel-related costs, business development and marketing costs incurred during the first quarter of 2003 associated with the SAPPHIRE and SILVER trial.

Our net loss applicable to common stockholders was \$4,731,000 for the three months ended March 31, 2004, compared to \$6,129,000 in the same period in 2003, a decrease of 22.8%, primarily related to a decline in variable non-cash stock compensation expense and decreased clinical trial expenses partially offset by higher manufacturing expenses. Included in the net loss applicable to common stockholders are preferred stock dividends of \$996,000 and \$905,000 for the three months ended March 31, 2004 and 2003, respectively.

#### LIQUIDITY AND CAPITAL RESOURCES

We had cash and cash equivalents at March 31, 2004, of \$13,115,000, compared to \$16,679,000 at December 31, 2003. The decrease is attributed to \$3,492,000 of cash used in operations, consisting primarily of research and development expenses, personnel-related costs and facility expenses and \$76,000 in capital expenditures, offset by \$5,000 in cash received for the exercise of

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

employee stock options. At March 31, 2004, we had working capital of \$11,250,000.

At December 31, 2003, we had available federal net operating loss carryforwards, which expire in various amounts from the years 2006 through 2023, of approximately \$144,952,000 and State net operating loss carryforwards, which expire in the years 2004 through 2010, of approximately \$91,343,000. In addition, we had federal research and development tax credit carryforwards of approximately \$6,401,000 and State research and development tax credit carryforwards of approximately \$1,600,000 at December 31, 2003. The amount of federal net operating loss and research and development tax credit carryforwards which can be utilized in any one period may become limited by federal income tax regulations if a cumulative change in ownership of more than 50% occurs within a three-year period.

10

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

In December 2003, we sold \$2,083,000 of our gross State net operating loss carryforwards and \$209,000 of our State research and development tax credit carryforwards under the State of New Jersey's Technology Business Tax Certificate Transfer Program (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. The proceeds from the sale in 2003 were \$345,000 and were recorded as a tax benefit in the December 31, 2003 statement of operations. The State renews the Program annually and limits the aggregate proceeds to \$10,000,000. 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 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 new Phase 2 trials. The remaining cost of these trials, exclusive of our internal cost, is currently estimated to be approximately \$7.6 million for the systolic hypertension trial and \$0.2 million for the first phase of the diastolic dysfunction trial. 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 or complete the 2004 fiscal year and therefore will require additional funding. As a result, throughout 2004, we will monitor our liquidity position and the status of our clinical trials. The Company is actively pursuing fund-raising possibilities through the sale of our equity securities at the current time. 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

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

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 into 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 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.

Because of our short-term and long-term capital requirements, we, as stated above, may seek access to the public or private equity markets. This 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, potentially including off-balance sheet financing through limited partnerships or corporations. 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 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

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

for the year ended December 31, 2003, and accompanying audited financial

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

statements and related notes thereto. We believe the effect of the following accounting policy is significant to our results of operations and financial condition.

We account for options granted to employees and directors 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 March 31, 2004, there were 548,409 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.

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, 2004, we had working capital of \$11,250,000, including \$13,115,000 of cash and cash equivalents. Our cash used in operations for the three months ended March 31, 2004 was \$3,492,000. We believe that our lead compound, alagebrium, is the only A.G.E. Crosslink Breaker in advanced human testing. Several Phase 2 clinical trials have been completed: the DIAMOND, the SAPPHIRE and 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 a strong and consistent safety profile, we are proceeding with Phase 2 development of alagebrium in two major cardiovascular indications, systolic hypertension and heart failure.

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

We expect to utilize cash and cash equivalents to fund our operations, including the new Phase 2 trials. The remaining cost of these trials, exclusive of our internal cost, is currently estimated to be approximately \$7.6 million for the systolic hypertension trial and \$0.2 million for the first phase of the diastolic dysfunction trial. The cost includes executed, but cancelable agreements with outside organizations. The first of these Phase 2 trials was initiated in March 2004, SPECTRA (Systolic Pressure Efficacy and Safety Trial of Alagebrium) and the second, PEDESTAL (Patients with Impaired Ejection Fraction and Diastolic Dysfunction: Efficacy and Safety Trial of ALagebrium), 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 or complete the 2004 fiscal year, and therefore will require additional funding during 2004. As a result, throughout 2004 and 2005, we will monitor our liquidity position and the status of our clinical trials. We are actively pursuing fund-raising possibilities through the sale of our equity securities at the current time. 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 into 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 conduct of pre-clinical tests and clinical trials, the development

12

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.

We will require, over the long-term, substantial new funding to pursue development and commercialization of alagebrium and our other product candidates 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.

Because of our short-term and long-term capital requirements, we will seek access to the public or private equity markets whenever conditions are favorable. This 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, potentially including off-balance sheet financing through limited partnerships or corporations. 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 or 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, WE MAY NOT DERIVE ANY REVENUES.

We have not yet requested or received regulatory approval for any product from the FDA or any other regulatory body. All of our product

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

candidates, including our lead candidate, alagebrium, are still in research 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. 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. 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: (i) 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; (ii) lower than expected retention rates of patients in a clinical trial; (iii) inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials; (iv) delays in approvals from a study site's review board; (v) longer treatment time required to demonstrate effectiveness or determine the appropriate product dose; (vi) lack of sufficient supplies of the product candidate; (vii) adverse medical events or side effects in treated patients; (viii) lack of effectiveness of the product candidate being tested, and (ix) 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 DERIVE REVENUES FROM PRODUCT SALES, WE MAY 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.



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

At March 31, 2004, we had an accumulated deficit of \$192,350,000. We anticipate that we will incur substantial, potentially greater, losses in the future. Our products under development may not be successfully developed and our products, if successfully developed, may not generate revenues sufficient to enable us to earn a profit. We expect to incur substantial additional operating expenses over the next several years as our research, development and clinical trial activities continue. We do not expect to generate revenues from the sale of products, if any, for a number of years. Our ability to achieve profitability depends, in part, on our ability to enter into agreements for product development, obtain regulatory approval for our products and develop the capacity, or enter into agreements, for the manufacture, marketing and sale of any products. We may not obtain required regulatory approvals, or successfully develop, manufacture, commercialize and market product candidates, and we may never achieve product revenues or profitability.

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 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 are seeking to establish these relationships to provide the funding necessary for continuation of our product development, but if such efforts may not be successful, our programs may suffer and we may be unable to develop products.

IF WE ARE ABLE TO FORM OUR 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 will, in some cases, make us dependent upon outside partners to conduct pre-clinical testing and clinical trials and to provide adequate funding for our development programs. Such corporate partners, if any, may have all or a significant portion of the development and regulatory approval responsibilities. Failure of the corporate partners to develop marketable products or to gain the appropriate regulatory approvals on a timely basis, if at all, would have a material adverse effect on our business, financial condition and results of operations.

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

In most cases, we will not be able to control the amount and timing of resources that our corporate partners devote to our programs or potential products. If any of our corporate partners breached or terminated its agreement with us or otherwise failed to conduct its collaborative activities in a timely manner, the pre-clinical or clinical development or commercialization of product candidates or research programs could be delayed, and we would be required to devote additional resources to product development and commercialization or terminate certain development programs.

Disputes may arise in the future with respect to the ownership of rights to any technology we develop with third parties. These and other possible disagreements between us and collaborators could lead to delays in the collaborative research, development or commercialization of product candidates, or could require or result in litigation or arbitration, which would be time-consuming and expensive and would have a material adverse effect on our business, financial condition and results of operations.

Any corporate partners we have may develop, either alone or with others, products that compete with the development and marketing of our products. Competing products, either developed by the corporate partners or to which the corporate partners have rights, may result in their withdrawal of support with respect to all or a portion of our technology, which would have a material adverse effect on our business, financial condition and results of operations.

14

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

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 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. We may

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

not be able to enter into agreements for the manufacture of future products with manufacturers whose facilities and procedures comply with cGMP and other regulatory requirements. Our current dependence upon others for the manufacture of our products may adversely affect our profit margin, if any, on the sale of future products and our ability to develop and deliver such products on a timely and competitive basis.

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

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

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

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

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

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.

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

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

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

16

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

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

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

us.

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) 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.

17

PART II - OTHER INFORMATION

ITEM 6. REPORTS ON FORM 8-K AND EXHIBITS

a) The following reports on Form 8-K were filed during the quarter ended March 31, 2004:

On March 15, 2004, we filed a current report on Form 8-K, dated March 12, 2004, regarding our financial condition and results of operations for the year ended December 31, 2003.

On March 12, 2004, we filed a current report on Form 8-K, dated March 10, 2004, announcing the initiation of SPECTRA, a trial of alagebrium chloride (ALT-711) in patients with systolic hypertension.

b) Exhibits

See the "Exhibit Index" on page 20 for exhibits required to be filed with this Quarterly Report on Form 10-Q.

18

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, 2004

ALTEON INC.

By: /s/Kenneth I. Moch

-----  
Kenneth I. Moch

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

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)

19

### INDEX TO EXHIBITS

Exhibit No.	Description of Exhibit
3.1	Restated Certificate of Incorporation, as amended. (Incorporated by reference to Exhibit 3.1 to the Company's Report on Form 10-Q filed on November 10, 1999, S.E.C. File Number 000-19529.)
3.2	Certificate of the Voting Powers, Designations, Preference and Relative Participating, Optional and Other Special Rights and Qualifications, Limitations or Restrictions of Series F Preferred Stock Alteon Inc. (Incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, S.E.C. File Number 001-16043.)
3.3	Certificate of Retirement dated September 10, 2000, of Alteon Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Report on Form 10-Q filed on November 10, 1999, S.E.C. File Number 000-19529.)
3.4	Certificate of Designations of Series G Preferred Stock of Alteon Inc. (Incorporated by reference to Exhibit 3.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1997, S.E.C. File Number 000-19529.)
3.5	Certificate of Amendment of Certificate of Designations of Series G Preferred Stock of Alteon Inc. (Incorporated by reference to Exhibit 3.4 to the Company's Report on Form 10-Q filed on August 14, 1998, S.E.C. File Number 000-19529.)
3.6	Certificate of Designations of Series H Preferred Stock of Alteon Inc. (Incorporated by reference to Exhibit 3.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 1997, S.E.C. File Number 000-19529.)
3.7	Amended Certificate of Designations of Series H Preferred Stock of Alteon Inc. (Incorporated by reference to Exhibit 3.6 to the Company's Report on Form 10-Q filed on August 14, 1998, S.E.C. File Number 000-19529.)
3.8	Certificate of Retirement dated November 20, 2000, of Alteon Inc. (Incorporated by reference to Exhibit 3.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, S.E.C. File Number 001-16043.)
3.9	Certificate of Amendment to Restated Certificate of Incorporation of Alteon Inc., dated June 7, 2001. (Incorporated by reference to

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

Exhibit 3.8 to the Company's Report on Form 10-Q filed on August 14, 2001, S.E.C. File Number 001-16043.)

- 3.10 By-laws, as amended. (Incorporated by reference to Exhibit 3.10 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, S.E.C. File Number 001-16043.)
  - 4.1 Stockholders' Rights Agreement dated as of July 27, 1995, between Alteon Inc. and Registrar and Transfer Company, as Rights Agent. (Incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, S.E.C. File Number 001-16043.)
  - 4.2 Amendment to Stockholders' Rights Agreement dated as of April 24, 1997, between Alteon Inc. and Registrar and Transfer Company, as Rights Agent. (Incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed on May 9, 1997, S.E.C. File Number 000-19529.)
  - 4.3 Registration Rights Agreement dated as of April 24, 1997, between Alteon Inc. and the investors named on the signature page thereof. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 9, 1997, S.E.C. File Number 000-19529.)
  - 4.4 Form of Common Stock Purchase Warrant. (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on May 9, 1997, S.E.C. File Number 000-19529.)
  - 4.5 Amendment to Stockholders' Rights Agreement dated as of December 1, 1997, between Alteon Inc. and Registrar and Transfer Company, as Rights Agent. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 10, 1997, S.E.C. File Number 000-19529.)
  - 4.6 Registration Rights Agreement dated September 29, 2000. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on October 5, 2000, S.E.C. File Number 001-16043.)
- 20
- 4.7 Form of Series 1 Common Stock Purchase Warrant. (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on October 5, 2000, S.E.C. File Number 001-16043.)
  - 4.8 Form of Series 2 Common Stock Purchase Warrant. (Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on October 5, 2000, S.E.C. File Number 001-16043.)
  - 4.9 Notice of Appointment, dated August 29, 2002, of The American Stock Transfer & Trust Company as successor Rights Agent, pursuant to Stockholders' Rights Agreement dated as of July 27, 1995. (Incorporated by reference to Exhibit 4.4 of the Company's Report on Form 10-Q filed on November 13, 2002, S.E.C. File Number 001-16043.)
  - 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



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

2002.

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

21