

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

ALTEON INC /DE
Form 10-Q
November 13, 2002

FORM 10-Q

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2002

OR

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

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.)

170 WILLIAMS DRIVE, RAMSEY, NEW JERSEY 07446

(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

On November 4, 2002, 31,884,556 shares of Registrant's Common Stock were outstanding.

Page 1 of 24 pages
The Exhibit Index is on page 23

ALTEON INC.

INDEX

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

	Page
PART I - FINANCIAL INFORMATION	
Item 1. Financial Statements (Unaudited)	
Balance Sheets as of September 30, 2002 and December 31, 2001	3
Statements of Operations for the three and nine months ended September 30, 2002 and 2001	4
Statements of Cash Flows for the nine months ended September 30, 2002 and 2001	5
Notes to Financial Statements	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	9
Item 3. Quantitative and Qualitative Disclosures about Market Risk	17
Item 4. Controls and Procedures	18
PART II - OTHER INFORMATION	
Item 1. Legal Proceedings	19
Item 6. Exhibits and Reports on Form 8-K	19
SIGNATURES	20
CERTIFICATIONS	21
INDEX TO EXHIBITS	23

2

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ALTEON INC. BALANCE SHEETS (UNAUDITED)

ASSETS

Current Assets:

Cash and cash equivalents	
Short-term investments	
Other current assets	

September
2002

\$ 11,877,6
5,983,5
409,3

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

Total current assets	18,270,5
Property and equipment, net	669,8
Deposits and other assets	
Total assets	\$ 18,940,3

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities:

Accounts payable	\$ 755,4
Accrued expenses	3,784,4
Total current liabilities	4,539,9

Commitments and Contingencies

Stockholders' Equity:

Preferred Stock, \$0.01 par value, 1,993,329 shares authorized, and 1,057 and 992 of Series G and 3,173 and 2,980 of Series H shares issued and outstanding, as of September 30, 2002 and December 31, 2001, respectively

Common Stock, \$0.01 par value, 80,000,000 shares authorized, and 31,878,525 and 27,314,846 shares issued and outstanding, as of September 30, 2002 and December 31, 2001, respectively

Additional paid-in capital 179,467,0

Accumulated deficit (165,386,3

Accumulated other comprehensive income 9

Total stockholders' equity 14,400,4

Total liabilities and stockholders' equity \$ 18,940,3

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

3

ALTEON INC. STATEMENTS OF OPERATIONS (UNAUDITED)

Three Months
Ended September 30,

2002 2001

Revenues:

Investment income \$ 93,376 \$ 107,404 \$

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

Expenses:

Research and development (which includes non-cash variable stock compensation (benefit)/expense of \$0 and \$(52,676) for the three months ended September 30, 2002 and 2001, respectively, and \$(93,516) and \$83,479 for the nine months ended September 30, 2002 and 2001, respectively)	4,330,899	1,824,239	11
General and administrative (which includes non-cash variable stock compensation (benefit)/expense of \$0 and \$(401,344) for the three months ended September 30, 2002 and 2001, respectively, and \$(1,315,635) and \$(328,055) for the nine months ended September 30, 2002 and 2001, respectively)	975,540	497,236	2
Total expenses	5,306,439	2,321,475	14
Net loss	\$ (5,213,063)	\$ (2,214,071)	\$ (13
Preferred stock dividends	887,158	815,591	2
Common stock warrant deemed dividend	--	209,528	
Net loss applicable to common stockholders	\$ (6,100,221)	\$ (3,239,190)	\$ (16
Basic/diluted net loss per share applicable to common stockholders	\$ (0.19)	\$ (0.13)	\$
Weighted average common shares used in computing basic/diluted net loss per share	31,878,525	25,791,322	31

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

4

ALTEON INC. STATEMENTS OF CASH FLOWS (UNAUDITED)

	Nine Months Ended September 30, 2002	
Cash Flows from Operating Activities:		
Net loss	\$ (13,798,853)	\$
Adjustments to reconcile net loss to cash used in operating activities:		

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

Depreciation and amortization	477,261
Amortization of deferred compensation	20,332
Non-cash compensation (benefit)/expense related to variable plan employee stock options	(1,409,151)
Changes in operating assets and liabilities:	
Other assets	988,183
Accounts payable and accrued expenses	2,177,815

Net cash used in operating activities	(11,544,413)

Cash Flows from Investing Activities:	
Capital expenditures	(37,389)
Purchases of marketable securities	(15,018,675)
Maturities of marketable securities	15,503,000

Net cash provided by/(used in) investing activities	446,936

Cash Flows from Financing Activities:	
Net proceeds from issuance of common stock	18,725,731

Net increase in cash and cash equivalents	7,628,254
Cash and cash equivalents, beginning of period	4,249,439

Cash and cash equivalents, end of period	\$ 11,877,693
	=====
Non-cash transactions:	
Preferred stock dividends	\$ 2,578,877
Common stock warrant deemed dividend	--

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

5

ALTEON INC. NOTES TO 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 with 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 and nine months ended September 30, 2002, are not necessarily indicative of the results that may be expected for the year ending December 31, 2002. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2001, filed with the Securities and Exchange Commission.

The Company's business is subject to significant risks including, but not limited to, (i) our ability to obtain funding, (ii) the risks inherent in our research and development efforts, including clinical trials, (iii) uncertainties associated with obtaining and enforcing our patents and with the patent rights of others, (iv) the lengthy, expensive and uncertain process of seeking regulatory approvals, (v) uncertainties regarding government reforms and

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

product pricing and reimbursement levels, (vi) technological change and competition, (vii) manufacturing uncertainties and (viii) dependence on collaborative partners and other third parties. Even if our product candidates appear promising at an early stage of development, they may not reach the market for numerous reasons. Such reasons include the possibilities that the products will prove ineffective or unsafe during clinical trials, will fail to receive necessary regulatory approvals, will be difficult to manufacture on a large scale, will be uneconomical to market or will be precluded from commercialization by proprietary rights of third parties.

NOTE 2 - LIQUIDITY

Alteon has incurred an accumulated deficit of \$165,386,000 as of September 30, 2002, and expects to incur operating losses, potentially greater than losses in prior years, for a number of years. 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.

The Company has financed its operations through proceeds from the sale of common and preferred equity securities, revenue from present and former collaborative relationships, reimbursement of certain of our 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 our New Jersey net operating loss carryforwards.

As of September 30, 2002, the Company has working capital of \$13,731,000, including \$17,861,000 of cash, cash equivalents and short-term investments. The Company's cash used in operations for the nine months ended September 30, 2002, and for the year ended December 31, 2001, was \$11,544,000 and \$8,211,000, respectively. The Company anticipates that at its current spending level, its existing available cash and cash equivalents and short-term investments will be adequate to satisfy its working capital requirements for its current operations through the second quarter of 2003. If it becomes necessary, the Company has the ability to reduce the cash burn rate, as it has limited fixed commitments. If the Company is unable to obtain additional funding prior to the completion of the DIAMOND, SAPPHIRE and SILVER trials, it expects to devote all of its resources to these trials. This will require Alteon to significantly curtail its other research and product development activities. Following completion of the trials, the Company will require substantial new funding to pursue development of ALT-711 and continue its operations.

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 long-term capital requirements, the Company may seek access to the public or private equity markets whenever conditions are favorable. 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 adequate funds are not available, the Company may be required to curtail significantly one or more of its research or development programs. 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.

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

6

NOTE 3 - CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Cash and cash equivalents include cash and highly liquid investments, which have a maturity of less than three months at the time of purchase. Short-term investments are considered available-for-sale and are recorded at fair value, as determined by quoted market value, with changes in fair value recorded as a component of accumulated other comprehensive income. As of September 30, 2002 and December 31, 2001, short-term investments were invested in debt instruments of the U.S. government, government agencies, financial institutions and corporations with strong credit ratings. They consist of the following:

	September 30, 2002 ----	December 31, 2001 ----
U.S. government agency funds	\$5,983,500	\$5,479,434
Corporate obligations	--	996,950
	-----	-----
	\$5,983,500	\$6,476,384
	=====	=====

NOTE 4 - NET LOSS PER SHARE

Basic loss per share is based on the weighted average number of shares outstanding during the period. Diluted loss per share is the same as basic loss per share, since the assumed exercise of stock options and warrants and the conversion of preferred stock would be antidilutive. The amount of common stock equivalents excluded from the calculation as of September 30, 2002 and 2001, was 29,427,492 and 19,633,637, respectively.

NOTE 5 - COMPREHENSIVE LOSS

The following sets forth comprehensive income/(loss) for the three and nine months ended September 30, 2002 and 2001:

	Three Months Ended September 30, ----- 2002 ----		Nine Months Ended September 30, ----- 2002 ----	
		2001 ----		2001 ----
Net Loss	\$ (5,213,063)	\$ (2,214,071)	\$ (13,798,853)	\$ (8,542,000)
Net Unrealized Gain/(Loss) on Short-Term Investments	(2,073)	17,498	(8,559)	2,000
	-----	-----	-----	-----
Comprehensive Loss	\$ (5,215,136)	\$ (2,196,573)	\$ (13,807,412)	\$ (8,520,000)
	=====	=====	=====	=====

NOTE 6 - STOCK COMPENSATION

In March 2000, the Financial Accounting Standards Board ("FASB") released Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation, An Interpretation of APB Opinion No. 25." The interpretation

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

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. This interpretation requires the Company 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 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 (benefit)/expense resulting from the repricing for the three months ended September 30, 2002 and September 30, 2001, is \$0 and \$(454,020), respectively, and for the nine months ended September 30, 2002 and September 30, 2001, is \$(1,409,151) and \$(244,576), respectively. No stock compensation (benefit)/expense resulting from the repricing was incurred for the three months ended September 30, 2002, as the Company's stock price was below the value at July 1, 2000.

NOTE 7 - RECENTLY ISSUED ACCOUNTING STANDARDS

In June 2002, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." The standard requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of commitment to an exit or disposal plan. SFAS No. 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002.

NOTE 8 - STOCKHOLDERS' EQUITY

In January 2002, Alteon completed a public offering of 4,450,000 shares of common stock at \$4.25 per share, which provided net proceeds of \$18,610,521.

7

Series G Preferred Stock and Series H Preferred Stock dividends are payable quarterly in shares of preferred stock. For the three months ended September 30, 2002 and September 30, 2001, preferred stock dividends were \$887,158 and \$815,591, respectively, and for the nine months ended September 30, 2002 and September 30, 2001, preferred stock dividends were \$2,578,877 and \$2,370,841, respectively.

In July 2001, the Company completed a public offering of 4,500,000 shares of Common Stock, which provided net proceeds of approximately \$9.4 million. In connection with the offering, certain previously issued warrants were repriced pursuant to antidilution provisions contained in the warrants. This resulted in a one-time, deemed dividend in the quarter of \$209,528.

NOTE 9 - SUBSEQUENT EVENT

On November 6, 2002, Alteon and The Picower Institute for Medical Research ("Picower") entered into an agreement which terminated, effective April 15, 2002, their license agreement dated as of September 5, 1991. Pursuant to this termination agreement, Picower assigned to Alteon all of its patents, patent applications and other technology related to AGE's and Alteon agreed to prosecute and maintain the patents and patent applications. Alteon will pay Picower royalties on any sales of products falling within the claims of these patents and patent applications until they expire or are allowed to lapse.

8

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

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

OVERVIEW

We are a product-based biopharmaceutical company primarily engaged in the discovery and development of oral 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. Two of our compounds are in clinical development; several others are in early development. These pharmaceutical candidates were developed as a result of our research on the 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.

Our lead compound, ALT-711, is being developed initially for cardiovascular indications, including systolic hypertension and diastolic heart failure ("DHF"). We have completed a Phase IIa trial to evaluate the effect of ALT-711 on cardiovascular compliance. Based on positive results that demonstrated the ability of ALT-711 to decrease pulse pressure and increase the elasticity of the cardiovascular system, we have initiated two Phase IIb efficacy trials of ALT-711, the SAPPHIRE (Systolic And Pulse Pressure Hemodynamic Improvement by Restoring Elasticity) and SILVER (Systolic Hypertension Interaction with Left VEntricular Remodeling) trials in patients with systolic hypertension and systolic hypertension with left ventricular hypertrophy. The compound is also being evaluated in a Phase IIa trial in DHF, the DIAMOND (Distensibility Improvement And ReModeliNg in Diastolic Heart Failure) trial, as well as a Phase I program in end-stage renal disease patients undergoing peritoneal dialysis.

We recently announced that we have reached the targeted enrollment of 450 patients in our Phase IIb SAPPHIRE trial of ALT-711 in systolic hypertension, and that we have also completed enrollment in our companion Phase IIb SILVER trial in patients with both systolic hypertension and left ventricular hypertrophy, substantially exceeding the minimum enrollment of 180 patients. A total of approximately 750 patients are now enrolled in the SAPPHIRE/SILVER program and data is expected to be released concurrently mid-year 2003. Additionally, we announced the completion of enrollment in our Phase IIa DIAMOND clinical trial in diastolic heart failure (DHF). Data from the DIAMOND study is expected during the first quarter of 2003.

As we continue clinical development of ALT-711, we are evaluating potential corporate partnerships for further development and ultimate marketing of the compound in territories throughout the world. We plan to retain development and marketing rights for one or several indications in the United States.

A topical formulation of an A.G.E. Crosslink Breaker, ALT-744, is being clinically evaluated in skin aging for cosmetic applications. We continue to evaluate product development opportunities from among our A.G.E. Crosslink Breaker compounds and other classes of compounds in our patent estate.

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 \$165,386,000 as of September 30, 2002, 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, public offerings of common stock,

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

private placements of common and preferred equity securities, revenue from present and former 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 including, but not limited to, (i) our ability to obtain funding, (ii) the risks inherent in our research and development efforts, including clinical trials, (iii) uncertainties associated with obtaining and enforcing our patents and with the patent rights of others, (iv) the lengthy, expensive and uncertain process of seeking regulatory approvals, (v) uncertainties regarding government reforms and product pricing and reimbursement levels, (vi) technological change and competition, (vii) manufacturing uncertainties and (viii) dependence on collaborative partners and other third parties. Even if our product candidates appear promising at an early stage of development, they may not reach the market for numerous reasons. Such reasons include the possibilities that the products will prove ineffective or unsafe during clinical trials, will fail to receive necessary regulatory approvals, will be difficult to manufacture on a large scale, will be uneconomical to market or will be precluded from commercialization by proprietary rights of third parties. These risks and others are discussed under the heading "Forward-Looking Statements and Cautionary Statements."

9

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

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2002 AND 2001

Total revenues for the three months ended September 30, 2002 and 2001, were \$93,000 and \$107,000, respectively. Revenues were derived from interest earned on cash and cash equivalents and short-term investments. The 13.0% decrease in income was attributable to the decrease in short-term interest rates, partially offset by larger investment balances.

Our total expenses were \$5,306,000 for the three months ended September 30, 2002, compared to \$2,321,000 for the three months ended September 30, 2001, and in each year 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 \$4,331,000 for the three months ended September 30, 2002, and primarily consisted of \$2,204,000 in clinical trial expenses related to the Phase IIb SAPPHIRE and SILVER trials, \$411,000 related to manufacturing (process development and packaging) and drug stability studies, \$149,000 in pre-clinical expenses and \$868,000 in personnel and personnel-related expenses. Research and development expenses for the three months ended September 30, 2001, were \$1,824,000, and primarily consisted of \$569,000 in clinical trial expenses related to the start-up of the Phase IIb SAPPHIRE trial, \$326,000 of manufacturing expenses (packaging of clinical trial supplies and process development) and drug stability studies associated with the ALT-711 programs, \$508,000 in personnel and personnel-related expenses and a non-cash variable stock compensation (benefit)/expense of \$(53,000).

Excluding the non-cash variable stock compensation benefit in 2001, research and development expenses increased by \$2,454,000, or 130.8%, primarily due to the Phase IIb SAPPHIRE and SILVER clinical trials. These trials were

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

initiated during the second half of 2001. We have reached our targeted enrollment of 450 patients in the SAPPHIRE trial and have exceeded the targeted enrollment of 180 patients in the SILVER trial. The release of data for these trials is targeted for mid-year 2003.

The development and successful commercialization of ALT-711 are subject to substantial risks described in this Report. See, for example, "Forward-Looking Statements and Cautionary Statements -- If we do not successfully develop any products, we may not derive any revenues."

General and administrative expenses increased to \$976,000 for the three months ended September 30, 2002, compared to \$497,000 for the same period in 2001, and included a non-cash variable stock compensation benefit of \$401,000 in the 2001 period, which resulted from a decline in our stock price. Excluding the non-cash variable stock compensation, general and administrative expenses increased \$77,000, or 8.6%, primarily due to increased personnel costs.

Our net loss applicable to common stockholders increased to \$6,100,000 for the three months ended September 30, 2002, compared to \$3,239,000 in the same period in 2001, an increase of 88.3%. This was primarily a result of increased clinical trial expenses due to the ongoing Phase IIB SAPPHIRE and SILVER trials. Included in the net loss applicable to common stockholders are preferred stock dividends of approximately \$887,000 and \$816,000 for the three months ended September 30, 2002 and 2001, respectively, and common stock deemed dividends of \$210,000 in the 2001 period.

NINE MONTHS ENDED SEPTEMBER 30, 2002 AND 2001

Total revenues for the nine months ended September 30, 2002, and 2001, were \$346,000 and \$360,000, respectively. Revenues were derived from interest earned on cash and cash equivalents and short-term investments. Total revenues decreased due to a significant decrease in short-term interest rates, partially offset by larger investment balances.

Our total expenses were \$14,145,000 for the nine months ended September 30, 2002, compared to \$8,909,000 for the nine months ended September 30, 2001, and in each year consisted primarily of research and development expenses. Research and development expenses for the nine months ended September 30, 2002 were \$11,982,000 and primarily consisted of \$5,148,000 in clinical trial expenses related to the Phase IIB SAPPHIRE and SILVER trials, \$2,045,000 related to manufacturing (process development, tablet manufacturing and packaging) and drug stability studies, \$568,000 in pre-clinical expenses, \$2,417,000 in personnel and personnel-related expenses and a non-cash variable stock compensation (benefit)/expense of \$(94,000). Research and development expenses for the nine months ended September 30, 2001, were \$6,025,000 and primarily consisted of \$826,000 in clinical trial expenses related to the start-up of the Phase IIB SAPPHIRE and SILVER trials and a Phase I pharmacokinetic study of ALT-711, \$1,618,000 of manufacturing expenses (tableting, packaging and process development) and drug stability studies

10

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

associated with the ALT-711 programs, \$1,843,000 in personnel and personnel-related expenses and a non-cash variable stock compensation (benefit)/expense of \$83,000.

Excluding the non-cash variable stock compensation (benefit)/expense, research and development expenses increased by \$6,134,000, or 103.2%, primarily due to the Phase IIB SAPPHIRE and SILVER clinical trials.

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

These trials were initiated during the second half of 2001. We have reached our targeted enrollment of 450 patients in the SAPPHIRE trial and have exceeded the targeted enrollment of 180 patients in the SILVER trial. The release of data for these trials is targeted for mid-year 2003.

The development and successful commercialization of ALT-711 are subject to substantial risks described in this Report. See, for example, "Forward-Looking Statements and Cautionary Statements -- If we do not successfully develop any products, we may not derive any revenues."

General and administrative expenses decreased to \$2,163,000 for the nine months ended September 30, 2002, compared to \$2,883,000 for the same period in 2001, and included a non-cash variable stock compensation (benefit)/expense of \$(1,316,000) and \$(328,000), respectively. Excluding the non-cash variable stock compensation (benefit)/expense, general and administrative expenses increased \$267,000, or 8.3%, primarily due to increased patent and recruiting fees.

Our net loss applicable to common stockholders increased to \$16,378,000 for the nine months ended September 30, 2002, compared to \$11,129,000 in the same period in 2001, an increase of 47.2%. This was primarily a result of increased research and development expenses due to increased enrollment in the Phase IIb SAPPHIRE and SILVER clinical trials and increased preferred stock dividends, offset by a non-cash stock compensation benefit. Included in the net loss applicable to common stockholders are preferred stock dividends of approximately \$2,579,000 and \$2,371,000 for the nine months ended September 30, 2002 and 2001, respectively, and common stock deemed dividends of \$210,000 in the 2001 period.

LIQUIDITY AND CAPITAL RESOURCES

We had cash, cash equivalents and short-term investments at September 30, 2002, of \$17,861,000, compared to \$10,726,000 at December 31, 2001. This is an increase in cash and cash equivalents and short-term investments for the nine months ended September 30, 2002, of \$7,135,000. This consisted of \$18,611,000 of net proceeds from a public offering of common stock in January 2002, and \$115,000 of proceeds from stock option exercises. This was offset by \$11,544,000 of net cash used in operations, and consisted primarily of research and development expenses, personnel-related costs and facility expenses and approximately \$37,000 in capital expenditures.

At December 31, 2001, we had available federal net operating loss carryforwards, which expire in various amounts from the years 2006 through 2020, of approximately \$135,500,000 and New Jersey net operating loss carryforwards, which expire in the years 2002 through 2007, of approximately \$85,100,000. In addition, we had federal research and development tax credit carryforwards of approximately \$5,100,000 and New Jersey research and development tax credit carryforwards of approximately \$1,600,000 at December 31, 2001. 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.

In December 2001, we sold \$6,243,000 of our gross New Jersey net operating loss carryforwards and \$802,000 of our New Jersey 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 2001 were \$1,187,000 and were recorded as a tax benefit in the December 31, 2001 statement of operations. The proceeds from the sale of the net operating loss carryforwards and the

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

research and development tax credit carryforwards sold in 2001 were received on January 4, 2002. The State of New Jersey may renew the Program annually and limits the aggregate proceeds to \$10,000,000. We cannot be certain if we will be able to sell any of the carryforwards in the future.

We anticipate that at our current spending level, our existing available cash and cash equivalents and short-term investments will be adequate to satisfy our working capital requirements for our current operations through the second quarter of 2003. If it becomes necessary, we have the ability to reduce the cash burn rate, as we have limited fixed commitments. If we are unable to obtain additional funding prior to the completion of the DIAMOND, SAPPHIRE and SILVER trials, we expect to devote all of our resources to these trials. This will require us to significantly curtail our other research and product development activities. Following completion of the trials, we will require substantial new funding to pursue development of ALT-711 and continue our operations.

11

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

The amount of our future capital requirements will depend on numerous factors, including the progress of our discovery research programs, the initiation 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 long-term capital requirements, we may seek access to the public or private equity markets whenever conditions are favorable. 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.

Our current priorities are the evaluation and continued development of ALT-711, our lead A.G.E. Crosslink Breaker candidate, and determining the optimal course for the continued development of additional A.G.E. Crosslink Breaker compounds and A.G.E.-Formation Inhibitors. We are focusing our resources on the development of ALT-711. As we continue clinical development of ALT-711, we are evaluating potential corporate partnerships for further development and ultimate marketing of the compound in territories throughout the world. We plan to retain development and marketing rights for one or several indications in the United States. In addition, we are exploring partnering and regulatory pathways for the continued development of pimagedine. As described above, we believe that additional development of this compound and other product candidates will require us to find additional sources of funding.

RECENTLY ISSUED ACCOUNTING STANDARDS

In June 2002, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." The standard requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of commitment to an exit or disposal plan. SFAS No. 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002.

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

CRITICAL ACCOUNTING POLICIES

In December 2001, the U.S. 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, 2001, and accompanying audited financial statements and related notes thereto, as well as our definitive proxy statement for the 2002 Annual Meeting. 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 Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. As such, compensation expense is recorded on fixed stock grants only if the current fair value of the underlying stock exceeds the exercise price of the option at the date of grant and it is recognized on a straight-line basis over the vesting period. Based on the performance of our stock, we repriced certain employee stock options on February 2, 1999. As a result of this repricing, options to purchase 1.06 million shares of stock were repriced and certain vesting periods related to these options were modified or extended. 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 income applicable to common stockholders and net loss per share to common stockholders may be subject to volatility.

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

12

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

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

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

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.

We anticipate that at our current spending level, our existing available cash and cash equivalents and short-term investments will be adequate to satisfy our working capital requirements for our current operations through the second quarter of 2003. If it becomes necessary, we have the ability to reduce the cash burn rate, as we have limited fixed commitments. If we are unable to obtain additional funding prior to the completion of the DIAMOND, SAPPHIRE and SILVER trials, we expect to devote all of our resources to these trials. This will require us to significantly curtail our other research and product development activities. Following completion of the trials, we will require substantial new funding to pursue development of ALT-711 and continue our operations.

Our future capital requirements will depend on many factors, including continued scientific progress in our discovery research, the size and complexity of these programs, progress with pre-clinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patent claims, competing technological and market developments, the establishment of additional collaborative arrangements, the cost of manufacturing arrangements, commercialization activities and the cost of product in-licensing and strategic acquisitions, if any. We may not be able to obtain sufficient funding to satisfy our longer-term capital and operating requirements.

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 candidates are still in research or clinical development. We may not succeed in the development and marketing of any therapeutic or diagnostic product. 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 ALT-711 and pimagedine, to be commercially available for a number of years, if at all.

CLINICAL TRIALS REQUIRED FOR OUR PRODUCT CANDIDATES ARE EXPENSIVE AND 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

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

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.

13

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

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 financing activities, or interest income earned on these funds. We have not received any revenues from product sales. We may not realize product revenues on a timely basis, if at all.

At September 30, 2002, we had an accumulated deficit of \$165,386,000. 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 increase. 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, we repriced certain employee stock options on February 2, 1999, in order to bolster employee retention. 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 Interpretation No. 44, "Accounting for Certain Transactions

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

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.

IF WE ARE NOT ABLE TO FORM AND MAINTAIN 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 such efforts may not be successful. If we are unable to enter into or manage additional collaborations, our programs may suffer and we may be unable to develop products.

IF WE ARE UNABLE TO MAINTAIN OUR COLLABORATIVE RELATIONSHIPS, OUR PRODUCT DEVELOPMENT MAY BE DELAYED AND DISPUTES OVER RIGHTS TO TECHNOLOGY MAY RESULT.

We will, in some cases, be dependent upon outside partners to conduct pre-clinical testing and clinical trials and to provide adequate funding for our development programs. Our corporate partners 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.

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 agreements 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.

14

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

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.

IF WE CANNOT SUCCESSFULLY DEVELOP A MARKETING AND SALES FORCE OR MAINTAIN SUITABLE ARRANGEMENTS WITH THIRD PARTIES TO MARKET AND SELL OUR PRODUCTS, OUR

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

ABILITY TO DELIVER PRODUCTS MAY BE IMPAIRED.

For certain of our products, we have licensed exclusive marketing rights to our corporate partners or formed collaborative marketing arrangements within specified territories in return for royalties to be received on sales, a share of profits or beneficial transfer pricing. These agreements are terminable at the discretion of our partners upon as little as 90 days' prior written notice. If the licensee or marketing partner terminates an agreement or fails to market a product successfully, our business, financial condition and results of operations may be adversely affected.

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 for commercial purposes 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 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 U.S. 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 U.S. 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

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

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

15

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

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 U.S. 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 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 and 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 U.S. 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.

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

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 HEALTH CARE, 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 U.S., 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 U.S. 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.

16

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

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 health care 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 increasingly attempting to contain health care 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.

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

The use of any of our potential products in clinical trials and the sale of any approved products, including the testing and commercialization of ALT-711 or other compounds, exposes us to liability claims resulting from the use of products or product candidates. A claim, which was subsequently settled, was made by a participant in one of our clinical trials, and additional claims might be made directly by other such participants, 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 health care 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.

OUR OPERATIONS INVOLVE A RISK OF INJURY OR DAMAGE FROM HAZARDOUS MATERIALS, AND IF AN ACCIDENT WERE TO OCCUR, WE COULD BE SUBJECT TO COSTLY AND DAMAGING LIABILITY CLAIMS, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Our research and development activities involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for handling and disposing of hazardous materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages or fines that result. Such liability could have a material adverse effect on our business, financial condition and results of operations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk for changes in interest rates relates primarily to our investments in short-term marketable securities. We do not use derivative financial instruments. Our investments consist primarily of debt instruments of the U.S. government, government agencies, financial institutions and corporations with strong credit ratings. We prepared a detailed market risk disclosure of these investments in our 2001 Annual Report on Form 10-K. There have been no material changes in our market risk position since December 31, 2001.

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

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

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures. Within the 90 days prior to the filing date of this Quarterly Report on Form 10-Q, our Chief Executive Officer and our Vice President, Finance, evaluated the effectiveness of Alteon's disclosure controls and procedures as defined in Rule 13a-14(c) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based upon that evaluation, the Chief Executive Officer and the Vice President, Finance, have concluded that Alteon's current disclosure controls and procedures are adequate and effective to ensure that information required to be disclosed in the reports Alteon files under the Exchange Act is recorded, processed, summarized and reported on a timely basis.

(b) Changes in internal controls. There have been no significant changes in Alteon's internal controls or in other factors that could significantly affect internal controls subsequent to the date of their evaluation by the Chief Executive Officer and the Vice President, Finance.

18

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On October 20, 2000, Charles L. Grimes, one of our stockholders, and his wife, Jane Gillespie Grimes, filed a complaint against us in the Court of Chancery in Delaware, claiming breach of an alleged agreement with us which would have purportedly entitled Mr. Grimes to purchase 10% of our private placement of \$6,235,000 of common stock and warrants in September 2000. We filed a motion to dismiss stating that Mr. and Mrs. Grimes had failed to state a claim as a matter of law. Pursuant to a decision and order of the Delaware Chancery Court, the case was dismissed on April 12, 2001. Mr. and Mrs. Grimes filed a notice of appeal to the Supreme Court of Delaware. On January 16, 2002, the Supreme Court of Delaware heard oral argument on the appeal of Mr. and Mrs. Grimes, and directed that oral argument on this appeal be heard en banc. On April 23, 2002, the Supreme Court of Delaware heard the appeal, and on July 19, 2002, affirmed the judgment of the Court of Chancery, dismissing the action.

On August 5, 2002, Lisa Weller, a former Alteon employee, filed suit against Alteon in the Superior Court of New Jersey asserting claims for alleged pregnancy, sex and handicap discrimination, wrongful termination and intentional infliction of emotional distress, all arising from the company's termination of her employment as an executive assistant. Alteon removed the case to the United States District Court for the District of New Jersey, where it is now pending as Civil Action No. 02-4492. Alteon denies all allegations and is vigorously defending the matter.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

a) Exhibits

See Exhibit Index on page 23 for Exhibits filed with this Quarterly Report on Form 10-Q.

b) The following report on Form 8-K was filed during the quarter ended September 30, 2002:

On July 18, 2002, the Company filed a Current Report on Form 8-K,

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

dated July 16, 2002, announcing the initiation of a fourth human trial of ALT-711, the DIAMOND trial.

19

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 13, 2002

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)

20

CERTIFICATIONS

I, Kenneth I. Moch, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Alteon Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements and other financial information included in this quarterly report fairly present, in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant, and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this quarterly report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

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

- c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- 5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: November 13, 2002

/s/ Kenneth I. Moch

Kenneth I. Moch
President and Chief Executive Officer

21

CERTIFICATIONS

I, Elizabeth O'Dell, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Alteon Inc.;
- 2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
- 3. Based on my knowledge, the financial statements and other financial information included in this quarterly report fairly present, in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
- 4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant, and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others within the entity, particularly during the period in which this quarterly report is being prepared;

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

- b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
- a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: November 13, 2002

/s/ Elizabeth O'Dell

Elizabeth O'Dell
Vice President, Finance
Secretary and Treasurer

22

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 Quarterly Report on Form 10-Q filed on November 10, 1999.)
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 of the Company. (Incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K filed for the year ended December 31, 2000.)
3.3	Certificate of Retirement dated September 10, 1999, of Alteon Inc. (Incorporated by reference to Exhibit 3.3 to the Company's Quarterly Report on Form 10-Q filed November 10, 1999.)

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

- 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.)
- 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.)
- 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.)
- 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.)
- 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.)
- 3.9 Certificate of Amendment to Restated Certificate of Incorporation of Alteon Inc. dated June 7, 2002. (Incorporated by reference to Exhibit 3.8 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2001.)
- 3.10 By-laws, as amended. (Incorporated by reference to Exhibit 3.7 to the Company's Report on Form 10-Q filed on May 12, 1999.)
- 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 filed for the year ended December 31, 2000.)
- 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.)
- 4.3 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.)
- 4.4 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.
- 4.5 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.)

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

- 4.6 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.)
- 4.7 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.)

23

- 4.8 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.)
- 4.9 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.)
- 99.1 Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

24