ALTEON INC /DE
Form 10-Q
May 11, 2001

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FORM 10-Q

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2001

OR

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

Commission file number 0-19529

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 May 4, 2001, 22,570,781 shares of Registrant's Common Stock were outstanding.

ALTEON INC.

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ALTEON INC.
BALANCE SHEETS
(UNAUDITED)

ASSETS

	March 31, 2001

Current Assets:	
Cash and cash equivalents	$ 619,572
Short-term investments	8,272,873
Other current assets	336,428
Total current assets	9,228,873
Property and equipment, net	1,550,499
Deposits and other assets	2,815
Total assets	$ 10,782,187
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current Liabilities:	
Accounts payable	$ 270,494
Accrued expenses	1,755,199
Total current liabilities	2,025,693
Stockholders' Equity:	
Preferred Stock, $0.01 par value, 1,993,329 shares authorized, and 931 and 912 of Series G and 2,797 and 2,739 of Series H shares issued and outstanding, as of March 31, 2001 and December 31, 2000, respectively	37
Common Stock, $0.01 par value, 40,000,000 shares authorized, and 22,570,781 and 22,399,660 shares issued and outstanding, as of March 31, 2001 and December 31, 2000, respectively	225,708
Additional paid-in capital	147,325,100
Accumulated deficit	(138,804,821)
Accumulated other comprehensive income/(loss)	10,470
Total stockholders' equity	8,756,494
Total liabilities and stockholders' equity	$ 10,782,187

The accompanying notes are an integral part of this statement.

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ALTEON INC.
STATEMENT OF OPERATIONS
(UNAUDITED)

	For the Three Months Ended March 31,	
	2001	200
Revenues:		
Investment income	$ 152,528	$ 166
Expenses:		
Research and development (which includes non-cash stock compensation of $237,637 and $0, at March 31, 2001 and March 31, 2000, respectively)	2,210,541	1,667
General and administrative (which includes non-cash stock compensation of $831,188 and $0, at March 31, 2001 and March 31, 2000, respectively)	1,970,120	1,094
Total expenses	4,180,661	2,762
Net loss	$(4,028,133)	$(2,596
Preferred stock dividends	765,265	709
Net loss applicable to common stockholders	$(4,793,398)	$(3,305
Basic/diluted loss per share to common stockholders	$ (0.21)	$ (
Weighted average common shares used in computing basic and diluted loss per share	22,489,934	19,231

The accompanying notes are an integral part of this statement.

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ALTEON INC.
STATEMENT OF CASH FLOWS
(UNAUDITED)

	For the Three Ended March
	2001
Cash Flows from Operating Activities:	
Net loss	$(4,028,133)

Adjustments to reconcile net loss to cash used in operating activities:	
Depreciation and amortization	164,346
Amortization of deferred compensation	87,536
Non-cash compensation expense related to variable plan employee stock options	1,068,825
Changes in operating assets and liabilities:	
Other current assets	1,399,232
Accounts payable and accrued expenses	89,335
Net cash used in operating activities	(1,218,859)
Cash Flows from Investing Activities:	
Capital expenditures	(18,762)
Purchases of marketable securities	(4,973,055)
Sales and maturities of marketable securities	3,066,000
Net cash (used in) provided by investing activities	(1,925,817)
Cash Flows from Financing Activities:	
Net proceeds from issuance of common stock	163,920
Net (decrease)/increase in cash and cash equivalents	(2,980,756)
Cash and cash equivalents, beginning of period	3,600,328
Cash and cash equivalents, end of period	$ 619,572

The accompanying notes are an integral part of this statement.

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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 generally accepted accounting principles 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, 2001, are not necessarily indicative of the results that may be expected for the year ending December 31, 2001. 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, 2000.

NOTE 2 - CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Cash and cash equivalents include highly liquid investments which have a maturity of less than three months at the time of purchase. Short-term investments are recorded at fair market value.

NOTE 3 - NET LOSS PER SHARE

Basic loss per share is based on the average number of shares outstanding during the year. Diluted loss per share is the same as basic loss per share, as the inclusion of common stock equivalents would be antidilutive.

NOTE 4 - COMPREHENSIVE INCOME/(LOSS)

The following sets forth comprehensive income as required by SFAS 130 for the periods ended March 31, 2001 and 2000 (dollars in thousands):

	2001	2000
Net Loss	$(4,028)	$(2,596)
Net Unrealized Gain/(Loss) on Marketable Securities	11	(2)
Comprehensive Loss	$(4,017)	$(2,598)

NOTE 5 - RECENTLY ISSUED ACCOUNTING STANDARDS

In June 2000, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard No. 138 ("SFAS 138"), "Accounting for Certain Derivative Instruments and Certain Hedging Activities, an Amendment of FASB Statement No. 133." SFAS No. 138 was issued to address a limited number of issues causing implementation difficulties for entities that apply SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," issued in June 1998. SFAS No. 133 and SFAS No. 138 require that all derivatives be measured at fair value and recognized as assets or liabilities on the balance sheet. Changes in the fair value of derivatives should be recognized in either net income/(loss) or other comprehensive income/(loss), depending on the designated purpose of the derivative. The Company is required to and has adopted SFAS No. 133 and SFAS No. 138 in the first quarter of 2001. Based on the Company's current activities, the adoption of these pronouncements does not have a material impact on the Company's results of operations, cash flows or financial position.

In March 2000, the FASB released Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation, An Interpretation of APB Opinion No. 25." The interpretation became effective on July 1, 2000, but in some circumstances applies to transactions that occurred prior to the effective date. Under the interpretation, stock options that are repriced must be accounted for as variable-plan arrangements until the options are exercised, forfeited or expire. This requirement applies to any options repriced after December 15, 1998. On February 2, 1999, the Company repriced certain stock options. The total non-cash stock compensation expense resulting from the repricing for three months ending March 31, 2001, is $1,068,825, which includes research and development charges of $237,637 and general and administrative charges of $831,188.

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

OVERVIEW

Alteon is discovering and developing oral drugs for the treatment of diseases of aging and diabetes. Our lead product candidates are unlike any drugs currently prescribed, and target some of the largest pharmaceutical markets, such as cardiovascular and kidney diseases. Two of our compounds are in clinical development and are being tested in humans; several others are undergoing pre-clinical testing. These potential pharmaceutical products were discovered as a result of our research on structures called Advanced Glycosylation End-products, or A.G.E.s, that are formed in our body and accumulate as we age, potentially resulting in many medical disorders.

Our lead compound, ALT-711, is initially being developed for cardiovascular disease, including isolated systolic hypertension. We recently completed a Phase IIa trial to evaluate the effect of ALT-711 on cardiovascular compliance. Based on the positive results of this trial, we plan to initiate a Phase IIb efficacy trial of ALT-711.

We are pursuing development of other compounds from our library of A.G.E. crosslink breakers and A.G.E.-formation inhibitors in additional aging- and diabetes-related diseases.

As we continue clinical development of ALT-711, 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.

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 $138,805,000 as of March 31, 2001, 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, a follow-on offering of Common Stock completed in 1995, and 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 State Net Operating Losses carryforwards.

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 became effective on July 1, 2000, but in some circumstances applies to transactions that occur 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, we repriced certain stock options. The total compensation expense resulting from the repricing and included in net loss for the quarter ended March 31, 2001, is $1,069,000.

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."

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

RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 2001 AND 2000

Total revenues for the three months ended March 31, 2001, and the three months ended March 31, 2000, were $153,000 and $166,000, respectively. Revenues were derived from interest earned on cash and cash equivalents and short-term investments. The 7.8% decrease in income was attributable to the decrease in cash, cash equivalents and short-term investment balances.

Our total expenses increased to $4,181,000 for the three months ended March 31, 2001, from $2,762,000 for the three months ended March 31, 2000, and in 2001 includes a non-cash stock compensation charge of $1,069,000 (See Note 5) as a result of the implementation of FASB Interpretation No. 44.

Research and development expenses were $2,211,000 for the three months ended March 31, 2001, which includes a charge of $238,000 for non-cash stock compensation, and $1,667,000 for the three months ended March 31, 2000, an increase of 32.6%. Excluding the non-cash stock compensation expense, research and development expenses increased by 18.4%. Expenses incurred for the three months ended March 31, 2001, included toxicology and manufacturing costs in preparation for upcoming clinical studies. For the three months ended March 31, 2000, expenses included costs for the Phase IIa clinical trial. This trial, which evaluated the safety, efficacy and pharmacology of ALT-711, was completed in the fourth quarter of 2000. The data was presented for the first time in March 2001.

Research and development expenses primarily consist of third-party expenses associated with pre-clinical and clinical studies, manufacturing costs of clinical supplies, personnel and personnel-related expenses and an allocation of facility expenses.

General and administrative expenses increased to $1,970,000 for the three months ended March 31, 2001 from $1,095,000 for the same period in 2000, and in 2001 includes a non-cash stock compensation charge of $831,000 (See Note 5). Excluding the non-cash stock compensation expense, general and administrative expenses increased $44,000 or 4.0%.

Our net loss applicable to common stockholders increased to $4,793,000 for the three months ended March 31, 2001, from $3,305,000 in the same period in 2000 an increase of 45.0%. This was primarily a result of increased research and development expenses, the inclusion of the non-cash stock compensation expense as a result of the implementation of FASB Interpretation No. 44, decreased investment income and increased preferred stock dividends. Included in the net loss applicable to common stockholders are preferred stock dividends of approximately $765,000 and $709,000 for the three months ended March 31, 2001 and 2000, respectively.

LIQUIDITY AND CAPITAL RESOURCES

We had cash, cash equivalents and short-term investments at March 31, 2001, of $8,892,000 compared to $9,955,000 at December 31, 2000. This is a decrease in cash, cash equivalents and short-term investments for the three months ended March 31, 2001, of $1,063,000. This consisted of $2,767,000 of cash used in operations consisting primarily of research and development expenses, personnel and related costs and facility expenses and approximately $19,000 of capital expenditures. This was offset by the receipt of $1,548,000 from the sale of our NOLs and $164,000 of financing activities related to proceeds from stock option exercises. As of March 31, 2001, we had invested $7,463,000 in capital equipment and leasehold improvements.

At December 31, 2000, we had available Federal net operating loss carryforwards, which expire in the years 2006 through 2020, of approximately $125.9 million for income tax purposes and State net operating loss carryforwards, which expire in the years 2000 through 2007, of approximately $81.8 million. In addition, we have Federal research and development tax credit carryforwards of approximately $4.9 million and State research and development tax credit carryforwards of approximately $2.2 million. 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.

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

In December 2000, we sold $14.1 million of our gross State net operating loss carryforwards and $590,000 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 allowed qualified technology and biotechnology business 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 2000 were $1,548,000 and were recorded as a tax benefit in the statements of operations. The proceeds from the sale of the net operating loss carryforwards and the research and development tax credit carryforwards sold in 2000 were received on January 8, 2001.

In September 2000, we entered into an agreement with several investors pursuant to which we sold them, in a private placement, an aggregate of 2,834,088 shares of common stock and warrants to purchase 1,133,636 shares of common stock (the "Warrants") for an aggregate purchase price of $6,235,000. The exercise price of the Warrants is $3.40 per share, while the term is seven years.

We anticipate that our existing available cash and cash equivalents and

short-term investments will be adequate to satisfy our working capital requirements for our current operations into the second quarter of 2002. The timing and extent of ALT-711's clinical development, including the initiation of the Phase IIb efficacy trial, will be determined by our ability to secure additional financing. We will require substantial new funding in order to continue the research, product development, pre-clinical testing and clinical trials of our product candidates, including ALT-711 and Pimagedine. We will also require additional funding for operating expenses, the pursuit of regulatory approvals for our product candidates and the establishment of marketing and sales capabilities.

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 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 the continued development of Pimagedine. We are focusing our resources on the development of ALT-711. As we continue clinical development of ALT-711, we will determine if it is appropriate to retain development and marketing rights for one or several indications in North America, while at the same time continuing to evaluate potential corporate partnerships for the further development and ultimate marketing of the compound throughout the world. We have also decided to pursue the continued development of Pimagedine and are actively seeking one or more corporate partners. We believe that additional development of this compound and other product candidates will require us to find sources of funding.

FORWARD-LOOKING STATEMENTS AND CAUTIONARY STATEMENTS

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

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

IF WE DO NOT OBTAIN SUFFICIENT ADDITIONAL FUNDING TO MEET OUR NEEDS, WE MAY HAVE TO CURTAIL OR DISCONTINUE THE RESEARCH, PRODUCT DEVELOPMENT, PRE-CLINICAL TESTING AND CLINICAL TRIALS OF SOME OR ALL OF OUR PRODUCT CANDIDATES.

We anticipate that our existing available cash and cash equivalents and short-term investments will be adequate to satisfy our working capital requirements for our current operations into the second quarter of 2002. The timing and extent of ALT-711's clinical development, including the initiation of the Phase IIb efficacy trial, will be determined by our ability to secure additional financing. We will require substantial new funding in order to continue the research, product development, pre-clinical testing and clinical trials of our product candidates, including ALT-711 and Pimagedine. We will also require additional funding for operating expenses, the pursuit of regulatory approvals for our product candidates and the establishment of marketing and sales capabilities.

Our future capital requirements will depend on many factors, including continued scientific progress in our research and development programs, 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. Our cash reserves and other liquid assets may not be adequate to satisfy our capital and operating requirements.

We intend to seek funding through arrangements with corporate collaborators and through public or private sales of our securities, including equity securities, when and if conditions permit. In addition, we may pursue opportunities to obtain debt financing, including capital leases, in the future. Additional funding may not be available on reasonable terms, however. Any additional equity financing would be dilutive to our stockholders. If adequate funds are not available, we may be required to curtail significantly or eliminate one or more of our research and development programs. If we obtain funds through arrangements with collaborative partners or others, we may be required to relinquish rights to certain of our technologies or product candidates.

IF WE DO NOT SUCCESSFULLY DEVELOP ANY PRODUCTS, WE MAY NOT DERIVE ANY REVENUES.

All of our product candidates are 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.

We have not yet requested or received regulatory approval for any product from the FDA or any other regulatory body. 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 results from pre-clinical studies and early clinical trials may not be predictive of results that will be obtained in large-scale testing. 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.

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.

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 March 31, 2001, we had an accumulated deficit of $138,805,000. 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 Involving Stock Compensation, An Interpretation of APB Opinion No. 25." This interpretation requires us to record compensation expense, which is adjusted every quarter, for increases or decreases in the fair market 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 have established collaborative arrangements with Yamanouchi Pharmaceutical Co., Ltd., Roche Diagnostics GmbH, IDEXX laboratories, Inc. and Gamida for Life with respect to the development of drug therapies and diagnostics utilizing our scientific platforms. To succeed, we will have to develop additional relationships. We are seeking to establish new collaborative relationships to provide the funding necessary for continuation of our product development, but such effort 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.

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 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 develop successfully marketing and sales experience. 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 current Good Manufacturing Practice, or 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 United States and abroad.

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 which impact A.G.E. or the formation of A.G.E. crosslinks.

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

The degree of patent protection afforded to pharmaceutical inventions is uncertain and our potential products are subject to this uncertainty. Pimagedine is not a novel compound and is not covered by a composition-of-matter patent. The patents covering Pimagedine are use patents containing claims covering therapeutic indications and the use of Pimagedine to inhibit the formation of A.G.E.s. Competitors may develop and commercialize Pimagedine or Pimagedine-like products for indications outside of the protection provided by the claims of our use patents. Physicians, pharmacies and wholesalers could then substitute for our Pimagedine products. Substitution for our Pimagedine products would have a material adverse effect on our business, financial condition and results of operations. Use patents may afford a lesser degree of protection in certain foreign countries due to their patent laws. 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 new drug application, or 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 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 DIABETES, CARDIOVASCULAR DISEASES 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 a cure for diabetes or the reduction of the incidence of diabetes and its complications. For example, a number of companies are investigating islet cell transplantation as a possible cure for Type 1 diabetes. Results of a study conducted by the National Institutes of Health, known as the Diabetes Control and Complications Trial, published in 1993, showed that tight glucose control reduced the incidence of diabetic complications. Several pharmaceutical companies have introduced new products for glucose control for the management of hyperglycemia in Type 2 diabetes. In addition, several large companies have initiated or expanded research, development and licensing efforts to build a diabetic pharmaceutical franchise focusing on diabetic nephropathy, neuropathy, retinopathy and related conditions. An example of this is research seeking anti-angiogenesis drugs for the potential treatment of diabetic retinopathy. It is possible that one or more of these initiatives may reduce or eliminate the market for some of our products.

In addition, a broad range of cardiovascular drugs is under development by many pharmaceutical and biotechnology companies. It is possible that one or more of these initiatives may reduce or eliminate the market for some of our products.

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 United States, we expect that there will continue to be federal and state initiatives

to control and/or reduce pharmaceutical expenditures. In addition, increasing emphasis on managed care in the United States will continue to put pressure on pharmaceutical pricing. Cost control initiatives could decrease the price that we receive for any products we may develop and sell in the future and have a material adverse effect on our business, financial condition and results of operations. Further, to the extent that cost control initiatives have a material adverse effect on our corporate partners, our ability to commercialize our products may be adversely affected.

Our ability to commercialize pharmaceutical products may depend, in part, on the extent to which reimbursement for the products will be available from government health administration authorities, private health insurers and other third-party payers. Significant uncertainty exists as to the reimbursement status of newly approved 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.

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 Pimagedine, may expose us to liability claims resulting from the use of products or product candidates. These claims might be made directly by 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 insurance or, if maintained, that insurance may not be available 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, chemicals and various radioactive compounds. 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 investment in marketable securities. We do not use derivative financial instruments in our investments. 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 2000 annual report on Form 10-K. There have been no material changes in our market risk position since December 31, 2000.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On July 13, 2000 and August 8, 2000, Colby S. Parks and Marion H. Parks filed suits against us in the United States District Court for the Middle District of North Carolina and the Superior Court of Chatham County, North Carolina, respectively, claiming unspecified damages for injuries Mr. Parks allegedly sustained as a result of his participation in one of our clinical trials. Our liability insurance carrier is defending these actions.

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 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 have filed a notice of appeal to the Supreme Court of Delaware.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

a) 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 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.)
3.4	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.)
3.5	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.)
3.6	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.)
3.7	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.)
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.)
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.)
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4.4	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.)
4.5	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.)
4.6	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.)
4.7	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.)
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b) The following reports on Form 8-K were filed during the quarter ended March 31, 2001.

On January 5, 2001, the Company filed a Current Report on Form 8-K, dated January 3, 2001, which reported that the Company's lead A.G.E. Crosslink Breaker, ALT-711, demonstrated potential as a novel treatment for isolated systolic hypertension.

On January 10, 2001, the Company filed a Current Report on Form 8-K, dated January 9, 2001, which reported that the Company had raised more than $1.5 million through the sale of net operating loss carryforwards under the State of New Jersey's Technology Business Tax Certificate Transfer Program.

On January 25, 2001, the Company filed a Current Report on Form 8-K, dated January 24, 2001, which reported that the Company's A.G.E. Formation Inhibitor, ALT-946, demonstrated a protective effect on kidneys in a pre-clinical study.

On February 1, 2001, the Company filed a Current Report on Form 8-K, dated January 30, 2001, which reported that the Company's lead A.G.E. Crosslink Breaker, ALT-711, demonstrated the ability to decrease blood vessel stiffness in older non-human primates in a pre-clinical study.

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 11, 2001

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 and Administration,
Secretary and Treasurer
(principal finance and accounting officer)

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