ALTEON INC /DE
Form 10-Q
November 13, 2003

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2003

OR

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

FOR THE TRANSITION PERIOD FROM ---------- TO ----------

Commission file number 001-16043

ALTEON INC.
(Exact name of registrant as specified in its charter)

| DELAWARE | 13-3304550 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

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 [ ]

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

On November 5, 2003, 40,467,148 shares of the registrant's Common Stock were outstanding.

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ALTEON INC.

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PART I - FINANCIAL INFORMATION

ITEM I. FINANCIAL STATEMENTS (UNAUDITED)

ALTEON INC.
BALANCE SHEETS
(UNAUDITED)

| | September 30, 2003 | December 2002 |
|---|---|---|

ASSETS

| | | |
|---|---|---|
| Current Assets: | | |
| Cash and cash equivalents | $ 8,937,591 | $ 14,45 |
| Short-term investments | 2,996,100 | 2,98 |
| Other current assets | 396,571 | 14 |
| Total current assets | 12,330,262 | 17,58 |
| Property and equipment, net | 88,926 | 51 |
| Total assets | $ 12,419,188 | $ 18,09 |

LIABILITIES AND STOCKHOLDERS' EQUITY

| | | |
|---|---|---|
| Current Liabilities: | | |
| Accounts payable | $ 819,894 | $ 53 |
| Accrued expenses | 1,553,553 | 3,25 |
| Total current liabilities | 2,373,447 | 3,79 |
| Stockholders' Equity: | | |
| Preferred Stock, $0.01 par value, 1,993,329 shares authorized, and 1,149 and 1,079 of Series G and 3,451 and 3,241 of Series H shares issued and outstanding, as of September 30, 2003 and December 31, 2002, respectively | 46 | |
| Common Stock, $0.01 par value, 80,000,000 shares authorized, and 35,988,922 and 33,600,841 shares issued and outstanding, as of September 30, 2003 and December 31, 2002, respectively | 359,889 | 33 |
| Additional paid-in capital | 193,857,816 | 183,34 |
| Accumulated deficit | (184,172,558) | (169,37 |
| Accumulated other comprehensive income | 548 | |
| Total stockholders' equity | 10,045,741 | 14,30 |
| Total liabilities and stockholders' equity | $ 12,419,188 | $ 18,09 |

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



ALTEON INC.
STATEMENTS OF OPERATIONS
(UNAUDITED)

| | Three Months Ended September 30, | |
|---|---|---|
| | 2003 | 2002 |
| Revenues: | | |
| Investment income | $ 35,623 | $ 93,376 |
| Expenses: | | |
| Research and development (which includes non-cash variable stock compensation (benefit)/expense of $(63,620) and $0 for the three months ended September 30, 2003 and 2002, respectively, and $20,019 and $(93,516) for the nine months ended September 30, 2003 and 2002, respectively) | 2,165,182 | 4,330,899 |
| General and administrative (which includes non-cash variable stock compensation (benefit)/expense of $(1,475,917) and $0 for the three months ended September 30, 2003 and 2002, respectively, and $0 and $(1,315,635) for the nine months ended September 30, 2003 and 2002, respectively) | (422,294) | 975,540 |
| Total expenses | 1,742,888 | 5,306,439 |
| Net loss | (1,707,265) | (5,213,063) |
| Preferred stock dividends | 965,004 | 887,158 |
| Net loss applicable to common stockholders | $ (2,672,269) | $ (6,100,221) |
| Basic/diluted net loss per share applicable to common stockholders | $ (0.07) | $ (0.19) |
| Weighted average common shares used in computing basic/diluted net loss per share | 35,961,899 | 31,878,525 |

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

ALTEON INC.
STATEMENTS OF CASH FLOWS
(UNAUDITED)

| | End |
|---|---|
| | 2003 |
| Cash Flows from Operating Activities: | |
| Net loss | $ (11,991 |
| Adjustments to reconcile net loss to cash used in operating activities: | |
| Depreciation and amortization | 479 |
| Amortization of deferred compensation | 26 |
| Non-cash compensation expense/(benefit) related to variable plan employee stock options | 20 |
| Changes in operating assets and liabilities: | |
| Other assets | (253 |
| Accounts payable and accrued expenses | (1,422 |
| Net cash used in operating activities | (13,142 |
| Cash Flows from Investing Activities: | |
| Capital expenditures | (50 |
| Purchases of marketable securities | (3,010 |
| Maturities of marketable securities | 3,000 |
| Net cash (used in)/provided by investing activities | (61 |
| Cash Flows from Financing Activities: | |
| Net proceeds from issuance of common stock | 7,655 |
| Net proceeds from exercise of employee stock options | 33 |
| Net cash provided by financing activities | 7,688 |
| Net (decrease)/increase in cash and cash equivalents | (5,514 |
| Cash and cash equivalents, beginning of period | 14,452 |
| Cash and cash equivalents, end of period | $ 8,937 |

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



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 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, 2003, are not necessarily indicative of the results that may be expected for the year ending December 31, 2003. 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, 2002, filed with the Securities and Exchange Commission.

NOTE 2 - LIQUIDITY

Alteon has incurred an accumulated deficit of $184,172,558 as of September 30, 2003, 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 collaborative relationships, reimbursement of certain of its research and development expenses by its collaborative partners, investment income earned on cash balances and short-term investments and the sale of a portion of its New Jersey net operating loss carryforwards.

As of September 30, 2003, the Company had working capital of $9,956,815, including $11,933,691 of cash and cash equivalents and short-term investments. The Company's net cash used in operations for the nine months ended September 30, 2003, was $13,142,156 and for the year ended December 31, 2002 was $14,931,030. The Company raised $7,655,945 of net proceeds through the sale of common stock in March 2003 (see Note 7 to the unaudited financial statements).

Pursuant to a Stock Purchase Agreement dated October 15, 2003, as amended, the Company sold 4,457,146 shares of common stock to a number of unaffiliated institutional investors at a purchase price of $1.75 per share for approximately $7,760,000 in net proceeds. The Stock Purchase Agreement provides that the Company will sell up to a total of 1,559,456 additional shares of common stock at $1.85 per share for $2,884,994 in gross proceeds to such of the investors who elect to purchase shares during the period ending 120 business days after the initial closing. The investors are not obligated, and at their discretion may elect not to purchase additional shares. The shares were offered through a prospectus supplement pursuant to the Company's effective shelf registration statement.

Alteon's lead compound, ALT-711 is the only Advanced Glycation End-Product ("A.G.E.") Crosslink Breaker in advanced human testing. Several Phase 2 clinical trials have been completed: the DIAMOND (Distensibility Improvement and Remodeling in Diastolic Heart Failure) trial in diastolic heart failure ("DHF"); the SAPPHIRE (Systolic And Pulse Pressure Hemodynamic Improvement by Restoring Elasticity) and SILVER (Systolic Hypertension Interaction with Left VEntricular Remodeling) trial in systolic hypertension; and a trial in cardiovascular compliance. Based on evidence of ALT-711's demonstrated efficacy and biological activity in these Phase 2 trials, as well

as a strong and consistent safety profile, the Company is proceeding with Phase 2 development of ALT-711 in two major cardiovascular indications, systolic hypertension and heart failure. Alteon continues to work with its external advisors to determine the appropriate clinical development strategy, timeline and related costs. The Company believes it currently has adequate resources, including the proceeds received in connection with the October 15, 2003 Stock Purchase Agreement, as amended, to sustain its operations, exclusive of the full cost of the clinical trials, into early 2005. The Company will require additional new funding to complete the contemplated Phase 2 development of ALT-711 and any other clinical trials it may initiate in the first half of 2004.

Alteon will continue to monitor its liquidity position and continue to explore fund-raising alternatives. The Company has the ability to quickly and significantly reduce its cash burn rate, if necessary, as it has limited fixed commitments. Depending upon the results of any attempts made by the Company to raise additional funds through the



sale of additional equity securities or through strategic collaborations, the Company may be required to further reduce or curtail its research and product development activities and other operations (including any new clinical trials) if cash and cash equivalents fall below pre-determined levels.

The amount and timing of Alteon's future capital requirements will depend on numerous factors, including the progress of its 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 and the development of marketing and sales capabilities.

The Company will require, over the long-term, substantial new funding to pursue development and commercialization of ALT-711 and its other product candidates to continue its operations. The Company believes that satisfying these capital requirements over the long-term will require successful commercialization of its product candidates. However, it is uncertain whether any products will be approved or will be commercially successful.

Because of Alteon's near-term and long-term capital requirements, the Company will seek access to the public or private equity markets whenever conditions are favorable. This may have the effect of materially diluting the current holders of the Company's outstanding stock. The Company may also seek additional funding through corporate collaborations and other financing vehicles, potentially including off-balance sheet financing through limited partnerships or corporations. There can be no assurance that such funding will be available at all or on terms acceptable to Alteon. If 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.

NOTE 3 - CASH AND 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 values, with changes in fair value recorded as a component of accumulated other comprehensive income. Premiums or discounts on the purchase of short-term debt securities are amortized to interest income. As of September 30, 2003 and December 31, 2002, short-term investments were invested in debt instruments of the U.S. government and

government agencies. They consist of the following:

| | September 30, 2003 | December 31, 2002 |
|---|---|---|
| U.S. government agency funds..... | $ 2,996,100 | $ 2,986,200 |

NOTE 4 - NET LOSS PER SHARE

Basic loss per share is based on the weighted average number of shares outstanding during the period. For the three- and nine-month periods ended September 30, 2003 and 2002, 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, 2003 and 2002, was 28,218,949 and 29,427,473, respectively.

NOTE 5 - STOCK COMPENSATION

The Company accounts for employee stock-based compensation and awards issued to non-employee directors under Accounting Principles Board Opinion No. 25 ("APB Opinion No. 25"), "Accounting for Stock Issued to Employees," and related interpretations, under which no compensation cost (excluding those options granted below fair value) has been recognized. Stock option awards issued to consultants and contractors are accounted for in accordance with Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation." In March 2000, the Financial Accounting Standards Board ("FASB") released Interpretation No. 44 ("FIN 44"), "Accounting for Certain Transactions Involving Stock Compensation, An Interpretation of APB Opinion No. 25." The interpretation became effective on July 1, 2000, but in some circumstances applies to transactions that occurred prior to the effective date. Under the interpretation, stock options that are repriced must be accounted for as variable-plan arrangements until the options are exercised, forfeited or expire. This requirement applies to any options repriced after December 15, 1998.

On February 2, 1999, the Company repriced certain stock options. The total non-cash stock compensation (benefit)/expense resulting from the 1999 repricing for the three months ended September 30, 2003 and 2002, is $(1,539,537) and $0, respectively, and for the nine months ended September 30, 2003 and 2002, is $20,019 and $(1,409,151), respectively. As of September 30, 2003, there were 569,489 repriced options outstanding, which expire on various dates through January 2008.



If the Company had applied the fair value recognition provisions of SFAS No. 123 to all of its option grants, the Company's pro forma net loss and net loss per share applicable to common stockholders for the three and nine months ended September 30, 2003 and 2002, would be as follows:

| | Three Months Ended September 30, | |
|---|---|---|
| | 2003 | 2002 |

| | | | |
|---|---|---|---|
| Net loss, as reported | $ (1,707,265) | $ (5,213,063) | $ |
| Add: Variable non-cash stock compensation (benefit)/ expense included in reported net loss | (1,539,537) | -- | |
| Less: Total stock-based employee compensation expense determined under fair value method | (305,775) | (413,185) | |
| Pro forma net loss | (3,552,577) | (5,626,248) | |
| Preferred stock dividends | 965,004 | 887,158 | |
| Pro forma net loss applicable to common stockholders | $ (4,517,581) | $ (6,513,406) | $ |
| Earnings per share applicable to common stockholders: | | | |
| Basic/diluted, as reported | $ (0.07) | $ (0.19) | $ |
| Basic/diluted, pro forma | $ (0.13) | $ (0.20) | $ |

NOTE 6 - COMPREHENSIVE LOSS

The following sets forth comprehensive loss for the three and nine months ended September 30, 2003 and 2002:

| | Three Months Ended September 30, | | |
|---|---|---|---|
| | 2003 | 2002 | |
| Net Loss | $ (1,707,265) | $ (5,213,063) | $ |
| Net Unrealized Loss on Short-Term Investments | (1,642) | (2,073) | |
| Comprehensive Loss | $ (1,708,907) | $ (5,215,136) | $ |

NOTE 7 - STOCKHOLDERS' EQUITY

In March 2003, Alteon completed a public offering of 2,300,000 shares of common stock at $3.50 per share, which provided net proceeds of $7,655,945, after deducting $394,055 of offering costs.

Series G Preferred Stock and Series H Preferred Stock dividends are payable quarterly in shares of preferred stock at a rate of 8.5%. Each share of Series G Preferred Stock and Series H Preferred Stock is convertible, upon 70 days' prior written notice, into the number of shares of common stock determined by dividing $10,000 by the average of the closing sales price of the common stock, as reported on the American Stock Exchange, for the 20 business days immediately preceding the date of conversion. For the three months ended September 30, 2003 and 2002, preferred stock dividends were $965,004 and $887,158, respectively, and for the nine months ended September 30, 2003 and 2002, preferred stock dividends were $2,805,168 and $2,578,877, respectively.

NOTE 8 - SUBSEQUENT EVENT

The Company's lease for its office and laboratory space in Ramsey, New Jersey, expired on November 1, 2003, and has been extended through December 31, 2003. Alteon has signed a three-year lease, commencing December 1, 2003, for 10,800 square feet of office space in Parsippany, New Jersey. Annual rent over the term of the lease ranges from approximately $260,000 in the first year to $280,000 in the third year. As a provision of the lease, Alteon is required to provide a letter of credit, which is collateralized with a $250,000 restricted certificate of deposit.



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

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. Our lead compound is in clinical development; several others are in earlier development stages. These pharmaceutical candidates were developed as a result of our research on the Advanced Glycation End-product ("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 the only A.G.E. Crosslink Breaker in advanced human testing. Several Phase 2 clinical trials have been completed: the DIAMOND (Distensibility Improvement and Remodeling in Diastolic Heart Failure) trial in diastolic heart failure ("DHF"); the SAPPHIRE (Systolic and Pulse Pressure Hemodynamic Improvement by Restoring Elasticity) and SILVER (Systolic Hypertension Interaction with Left VEntricual Remodeling) trial in systolic hypertension; and a trial in cardiovascular compliance. Based on evidence of ALT-711's demonstrated efficacy and biological activity in these Phase 2 trials, as well as a strong and consistent safety profile, we are proceeding with Phase 2 development of ALT-711 in two major cardiovascular indications, systolic hypertension and heart failure. We continue to work with our external advisors to determine the appropriate clinical development strategy, timeline and related costs. We believe we currently have adequate resources, including the proceeds received in connection with the October 15, 2003 Stock Purchase Agreement, as amended, to sustain our operations, exclusive of the full cost of the clinical trials, into early 2005. We will require additional new funding to complete the contemplated Phase 2 development of ALT-711 and any other clinical trials we may initiate in the first half of 2004.

We will require, over the long-term, substantial new funding to pursue development and commercialization of ALT-711 and our other product candidates to continue our operations. We believe that satisfying these capital requirements over the long-term will require successful commercialization of our product candidates. However, it is uncertain whether any products will be approved or will be commercially successful. The amount and timing of our future capital requirements will depend on numerous factors, including the progress of our research and development 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 and the development of marketing and sales capabilities.

Because of our near-term and long-term capital requirements, we will

seek access to the public or private equity markets whenever conditions are favorable. This may have the effect of materially diluting the current holders of our outstanding stock. We may also seek additional funding through corporate collaborations and other financing vehicles, potentially including off-balance sheet financing through limited partnerships or corporations. There can be no assurance that such funding will be available at all or on terms acceptable to us. If adequate funds are not available, we may be required to curtail significantly one or more of our research or development programs. If we obtain funds through arrangements with collaborative partners or others, we may be required to relinquish rights to certain of our technologies or product candidates.

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. We believe that ALT-711 may address the cardiovascular, diabetes and primary care physician markets.

We will continue to explore the use of topical A.G.E. Crosslink Breakers in skin and photo aging, as a result of our recent evaluation of ALT-744's positive activity in this area. We will focus efforts on bringing forward other crosslink breaker compounds with more attractive formulation characteristics than those of ALT-744 to address the pharmaceutical market for skin and photo aging, and will discontinue research on the ALT-744 prototype.

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 $184,172,558 as of September 30, 2003, and expect to incur operating losses, potentially greater than losses in prior years, for a number of years.

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



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

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

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2003 AND 2002

Total revenues for the three months ended September 30, 2003 and 2002, were $35,623 and $93,376, respectively. Revenues were derived from interest earned on cash and cash equivalents and short-term investments. Total revenues decreased due to lower investment balances and a decrease in short-term interest rates.

Our total expenses were $1,742,888 for the three months ended September 30, 2003, compared to $5,306,439 for the three months ended September 30, 2002, and in each period consisted primarily of research and development expenses. Research and development expenses includes third-party expenses associated with pre-clinical and clinical studies, manufacturing costs, including the development and preparation of clinical supplies, personnel and personnel-related expenses and facility expenses. Research and development expenses were $2,165,182 for the three months ended September 30, 2003, as compared to $4,330,899 for the same period in 2002. In 2003, they primarily consisted of $1,023,128 in personnel and personnel-related expenses, $350,848 in clinical trial expenses, including $240,113 related to the Phase 2b SAPPHIRE and SILVER open-label trial, $151,090 related to process development and drug stability studies, $145,516 in pre-clinical expenses and non-cash variable stock compensation benefit of $63,620. Research and development expenses for the three months ended September 30, 2002, primarily consisted of $2,204,190 in clinical trial expenses related to the Phase 2b SAPPHIRE and SILVER trial, $867,745 in personnel and personnel-related expenses, $410,548 of manufacturing expenses (process development and packaging) and drug stability studies associated with the ALT-711 programs, and $148,626 in pre-clinical expenses.

Research and development expenses decreased by $2,165,717, or 50.0%, as compared to the three months ended September 30, 2002. The decrease was primarily attributed to lower clinical costs associated with the completion of the SAPPHIRE and SILVER trial in the second quarter of 2003 and lower manufacturing costs. These decreased costs were partially offset by higher personnel and personnel-related costs, including temporary help related to accumulating and assessing the data of the SAPPHIRE and SILVER trial.

General and administrative expenses decreased to $(422,294) for the three months September 30, 2003, compared to $975,540 for the same period in 2002 and in each period included a non-cash variable stock compensation benefit of $(1,475,917) and $0, respectively. Non-cash variable stock compensation expense/(benefit) is directly related to changes in our stock price (see Note 5 to the unaudited financial statements). Exclusive of the 2003 benefit, general and administrative expenses were $1,053,623. General and administrative expenses in 2003 included an increase in business development and marketing research costs associated with the unblinding of the SAPPHIRE and SILVER trial.

Our net loss applicable to common stockholders was $2,672,269 for the three months ended September 30, 2003, compared to $6,100,221 in the same period in 2002, a decrease of 56.2%, primarily related to variable non-cash stock compensation benefit, decreased clinical trial expenses and lower manufacturing expenses. Included in the net loss applicable to common stockholders are preferred stock dividends of $965,004 and $887,158 for the three months ended September 30, 2003 and 2002, respectively.

NINE MONTHS ENDED SEPTEMBER 30, 2003 AND 2002

Total revenues for the nine months ended September 30, 2003 and 2002, were $139,521 and $346,020, respectively. Revenues were derived from interest earned on cash and cash equivalents and short-term investments. Total revenues decreased due to lower investment balances and a decrease in short-term interest rates.

Our total expenses were $12,131,317 for the nine months ended September 30, 2003 compared to $14,144,873 for the nine months ended September 30, 2002, and in each year consisted primarily of research and development expenses. Research and development expenses for the nine months ended September 30, 2003 were $8,330,120, and included $3,352,234 in personnel and personnel-related expenses, $2,022,374 in clinical trial expenses, of which $1,637,197 related to the Phase 2b SAPPHIRE and SILVER trial, $628,574 in pre-clinical expenses,

manufacturing costs of $583,697, primarily related to drug stability studies and tablet manufacturing, $350,747 in third-party consulting, a non-cash variable stock compensation expense of $20,019 and $1,039,362 of facility and other overhead related costs. Research and development expenses for the nine months ended September 30, 2002 were $11,982,313 and included $5,147,849 in clinical trial expenses related to the Phase 2b SAPPHIRE and SILVER trial, $2,045,336 related to manufacturing (process development, tablet manufacturing and packaging) and drug stability studies, $568,270 in pre-





clinical expenses, $2,510,416 in personnel and personnel-related expenses and a non-cash variable stock compensation benefit of $93,516.

Research and development expenses decreased by $3,652,193 or 30.5%, primarily due to decreased clinical trial and manufacturing costs associated with the completion of the Phase 2b SAPPHIRE and SILVER clinical trial in 2003, partly offset by higher personnel and personnel-related costs, including temporary help related to accumulating and assessing the data of the SAPPHIRE and SILVER trial.

General and administrative expenses increased to $3,801,197 for the nine months ended September 30, 2003, compared to $2,162,560 for the same period in 2002 and includes a non-cash variable stock compensation benefit of $0 and $(1,315,635), respectively. In addition to the non-cash variable stock compensation benefit recorded in 2002, general and administrative expenses increased primarily due to higher business development and marketing research costs in 2003.

Our net loss applicable to common stockholders decreased to $14,796,964 for the nine months ended September 30, 2003, compared to $16,377,730 in the same period in 2002, a decrease of 9.7%. This was primarily a result of decreased research and development expenses and lower manufacturing expenses due to completion of the Phase 2b SAPPHIRE and SILVER clinical trial. Included in the net loss applicable to common stockholders are preferred stock dividends of $2,805,168 and $2,578,877 for the nine months ended September 30, 2003 and 2002, respectively.

LIQUIDITY AND CAPITAL RESOURCES

We had cash and cash equivalents and short-term investments at September 30, 2003, of $11,933,691, compared to $17,438,613 at December 31, 2002. This is a decrease in cash and cash equivalents and short-term investments of $5,504,922. Cash increased during the nine months ended September 30, 2003 by $7,655,945 from the net proceeds from a public offering of 2,300,000 shares of common stock at $3.50 per share in March 2003. This was more than offset by $13,142,156 of net cash used in operations, consisting primarily of research and development expenses, personnel-related costs and facility expenses and $50,941 of cash used in capital expenditures during the nine months ended September 30, 2003. At September 30, 2003, we had working capital of $9,956,815.

Pursuant to a Stock Purchase Agreement dated October 15, 2003, as amended, we sold 4,457,146 shares of common stock to a number of unaffiliated institutional investors at a purchase price of $1.75 per share for approximately $7,760,000 in net proceeds. The Stock Purchase Agreement provides that we will sell up to a total of 1,559,456 additional shares of common stock at $1.85 per share for $2,884,994 in gross proceeds to such of the investors who elect to purchase shares during the period ending 120 business days after the initial

closing. The investors are not obligated, and at their discretion may elect not to purchase additional shares. The shares were offered through a prospectus supplement pursuant to our effective shelf registration statement.

At December 31, 2002, we had available federal net operating loss carryforwards, which expire in various amounts from the years 2006 through 2022, of approximately $152,365,000 and New Jersey net operating loss carryforwards, which expire in the years 2004 through 2009, of approximately $106,771,000. In addition, we had federal research and development tax credit carryforwards of approximately $7,048,000 and New Jersey research and development tax credit carryforwards of approximately $811,000 at December 31, 2002. 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 2002, we sold $1,839,000 of our gross New Jersey net operating loss carryforwards and $578,000 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 2002 were $647,000 and were recorded as a tax benefit in the December 31, 2002 statement of operations. 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.

Our lead compound, ALT-711 is the only A.G.E. Crosslink Breaker in advanced human testing. Several Phase 2 clinical trials have been completed: the DIAMOND (Distensibility Improvement and Remodeling in Diastolic Heart Failure) trial in diastolic heart failure ("DHF"); the SAPPHIRE (Systolic And Pulse Pressure Hemodynamic Improvement by Restoring Elasticity) and SILVER (Systolic Hypertension Interaction with Left VEntricular Remodeling) trial in systolic hypertension; and a trial in cardiovascular compliance. Based on evidence of ALT-711's demonstrated efficacy and biological activity in these Phase 2 trials, as well as a strong and consistent safety profile, we are proceeding with Phase 2 development of ALT-711 in two major cardiovascular indications, systolic hypertension and heart failure. We continue to work with our external advisors to determine the appropriate clinical development strategy, timeline and related costs. We believe we currently have adequate resources, including the proceeds received in connection with the October 15, 2003 Stock Purchase Agreement, as amended, to sustain our operations, exclusive of the full cost of the clinical trials, into early 2005. We will require additional new funding to complete the contemplated Phase 2 development of ALT-711 and any other clinical trials we may initiate in the first half of 2004.



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

We will continue to monitor our liquidity position and continue to explore fund-raising alternatives. We have the ability to quickly and significantly reduce the cash burn rate, if necessary, as we have limited fixed commitments. Depending upon the results of any attempts made by us to raise additional funds through the sale of additional equity securities or through strategic collaborations, we may be required to further reduce or curtail our research and product development activities and other operations (including any new clinical trials) if cash and cash equivalents fall below pre-determined levels.

The amount and timing 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 near-term and long-term capital requirements, we will seek access to the public or private equity markets whenever conditions are favorable. This may have the effect of materially diluting the current holders of our outstanding stock. We may also seek additional funding through corporate collaborations and other financing vehicles, potentially including off-balance sheet financing through limited partnerships or corporations. There can be no assurance that such funding will be available at all or on terms acceptable to us. If adequate funds are not available, we may be required to curtail significantly one or more of our research or development programs. If we obtain funds through arrangements with collaborative partners or others, we may be required to relinquish rights to certain of our technologies or product candidates.

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. As described above, we believe that additional development of this compound and other product candidates will require us to find additional sources of funding.

Our lease for office and laboratory space in Ramsey, New Jersey, expired on November 1, 2003, and has been extended through December 31, 2003. We have signed a three-year lease, commencing December 1, 2003, for 10,800 square feet of office space in Parsippany, New Jersey. Annual rent over the term of the lease ranges from approximately $260,000 in the first year to $280,000 in the third year. As a provision of the lease, we are required to provide a letter of credit, which is collateralized with a $250,000 restricted certificate of deposit.

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, 2002, and accompanying audited financial statements and related notes thereto. We believe the effect of the following accounting policy is significant to our results of operations and financial condition.



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

AND RESULTS OF OPERATIONS (CONTINUED)

We account for options granted to employees and directors in accordance with APB Opinion No. 25, and related interpretations. As such, compensation expense is recorded on fixed stock grants only if the current fair value of the underlying stock exceeds the exercise price of the option at the date of grant and it is recognized on a straight-line basis over the vesting period. Based on the performance of our stock, we repriced certain employee stock options on February 2, 1999. As a result of this repricing, options to purchase 1.06 million shares of stock were repriced and certain vesting periods related to these options were modified or extended. Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation, An Interpretation of APB Opinion No. 25," requires us to record compensation expense or benefit, which is adjusted every quarter, for increases or decreases in the fair value of the repriced options based on changes in our stock price from the value at July 1, 2000, until the repriced options are exercised, forfeited or expire. As a result, net loss applicable to common stockholders and net loss per share to common stockholders may be subject to volatility. Had we accounted for repricing of stock option grants in accordance with SFAS No. 123, the expense related to the vested options would have been recorded at the repricing date, and the expense related to non-vested options would have been recorded over the vesting period. As of September 30, 2003, there were 569,489 repriced options outstanding, which expire on various dates through January 2008.

FORWARD-LOOKING STATEMENTS AND CAUTIONARY STATEMENTS

Statements in this Form 10-Q that are not statements or descriptions of historical facts are "forward-looking" statements under Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and are subject to numerous risks and uncertainties. These forward-looking statements and other forward-looking statements made by us or our representatives are based on a number of assumptions. The words "believe," "expect," "anticipate," "intend," "estimate" or other expressions, which are predictions of or indicate future events and trends and which do not relate to historical matters, identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, as they involve risks and uncertainties, and actual results could differ materially from those currently anticipated due to a number of factors, including those set forth in this section and elsewhere in this Form 10-Q. These factors include, but are not limited to, the risks set forth below.

The forward-looking statements represent our judgment and expectations as of the date of this Report. We assume no obligation to update any such forward-looking statements.

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

As of September 30, 2003, we had working capital of $9,956,815, including $11,933,691 of cash and cash equivalents and short-term investments. Our cash used in operations for the nine months ended September 30, 2003 was $13,142,156, and for the year ended December 31, 2002 was $14,931,030. In October 2003, we sold 4,457,146 shares of common stock, raising net proceeds of approximately $7,760,000.

Our lead compound, ALT-711 is the only A.G.E. Crosslink Breaker in advanced human testing. Several Phase 2 clinical trials have been completed: the DIAMOND (Distensibility Improvement and Remodeling in Diastolic Heart Failure) trail in diastolic heart failure ("DHF"); the SAPPHIRE (Systolic And Pulse Pressure Hemodynamic Improvement by Restoring Elasticity) and SILVER (Systolic Hypertension Interaction with Left VEntricular Remodeling) trial in

systolic hypertension; and a trial in cardiovascular compliance. Based on evidence of ALT-711's demonstrated efficacy and biological activity in these Phase 2 trials, as well as a strong and consistent safety profile, we are proceeding with Phase 2 development of ALT-711 in two major cardiovascular indications, systolic hypertension and heart failure. We continue to work with our external advisors to determine the appropriate clinical development strategy, timeline and related costs. We believe we currently have adequate resources, including the proceeds received in connection with the October 15, 2003 Stock Purchase Agreement, as amended, to sustain our operations, exclusive of the full cost of the clinical trials, into early 2005. We will require additional new funding to complete the contemplated Phase 2 development of ALT-711 and any other clinical trials we may initiate in the first half of 2004.

We will continue to monitor our liquidity position and continue to explore fund-raising alternatives. We have the ability to quickly and significantly reduce the cash burn rate, if necessary, as we have limited fixed commitments. Depending upon the results of any attempts made by us to raise additional funds through the sale of additional equity securities or through strategic collaborations, we may be required to further reduce or curtail our research and product development activities and other operations (including any new clinical trials) if cash and cash equivalents fall below pre-determined levels.

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.





We will require, over the long-term, substantial new funding to pursue development and commercialization of ALT-711 and our other product candidates to continue our operations. We believe that satisfying these capital requirements over the long-term will require successful commercialization of our product candidates. However, it is uncertain whether any products will be approved or will be commercially successful.

Because of our near-term and long-term capital requirements, we will seek access to the public or private equity markets whenever conditions are favorable. This may have the effect of materially diluting the current holders of our outstanding stock. We may also seek additional funding through corporate collaborations and other financing vehicles, potentially including off-balance sheet financing through limited partnerships or corporations. There can be no assurance that such funding will be available at all or on terms acceptable to us. If adequate funds are not available, we may be required to curtail significantly one or more of our research or development programs. If we obtain funds through arrangements with collaborative partners or others, we may be required to relinquish rights to certain of our technologies or product candidates.

IF WE 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 United States Food and Drug Administration ("FDA") or any other regulatory body. All of our product candidates, including our lead candidate, ALT-711, 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, to be commercially available for a number of years, if at all.

CLINICAL TRIALS REQUIRED FOR OUR PRODUCT CANDIDATES ARE TIME-CONSUMING, AND THEIR OUTCOME IS UNCERTAIN.

Before obtaining regulatory approvals for the commercial sale of any of our products under development, we must demonstrate through pre-clinical studies and clinical trials that the product is safe and effective for use in each target indication. The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Factors which can cause delay or termination of our clinical trials include: (i) slower than expected patient enrollment due to the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the study, competition with clinical trials for other drug candidates or other factors; (ii) lower than expected retention rates of patients in a clinical trial; (iii) inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials; (iv) delays in approvals from a study site's review board; (v) longer treatment time required to demonstrate effectiveness or determine the appropriate product dose; (vi) lack of sufficient supplies of the product candidate; (vii) adverse medical events or side effects in treated patients; (viii) lack of effectiveness of the product candidate being tested and (ix) regulatory changes.

Even if we obtain positive results from pre-clinical or clinical trials for a particular product, we may not achieve the same success in future trials of that product. In addition, some or all of the clinical trials we undertake may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals, which could prevent the creation of marketable products. Our product development costs will increase if we have delays in testing or approvals, if we need to perform more or larger clinical trials than planned or if our trials are not successful. Delays in our clinical trials may harm our financial results and the commercial prospects for our products.

IF WE ARE UNABLE TO DERIVE REVENUES FROM PRODUCT SALES, WE MAY NEVER BE PROFITABLE.

All of our revenues to date have been generated from collaborative research agreements and 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, 2003, we had an accumulated deficit of $184,172,558. We anticipate that we will incur substantial, potentially greater, losses in the future. Our products under development may not be successfully developed and our

products, if successfully developed, may not generate revenues sufficient to enable us to earn a





profit. We expect to incur substantial additional operating expenses over the next several years as our research, development and clinical trial activities continue. We do not expect to generate revenues from the sale of products, if any, for a number of years. Our ability to achieve profitability depends, in part, on our ability to enter into agreements for product development, obtain regulatory approval for our products and develop the capacity, or enter into agreements, for the manufacture, marketing and sale of any products. We may not obtain required regulatory approvals, or successfully develop, manufacture, commercialize and market product candidates, and we may never achieve product revenues or profitability.

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

Based on the performance of our stock, 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 the Financial Accounting Standards Board ("FASB") Interpretation No. 44 ("FIN 44"), "Accounting for Certain Transactions Involving Stock Compensation, An Interpretation of APB Opinion No. 25." This interpretation requires us to record compensation expense or benefit, which is adjusted every quarter, for increases or decreases in the fair value of the repriced options based on changes in our stock price from the value at July 1, 2000, until the repriced options are exercised, forfeited or expire. The options expire at various dates through January 2008.

IF WE ARE UNABLE TO FORM THE COLLABORATIVE RELATIONSHIPS THAT OUR BUSINESS STRATEGY REQUIRES, THEN OUR PROGRAMS WILL SUFFER AND WE MAY NOT BE ABLE TO DEVELOP PRODUCTS.

Our strategy for developing and deriving revenues from our products depends, in large part, upon entering into arrangements with research collaborators, corporate partners and others. We are seeking to establish these relationships to provide the funding necessary for continuation of our product development, but if such efforts may not be successful, our programs may suffer and we may be unable to develop products.

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

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

In most cases, we will not be able to control the amount and timing of

resources that our corporate partners devote to our programs or potential products. If any of our corporate partners breached or terminated its agreement with us or otherwise failed to conduct its collaborative activities in a timely manner, the pre-clinical or clinical development or commercialization of product candidates or research programs could be delayed, and we would be required to devote additional resources to product development and commercialization or terminate certain development programs.

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

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, results of operations and liquidity.

IF WE CANNOT SUCCESSFULLY DEVELOP A MARKETING AND SALES FORCE OR MAINTAIN SUITABLE ARRANGEMENTS WITH THIRD PARTIES TO MARKET AND SELL OUR PRODUCTS, OUR ABILITY TO DELIVER PRODUCTS MAY BE IMPAIRED.

We currently have no experience in marketing or selling pharmaceutical products. In order to achieve commercial success for any approved product, we must either develop a marketing and sales force or, where appropriate or permissible, enter into arrangements with third parties to market and sell our products. We might not be successful in developing marketing and sales capabilities. Further, we may not be able to enter into marketing and sales agreements with others on acceptable terms, and any such arrangements, if entered into, may be





terminated. If we develop our own marketing and sales capability, it will compete with other companies that currently have experienced, well funded and larger marketing and sales operations. To the extent that we enter into co-promotion or other sales and marketing arrangements with other companies, revenues will depend on the efforts of others, which may not be successful.

IF WE CANNOT SUCCESSFULLY FORM AND MAINTAIN SUITABLE ARRANGEMENTS WITH THIRD PARTIES FOR THE MANUFACTURING OF THE PRODUCTS WE MAY DEVELOP, OUR ABILITY TO DEVELOP OR DELIVER PRODUCTS MAY BE IMPAIRED.

We have no experience in manufacturing products and do not have manufacturing facilities. Consequently, we are dependent on contract manufacturers for the production of products for development and commercial purposes. The manufacture of our products for clinical trials and commercial purposes is subject to current Good Manufacturing Practice ("cGMP") regulations promulgated by the FDA. In the event that we are unable to obtain or retain third-party manufacturing for our products, we will not be able to commercialize such products as planned. 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.

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

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to maintain, develop and expand our competitive position, which we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and certain, but not all, corporate partners and consultants. Relevant inventions may be developed by a person not bound by an invention assignment agreement. Binding agreements may be breached, and we may not have adequate remedies for such breach. In addition, our trade secrets may become known to or be independently discovered by competitors.

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

Our research, pre-clinical testing and clinical trials of our product candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous regulation by numerous governmental authorities in the United States and in other countries where we intend to test and market our product candidates.

Prior to marketing, any product we develop must undergo an extensive regulatory approval process. This regulatory process, which includes pre-clinical testing and clinical trials and may include post-marketing surveillance of each compound to establish its safety and efficacy, can take many years and can require the expenditure of substantial resources. Data obtained from pre-clinical and clinical activities is susceptible to varying interpretations that could delay, limit or prevent regulatory approval. In addition, we may encounter delays or rejections based upon changes in FDA policy for drug approval during the period of product development and FDA regulatory review of each submitted new drug application ("NDA"). We may encounter similar delays in foreign countries. We may not obtain regulatory approval for the drugs we develop. Moreover, regulatory approval may entail limitations on the indicated uses of the drug. Further, even if we obtain regulatory approval, a marketed drug and its manufacturer are subject to continuing review and discovery of previously unknown problems with a product or manufacturer which

may have adverse effects on our business, financial condition and results of operations, including withdrawal of the product from the market. Violations of regulatory requirements at any stage, including pre-clinical testing, clinical trials, the approval process or post-approval, may result in various adverse consequences, including the FDA's delay in approving, or its refusal to approve a product, withdrawal of an approved product from the market and the imposition of criminal penalties against the manufacturer and NDA holder. None of our products has been approved for commercialization in the United States or elsewhere. We may not be able to obtain FDA approval for any products.





Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude our licensees or marketing partners from marketing our products or limit the commercial use of such products and will have a material adverse effect on our business, financial condition, results of operations and liquidity.

IF WE ARE NOT ABLE TO COMPETE SUCCESSFULLY WITH OTHER COMPANIES IN THE DEVELOPMENT AND MARKETING OF CURES AND THERAPIES FOR CARDIOVASCULAR DISEASES, DIABETES AND THE OTHER CONDITIONS FOR WHICH WE SEEK TO DEVELOP PRODUCTS, WE MAY NOT BE ABLE TO CONTINUE OUR OPERATIONS.

We are engaged in pharmaceutical fields characterized by extensive research efforts and rapid technological progress. Many established pharmaceutical and biotechnology companies with resources greater than ours are attempting to develop products that would be competitive with our products. Other companies may succeed in developing products that are safer, more efficacious or less costly than any we may develop and may also be more successful than us in production and marketing. Rapid technological development by others may result in our products becoming obsolete before we recover a significant portion of the research, development or commercialization expenses incurred with respect to those products.

Certain technologies under development by other pharmaceutical companies could result in better treatments for cardiovascular disease, or diabetes and its related complications. Several large companies have initiated or expanded research, development and licensing efforts to build pharmaceutical franchises focusing on these medical conditions. It is possible that one or more of these initiatives may reduce or eliminate the market for some of our products. In addition, other companies have initiated research in the inhibition or crosslink breaking of A.G.E.s.

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

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

Our ability to commercialize pharmaceutical products may depend, in part, on the extent to which reimbursement for the products will be available from government health administration authorities, private health insurers and other third-party payers. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and third-party payers, including Medicare, are increasingly challenging the prices charged for medical products and services. Third-party insurance coverage may not be available to patients for any products developed by us. Government and other third-party payers are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing in some cases to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. If adequate coverage and reimbursement levels are not provided by government and other third-party payers for our products, the market acceptance of these products would be adversely affected.

IF THE USERS OF THE PRODUCTS WE DEVELOP CLAIM THAT OUR PRODUCTS HAVE HARMED THEM, WE MAY BE SUBJECT TO COSTLY AND DAMAGING PRODUCT LIABILITY LITIGATION, WHICH COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS, FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS.

The use of any of our potential products in clinical trials and the sale of any approved products, including the testing and commercialization of ALT-711 or other compounds, exposes us to liability claims resulting from the use of products or product candidates. Claims could be made directly by participants in our clinical trials, consumers, pharmaceutical companies or others. We maintain product liability insurance coverage for claims arising from the use of our products in clinical trials. However, coverage is becoming increasingly expensive, and we may not be able to maintain or acquire insurance at a reasonable cost or in sufficient amounts to protect us against losses due to liability that could have a material adverse effect on our business, financial conditions and results of operations. We may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future and insurance coverage and our resources may not be sufficient to satisfy any liability resulting from product liability claims. A successful product liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition, results of operations and liquidity.





IF WE ARE UNABLE TO ATTRACT AND RETAIN THE KEY PERSONNEL ON WHOM OUR SUCCESS DEPENDS, OUR PRODUCT DEVELOPMENT, MARKETING AND COMMERCIALIZATION PLANS COULD SUFFER.

We are highly dependent on the principal members of our management and scientific staff. The loss of services of any of these personnel could impede the achievement of our development objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future will also be critical to our success. We may not be able to attract and retain personnel on acceptable terms given the competition between pharmaceutical and healthcare companies, universities and non-profit research institutions for experienced scientists. In addition, we rely on consultants to assist us in formulating our research and development strategy. All of our consultants are employed outside of us and may have commitments to or consulting or advisory contracts with other entities that may limit their availability to us.

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, results of operations and liquidity.



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 2002 Annual Report on Form 10-K. There have been no material changes in our market risk position since December 31, 2002.

ITEM 4. CONTROLS AND PROCEDURES

a) Evaluation of disclosure controls and procedures. Our Chief Executive Officer and our Vice President, Finance, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the fiscal quarter covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, the Chief Executive Officer and the Vice President, Finance, have concluded that as of the end of such fiscal quarter, our current disclosure controls and procedures are adequate and effective to ensure that information required to be disclosed in the reports we file under the Exchange Act is recorded, processed, summarized and reported on a timely basis.

b) Changes in internal control over financial reporting. There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the fiscal quarter covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



PART II - OTHER INFORMATION

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

a) Exhibits

See Exhibit Index on page 22 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, 2003:

On July 23, 2003, the Company filed a Current Report on Form 8-K, dated July 17, 2003, announcing initial results from its Phase 2b SAPPHIRE and SILVER clinical trial.



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, 2003

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)



INDEX TO EXHIBITS

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

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| 3.5 | Certificate of Amendment of Certificate of Designations of Series G Preferred Stock of Alteon Inc. (Incorporated by reference to Exhibit 3.4 to the Company's Report on Form 10-Q filed on August 14, 1998, S.E.C. File Number 000-19529.) |
| 3.6 | Certificate of Designations of Series H Preferred Stock of Alteon Inc. (Incorporated by reference to Exhibit 3.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 1997, S.E.C. File Number 000-19529.) |
| 3.7 | Amended Certificate of Designations of Series H Preferred Stock of Alteon Inc. (Incorporated by reference to Exhibit 3.6 to the Company's Report on Form 10-Q filed on August 14, 1998, S.E.C. File Number 000-19529.) |
| 3.8 | Certificate of Retirement dated November 20, 2000, of Alteon Inc. (Incorporated by reference to Exhibit 3.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, S.E.C. File Number 001-16043.) |
| 3.9 | Certificate of Amendment to Restated Certificate of Incorporation of Alteon Inc., dated June 7, 2001. (Incorporated by reference to Exhibit 3.8 to the Company's Report on Form 10-Q filed on August 14, 2001, S.E.C. File Number 001-16043.) |
| 3.10 | By-laws, as amended. (Incorporated by reference to Exhibit 3.10 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, S.E.C. File Number 001-16043.) |
| 4.1 | Stockholders' Rights Agreement dated as of July 27, 1995, between Alteon Inc. and Registrar and Transfer Company, as Rights Agent. (Incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, S.E.C. File Number 001-16043.) |
| 4.2 | Amendment to Stockholders' Rights Agreement dated as of April 24, 1997, between Alteon Inc. and Registrar and Transfer Company, as Rights Agent. (Incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed on May 9, 1997, S.E.C. File Number 000-19529.) |
| 4.3 | Registration Rights Agreement dated as of April 24, 1997, between Alteon Inc. and the investors named on the signature page thereof. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 9, 1997, S.E.C. File Number 000-19529.) |
| 4.4 | Form of Common Stock Purchase Warrant. (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on May 9, 1997, S.E.C. File Number 000-19529.) |
| 4.5 | Amendment to Stockholders' Rights Agreement dated as of December 1, 1997, between Alteon Inc. and Registrar and Transfer Company, as Rights Agent. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 10, 1997, S.E.C. File Number 000-19529.) |
| 4.6 | Registration Rights Agreement dated September 29, 2000. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on October 5, 2000, S.E.C. File Number 001-16043.) |

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| 4.7 | Form of Series 1 Common Stock Purchase Warrant. (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on October 5, 2000, S.E.C. File Number 001-16043.) |
| 4.8 | Form of Series 2 Common Stock Purchase Warrant. (Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on October 5, 2000, S.E.C. File Number 001-16043.) |
| 4.9 | Notice of Appointment, dated August 29, 2002, of The American Stock Transfer & Trust Company as successor Rights Agent, pursuant to Stockholders' Rights Agreement dated as of July 27, 1995. (Incorporated by reference to Exhibit 4.4 of the Company's Report on Form 10-Q filed on November 13, 2002, S.E.C. File Number 001-16043.) |
| 10.1 | Stock Purchase Agreement, dated October 15, 2003. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 20, 2003, S.E.C. File Number 001-16043.) |
| 10.2 | Amendment to Stock Purchase Agreement, dated October 24, 2003. |
| 10.3 | Lease, dated October 21, 2003, between Alteon Inc. and Mack-Cali Realty Corporation. |
| 31.1 | Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |