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ALTEON INC /DE
Form 10-K
March 10, 2003

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2002, 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)

Securities registered pursuant to Section 12(b) of the Act:

| Title of Each Class | Name of Each Exchange On Which Registered |
|---|--|
| Common Stock, Par Value \$.01 per share | American Stock Exchange |

Securities registered pursuant to Section 12(g) of the Act:

NONE

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the American Stock Exchange closing price of the common stock (\$2.06 per share), as of June 28, 2002, was \$65,516,106.

At February 28, 2003, 33,600,841 shares of the registrant's common stock, par value \$.01 per share, were outstanding.

Documents Incorporated By Reference

| Document ----- | Where Incorporated ----- |
|--|-----------------------------|
| Proxy Statement for 2003 Annual Meeting of Stockholders | Part III |

PART 1

ITEM 1. BUSINESS.

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 Phase 2b clinical development; several others are in earlier development stages. These pharmaceutical candidates were developed as a result of our research on the Advanced Glycation End-Products ("A.G.E.") pathway, a fundamental pathological process and inevitable consequence of aging that causes or contributes to many medical disorders, including cardiovascular, kidney and eye diseases.

A.G.E.s are glucose/protein complexes that form as a result of circulating blood glucose reacting with proteins. These A.G.E. complexes subsequently interact and bond (crosslink) with other proteins, resulting in "hardened" (stiffened) arteries, toughened tissues and impaired flexibility and function of many body organs. In healthy individuals, this pathological A.G.E.-formation process occurs slowly as the body ages. In diabetic patients, the rate of A.G.E. accumulation and the extent of protein crosslinking are accelerated because of high glucose levels.

Our current research and drug development activities targeting the A.G.E. pathway take three directions: the breaking of A.G.E. crosslinks between proteins in order to reverse damage ("A.G.E. Crosslink Breakers"); the prevention or inhibition of A.G.E. formation ("A.G.E.-Formation Inhibitors") and the reduction of the A.G.E. burden through a novel class of anti-hyperglycemic agents, Glucose Lowering Agents ("GLA"). We believe that we were the first company to focus on the development of compounds to treat diseases caused by A.G.E. formation and crosslinking. Since our inception, we have created an extensive library of novel compounds targeting the A.G.E. pathway, and have actively pursued patent protection for these discoveries. We have 99 issued United States patents and over 80 issued foreign patents focused primarily on A.G.E. technology.

ALT-711 is an A.G.E. Crosslink Breaker and our lead product candidate. ALT-711 offers the possibility of the first therapeutic approach to "breaking"

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A.G.E. crosslinks, the benefit of which may be to reverse tissue damage caused by aging and diabetes, thereby restoring flexibility and function to blood vessels and organs of the body. We are initially developing ALT-711 for the treatment of cardiovascular diseases, and have completed two Phase 2a safety, efficacy and pharmacology studies. Preliminary results from the first 17 patients in the recently conducted Phase 2a DIAMOND (Distensibility Improvement And REMODELING in Diastolic Heart Failure) clinical trial evaluating the activity of ALT-711 in diastolic heart failure ("DHF") patients demonstrated that patients who received ALT-711 for 16 weeks experienced a statistically significant reduction in left ventricular mass, a marked improvement in left ventricular diastolic filling and a positive effect on patients' quality of life. In 2001, we conducted a Phase 2a clinical trial, in which 93 patients received ALT-711 or placebo tablets once daily for eight weeks. Study results showed that ALT-711 patients experienced a statistically significant and clinically meaningful reduction in pulse pressure (p