ALTEON INC /DE
Form 8-K
July 23, 2003

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 or 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported) July 17, 2003

ALTEON INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	001-16043	13-3304550
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

170 Williams Drive, Ramsey, New Jersey	07446
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code (201) 934-5000

(Former Name or Former Address, If Changed Since Last Report)

Item 5. Other Events

On July 17, 2003, Alteon Inc. issued the following press release:

ALTEON'S ALT-711 SHOWS EFFICACY AGAINST UNCONTROLLED SYSTOLIC HYPERTENSION;
PRE-SPECIFIED ENDPOINTS NOT MET IN PHASE 2B SAPPHIRE AND SILVER TRIALS

-- Additional Phase 2 Studies Being Planned Based on
Drug's Activity at Lower Doses --

Ramsey, New Jersey, July 17, 2003 - Alteon Inc. (AMEX: ALT) today announced initial results from its multi-center Phase 2b SAPPHIRE and SILVER clinical trials of the company's lead A.G.E. Crosslink Breaker, ALT-711, in the treatment of patients with uncontrolled systolic hypertension. The five-arm SAPPHIRE trial and the two-arm SILVER trial evaluated ALT-711's effectiveness in a total of 768 patients having elevated systolic blood pressure (systolic hypertension) without or with enlargement of the left ventricle of the heart. The trials were dose-ranging, double-blind, placebo-controlled and conducted at over 60 sites nationwide. All patients were maintained on background hypertension medication.

ALT-711 did not demonstrate statistical significance as compared to placebo against the pre-specified primary endpoint of reduction of systolic blood pressure by office cuff pressure measurement at the highest of the four active dose levels, 210 mg per day. The data analysis was confounded by a 6-10 mm Hg drop in systolic blood pressures in all arms of the SAPPHIRE and SILVER trials, including placebo, during the first two weeks after patient randomization. However, patients in the SAPPHIRE "intent-to-treat" population demonstrated efficacy net of placebo, in the 2-3 mm Hg range by cuff pressure, at the lower end of the ALT-711 dosing range. In patients who completed their dosing regimen in the SAPPHIRE study, this effect at lower doses was amplified and strengthened to about 4 mm Hg net of placebo by ambulatory blood pressure measurements (ABPM). ALT-711 was safe and well tolerated across all dosing groups. No differences were noted between the SAPPHIRE and SILVER results.

"We believe that this is a meaningful signal of ALT-711's activity," said George L. Bakris, M.D., Professor of Preventive Medicine and Internal Medicine and Director of the Hypertension Clinical Research Center at Rush-Presbyterian St. Luke's Medical Center in Chicago and lead investigator on the SAPPHIRE and SILVER trials. "A 4 mm Hg reduction in systolic blood pressure on top of existing hypertension medications, if confirmed in further studies, would be an important addition to the treatment of this patient population."

"Based on discussions with our external advisors, we believe that the current results are robust and consistent with earlier findings about the biological activity of ALT-711," said Robert C. deGroof, Ph.D., Senior Vice President, Scientific Affairs. "We now have further evidence of efficacy against systolic hypertension in addition to existing evidence in diastolic heart failure (DHF), medical conditions that are due to age-related stiffening and for which there are clear, unmet needs."

"Following on what has been reported in previous preclinical and clinical evaluation, the SAPPHIRE and SILVER data support continued development of ALT-711 in systolic hypertension to confirm the appropriate dose," said Kenneth I. Moch, President and CEO of Alteon. "This new information leads us to plan a simple and relatively short confirmatory dose-ranging and mechanism of action study, and we are already working with our advisors to refine our follow-on clinical strategy. Assuming positive data from the next Phase 2 trial, we anticipate that we would enter into Phase 3 pivotal trials in systolic hypertension in 2005."

Earlier this year, Alteon announced that treatment with ALT-711 in DHF (the DIAMOND study) demonstrated that patients who received 210 mg of ALT-711 twice a day in an open-label, 16-week trial 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.

Alteon will hold a conference call at 8:30 a.m. (ET) this morning. Participating in the call along with Alteon senior management will be several external

advisors to the company. The call-in telephone number for the conference call will be 1-800-838-4403. International participants may call 1-973-317-5319. Participants should call approximately 5-10 minutes before 8:30 a.m. In addition, the conference call will be accessible through a webcast on the company's website, www.alteon.com at the Investor Relations section, and a digital rebroadcast will be available through July 24, 2003 by dialing 1-800-428-6051, passcode 301228 for domestic callers and 1-973-709-2089, passcode 301228 for international callers.

THE SAPPHIRE AND SILVER TRIALS IN SYSTOLIC HYPERTENSION

The Phase 2b SAPPHIRE (Systolic And Pulse Pressure Hemodynamic Improvement by Restoring Elasticity) and SILVER (Systolic Hypertension Interaction with Left VEntricular Remodeling) trials evaluated ALT-711's effectiveness in 768 patients having elevated systolic blood pressure (systolic hypertension) without or with enlargement of the left ventricle of the heart (left ventricular hypertrophy or LVH). The trials were dose-ranging, double-blind, placebo-controlled and conducted at over 60 sites nationwide.

In the SAPPHIRE trial, patients were randomized into one of five treatment arms (four different oral tablet doses of ALT-711 or placebo). In the SILVER trial, patients were randomized to one of two treatment arms (ALT-711 or placebo). Patients were dosed once a day for six months, in addition to their existing medications. Patients enrolled in the trial are older than 50 years of age, had a systolic blood pressure of greater than 150 mm Hg and diastolic blood pressure of less than 90 mm Hg, and had thickening of the left ventricle of the heart as measured by echocardiography. The trial included male and female, non-diabetic and diabetic patients. The primary endpoints of the studies were the change in systolic blood pressure. Secondary endpoints included additional blood pressure measurements and changes in certain urological characteristics.

For background information on the emergence of systolic hypertension as a leading risk factor for cardiovascular disease, visit the company's website, www.alteon.com.

About Alteon

Alteon is developing several new classes of drugs that reverse or slow down diseases of aging and complications of diabetes. These compounds have an impact on a fundamental pathological process caused by protein-glucose complexes called Advanced Glycation End-products (A.G.E.s). The formation and crosslinking of A.G.E.s lead to a loss of flexibility and function in body tissues, organs and vessels and have been shown to be a causative factor in many age-related diseases and diabetic complications. Alteon has created a library of novel classes of compounds targeting the A.G.E. Pathway. These include A.G.E. Crosslink Breakers, A.G.E. Formation Inhibitors and Glucose Lowering Agents. Alteon's lead compound ALT-711 is the only A.G.E. Crosslink Breaker in advanced human testing. For more information on Alteon, visit the company's website at www.alteon.com.

Any statements contained in this press release that relate to future plans, events or performance are forward-looking statements that involve risks and uncertainties including, but not limited to, those relating to technology and product development (including the possibility that early clinical trial results may not be predictive of results that will be obtained in large-scale testing or that any clinical trials will not demonstrate sufficient safety and efficacy to obtain requisite approvals or will not result in marketable products), regulatory approval processes, intellectual property rights and litigation, competitive products, ability to obtain financing, and other risks identified in

Alteon's filings with the Securities and Exchange Commission. The information contained in this press release is accurate as of the date indicated. Actual results, events or performance may differ materially. Alteon undertakes no obligation to publicly release the result of any revision to these forward-looking statements that may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events

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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 hereunto duly authorized.

Alteon Inc.

By: /s/ Elizabeth O'Dell

Elizabeth O'Dell
Vice President, Finance

Dated: July 23, 2003