ALTEON INC /DE
Form 8-K
March 12, 2004

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) March 10, 2004

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.)

6 Campus Drive, Parsippany, New Jersey 07054

(Address of Principal Executive Offices) (Zip Code)

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

170 Williams Drive, Ramsey, New Jersey 07446

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

Item 5. Other Events

On March 10, 2004, Alteon Inc. issued the following press release:

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ALTEON INITIATES "SPECTRA," TRIAL OF ALAGEBRIUM CHLORIDE (ALT-711)
IN PATIENTS WITH SYSTOLIC HYPERTENSION

- First in New Class of Drugs to Target Underlying Cause of Systolic Hypertension, Most Common Form of High Blood Pressure in People Over 50, and Type Least Likely to Be Well Treated -

Parsippany, New Jersey, March 10, 2004 - Alteon Inc. announced today that it has initiated a Phase 2b clinical trial of Alteon's lead A.G.E. Crosslink Breaker, alagebrium chloride, in patients with systolic hypertension. SPECTRA (Systolic Pressure EffiCacy and Safety TRial of Alagebrium) is designed to evaluate alagebrium's ability to lower systolic blood pressure in patients with a systolic blood pressure reading of greater than or equal to 140 mm Hg (by ambulatory blood pressure measurements), building upon positive data from previous Phase 2 trials. Alagebrium's activity in prior clinical trials demonstrated the drug's safety and ability to lower systolic blood pressure and pulse pressure in aging patients, especially in a difficult-to-treat hypertensive patient population. Notably, alagebrium's beneficial effect was demonstrated over and above standard treatments, and data thus far point to a mechanism of action unlike any existing blood pressure agent.

Systolic hypertension is the most common form of hypertension in people over age 50, and recent statistics estimate its prevalence at more than 20 million individuals in the U.S. alone. The condition is defined as an elevated systolic pressure (the top number in a blood pressure reading) of 140 mm Hg or higher. Systolic hypertension is also characterized by an increased pulse pressure, the difference between the systolic and diastolic (the bottom number in a blood pressure reading) blood pressures, a marker for vascular stiffness. The prevalence of systolic hypertension increases with age, with systolic hypertension becoming far more common than diastolic hypertension. Yet, it is the type of hypertension least likely to be well treated, according to the American Heart Association, in part due to the fact that current blood pressure drugs do not specifically target systolic hypertension. Current treatment options are therefore limited.

Alagebrium is the most clinically advanced drug in a new class of compounds known as Advanced Glycation End-product (A.G.E.) Crosslink Breakers, which were discovered by Alteon. By "breaking" the pathological bonds that cause tissues, organs and vessels to stiffen and lose function over time, alagebrium has demonstrated the ability to reverse certain age-related and diabetes-related conditions. In previous Phase 2 testing in cardiovascular disease, treatment with alagebrium resulted in statistically significant and clinically meaningful effects of increasing vascular wall elasticity and lowering pulse pressure. In a post hoc analysis of a recent Phase 2 trial, alagebrium treatment resulted in significant lowering of systolic blood pressures in patients (as measured by ambulatory blood pressure measurements) with baseline systolic pressures of 140 mm Hg or greater whose condition was uncontrolled despite treatment with one or more currently available blood pressure medications. SPECTRA will further evaluate alagebrium's activity in these patients, who represent a major unmet medical need.

"Initiation of SPECTRA is a key milestone in our program for the development of alagebrium in cardiovascular disease. We are enthusiastic about the potential that alagebrium has demonstrated in systolic hypertension and we are aggressively pursuing clinical development in this indication," said Robert C. deGroof, Senior Vice President, Scientific Affairs.

ABOUT SPECTRA

In SPECTRA, alagebrium will be tested in approximately 390 patients at over 50 clinical sites throughout the United States. The trial will include male and female patients at least 45 years of age. Recruited patients will undergo a wash-out period, when they are weaned from their existing antihypertensive treatment, followed by a run-in phase during which they will be stabilized on a diuretic. They will then receive alagebrium tablets or placebo once a day for 12 weeks.

SPECTRA will further extend the range of effective dosing defined in previous

Phase 2 testing. The study will consist of four treatment arms, comprising three different dose levels of alagebrium (10, 50 or 150 mg) or placebo. Patients enrolled in the trial must have systolic blood pressure of greater or equal to 140 mm Hg as measured by ambulatory blood pressure monitoring (ABPM), as well as additional qualifications. Automated office blood pressures (oscillometric) as well as ABPM pressures will be taken at scheduled time points. Change from baseline in mean 24-hour systolic ABPM pressure after 12 weeks of dosing (as compared to placebo) will be evaluated as the primary measure of efficacy. Secondary endpoints will include changes in diastolic, pulse and arterial pressures.

A.G.E. CROSSLINK BREAKERS AND ALAGEBRIUM

Advanced Glycation End-products (A.G.E.s) are permanent glucose structures that form when glucose binds to the surface of proteins. Many of these proteins, including structural proteins such as collagen and elastin, play an integral role in the maintenance of cardiovascular elasticity function and vascular wall integrity. This process can impair the normal function of organs that depend on flexibility for normal function, such as blood vessels and cardiac muscle. Alagebrium is the first in the A.G.E. Crosslink Breaker class that has been shown to reverse or "break" A.G.E. crosslinks, thereby restoring more normal function to organs and tissues that have lost flexibility. Pharmacologic intervention with alagebrium directly targets the biochemical pathway leading to the stiffness of the cardiovascular system. Its mechanism of action is new and novel, and is unrelated to that of any pharmaceutical agent either currently prescribed or in clinical development. Importantly, alagebrium does not disrupt the natural enzymatic glycation sites or peptide bonds that are responsible for maintaining the normal integrity of the collagen chain. Thus, normal structure and function is preserved while abnormal crosslinking is reduced.

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 alagebrium chloride (formerly ALT-711), the only A.G.E. Crosslink Breaker in advanced human testing, has demonstrated safety and efficacy in several Phase 2 trials and is actively being developed for systolic hypertension and heart failure. For more information on Alteon, visit the company's website at www.alteon.com.

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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/ Kenneth Moch

President & CEO

Dated: March 11, 2004