ALTEON INC /DE
Form 8-K
April 23, 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) April 20, 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

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

Item 5. Other Events

On April 20, 2004, Alteon issued the following press release:

"ALTEON INITIATES 'PEDESTAL,' A PHASE 2 TRIAL OF ALAGEBRIUM IN DIASTOLIC DYSFUNCTION

-STUDY BUILDS UPON POSITIVE DATA FROM DIAMOND TRIAL OF ALAGEBRIUM IN HEART FAILURE -

PARSIPPANY, N.J., Apr 20, 2004 /PRNewswire-FirstCall via Comtex/ -- Alteon Inc. (Amex: ALT) announced today that a Phase 2 trial of its novel A.G.E. Crosslink Breaker alagebrium, formerly known as ALT-711, has been initiated at Baylor

Heart Clinic, Baylor College of Medicine in Houston. PEDESTAL (Patients with Impaired Ejection Fraction and Diastolic Dysfunction: Efficacy and Safety Trial of ALagebrium) will continue the evaluation of alagebrium on diastolic function and ventricular mass in patients with significant heart failure. In the Phase 2a DIAMOND trial, treatment with alagebrium resulted in an unprecedented reduction in left ventricular mass within a 16-week treatment period, as well as a marked improvement in left ventricular diastolic filling and improvement in quality of life.

PEDESTAL is an open-label exploratory study to determine the effects of alagebrium at two oral dosages (35 mg qd or 210 mg bid) for 6, 12, 16 and 24 weeks on diastolic function and left ventricular mass in 20 patients diagnosed with systolic heart failure and diastolic dysfunction. Safety and quality of life will also be evaluated. The study will include men and women at least 30 years of age with or without diabetes, who are classified as having grade II- IV heart failure under the New York Heart Association guidelines. The primary endpoints include quantification of left ventricular mass and complete Doppler evaluation of changes in diastolic function. Secondary endpoints include a quality of life assessment as measured by the Minnesota Living With Heart Failure Questionnaire.

Diastolic dysfunction is uniformly present in patients with systolic heart failure. It is characterized by higher than normal pressures during the relaxing phase of the heart cycle (diastole). If the heart tissue (interstitium) has become stiffened, the relaxation cycle will be greatly affected. Current strategies designed to treat systolic heart failure have limited or no impact on the intrinsic tissue properties of the heart. Alagebrium is the first agent designed to reverse the stiffness of tissues, such as the interstitium in patients with systolic heart failure.

"The clinical and preclinical data generated to date by Alteon and outside investigators clearly support the potential of alagebrium in diastolic dysfunction," said Robert C. deGroof, Ph.D., Senior Vice President, Scientific Affairs. "To our knowledge, no other drug has demonstrated comparable cardiovascular effects within a 16-week time period as we observed in the DIAMOND trial. PEDESTAL will build upon that positive data and will give us additional insights into how the drug works in this important patient population."

How Alagebrium Works

Alagebrium is the first in a new class of compounds that have been shown in vitro and in vivo to reverse A.G.E. crosslinking, thereby restoring more normal function to tissues, vessels and

organs that have lost flexibility. Alteon believes that alagebrium's 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 glycosylation 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.

In addition to restoring elasticity of stiffened tissues by breaking pathological crosslinks, in preclinical studies alagebrium consistently demonstrates the ability to reverse the over-expression of genes for proteins and growth factors known to be associated with the pathological hypertrophy (enlargement) of tissues. Hypertrophy of the aorta and the left ventricle is correlated with the development of heart failure. These results indicate that restoration of normal tissue dynamics through breaking A.G.E. crosslinks may restore normal control of gene function.

Demonstrated Clinical Benefit

Alagebrium has demonstrated safety and efficacy in several Phase 2 trials and is actively being developed for systolic hypertension and heart failure. In previous 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 from the recent Phase 2b SAPPHIRE/SILVER trials, treatment with alagebrium resulted in statistically significant lowering of systolic blood pressures (as measured by ambulatory blood pressure measurements) in patients 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, a difficult-to-treat patient population. In addition, the DIAMOND trial of alagebrium in patients with diastolic heart failure showed that treatment with alagebrium over 16 weeks demonstrated a statistically significant reduction in left ventricular mass and a marked improvement in left ventricular diastolic filling, as well as statistically significant improvements in multiple quality of life measurements. Patients with Class III heart failure at baseline, the sickest patients in the study, appeared to benefit the most from alagebrium treatment.

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, 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.

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.

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: April 22, 2004