ALTEON INC /DE
Form 8-K
July 19, 2002

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 16, 2002

ALTEON INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	001-16043	13-3304550
(State or Other Juris-diction 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 16, 2002, Alteon Inc. issued the following press release:

ALTEON INITIATES FOURTH HUMAN TRIAL OF ALT-711, INVESTIGATIONAL DRUG SHOWN TO INCREASE THE ELASTICITY AND FUNCTION OF THE CARDIOVASCULAR SYSTEM

- Phase IIa DIAMOND Trial Focused on Diastolic Dysfunction, a Major Cause of Congestive Heart Failure -

RAMSEY, N.J., Jul 16, 2002 /PRNewswire-FirstCall via COMTEX/ -- Alteon Inc. (Amex: ALT) announced today that it has begun a Phase IIa trial of its lead A.G.E. Crosslink Breaker, ALT-711, in patients with diastolic heart failure (DHF). DHF is a condition characterized by the inability of the heart to relax properly and fill with blood, due to stiffening of the heart and impaired relaxation of the left ventricle. Diastolic dysfunction is estimated to account

for 30-50% of all heart failure cases, which total nearly 5 million in the U.S. alone.

The Phase IIa study, called the DIAMOND [Distensibility Improvement with ALT-711 Remodeling in Diastolic Heart Failure] trial, will seek to determine if ALT-711 can have a direct remodeling impact on the stiff heart, thus offering promise as a novel therapy for a medical condition that is currently poorly treated. In previous human clinical testing, ALT-711 has shown the ability to restore elasticity to blood vessel walls by cleaving pathological glucose-protein structures called Advanced Glycosylation End-product (A.G.E.) Crosslinks.(1) Additionally, in several preclinical studies, including a study that was presented at the September 2001 meeting of the American Heart Association's Council for High Blood Pressure Research,(2) ALT-711 has been shown to normalize the thickening of the left ventricle and remodel the heart.

ALT-711 is currently in three additional human clinical trials. Two Phase IIb trials, the SAPPHIRE and SILVER trials, are actively enrolling over 630 patients in order to evaluate the compound's effectiveness in patients with elevated systolic blood pressure [systolic hypertension] without or with enlargement of the left ventricle of the heart [left ventricular hypertrophy or LVH]. Systolic hypertension results from age-related or diabetes-related stiffening of the large arteries, and is a key factor in coronary heart disease in individuals over the age of 50. Alteon is also conducting a Phase I pharmacokinetic study in patients with end-stage renal disease undergoing peritoneal dialysis, a patient population with significant cardiovascular disease.

The DIAMOND Trial

The Phase IIa pilot trial of ALT-711 is being conducted at Wake Forest University Baptist Medical Center and the Medical University of South Carolina in patients at least 60 years of age with isolated diastolic heart failure. Primary endpoints will include changes in aortic stiffness, as measured by state-of-the-art magnetic resonance imaging, and exercise tolerance. Effects on LVH, diastolic filling and quality of life will also be assessed. Approximately 20 patients will receive 210 mg of ALT-711 twice daily on an

open-label, out-patient basis for 16 weeks. A historical control group of DHF patients who did not receive ALT-711 will be used for comparison. Data from the trial is anticipated during 2003.

Dalane W. Kitzman, M.D., Associate Professor of Medicine and Cardiology at Wake Forest University Baptist Medical Center, and an investigator in the trial, recently helped to identify diastolic heart failure as a more common condition than previously thought, particularly in people aged 65 and older, and especially in women. "Our study showed that the majority of older congestive heart failure patients have diastolic dysfunction, a less understood form of heart failure,"(3) said Dr. Kitzman. "We need more research on the progression of the disease and how best to treat it."

"ALT-711 may provide a novel treatment approach for diastolic dysfunction," said Michael Zile, M.D., FACC, FAHA, Charles Ezra Daniel Professor of Medicine, Medical University of South Carolina, and an investigator in the trial. "We are pleased to be a part of this important study."

About Alteon

Alteon is developing several new classes of drugs that reverse or slow down diseases of aging and complications of diabetes. These compounds impact a fundamental pathological process caused by protein-glucose complexes called Advanced Glycosylation End-products (A.G.E.s). The formation and crosslinking of A.G.E.s are an inevitable part of the aging and diabetic complications process, and leads to a loss of flexibility and function in body tissues, organs and

vessels. Alteon is initially developing therapies for cardiovascular and kidney diseases in older or diabetic individuals.

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. The Company's lead A.G.E. Crosslink Breaker, ALT-711, is being evaluated in the Phase IIb SAPPHIRE clinical trial focused on patients with systolic hypertension, and the Phase IIb SILVER trial in patients with systolic hypertension and left ventricular hypertrophy. ALT-711 is also undergoing Phase IIa evaluation in patients with diastolic heart failure, the DIAMOND trial, and a Phase I investigation in end-stage renal disease patients undergoing peritoneal dialysis, a patient population that has significant cardiovascular disease. Other A.G.E. compounds are being evaluated for skin aging, and additional indications. For more information on Alteon, visit the company's web site at http://www.alteon.com .

1 Kass DA, Shapiro EP, Kawaguchi M, Capriotti AR, Scuteri A, deGroof RC, Lakatta EG. Improved arterial compliance by a novel advanced glycation end- product crosslink breaker. Circulation 2001; 104:1464-70, Rapid Track Publication.

2 Veronesi M, Adam AG, Raij L. Abstract - ALT-711, A collagen cross- link breaker, decreases myocardial fibrosis and improves endothelial dysfunction in hypertensive Dahl

salt rats. American Heart Association 55th Annual Fall Conference and Scientific Sessions of the Council for High Blood Pressure Research, September 2001.

3 Kitzman DW, Gardin JM, Gottdiener JS, Arnold A, Boineau, R, Aurigemma G, Marino EK, Lyles M, Cushman M, Enright PL. Importance of heart failure with preserved systolic function in patients > 65 years of age. American Journal of Cardiology (2001; 87:413-9).

For more information on diastolic dysfunction and congestive heart failure, please see http://www.nhlbi.nih.gov/health/public/heart/other/hrtfail.htm http://www.americanheart.org/presenter.jhtml?identifier=4558; search for diastolic dysfunction

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 I. Moch

Kenneth I. Moch
President and Chief Executive Officer

Dated: July 18, 2002