ALTEON INC /DE
Form 8-K
November 13, 2001

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) November 7, 2001

ALTEON INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	0-19529	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 November 7, 2001 Alteon Inc. issued the following press release:

ALTEON ANNOUNCES INITIATION OF PHASE I HUMAN TESTING OF ALT-711 IN ESRD PATIENTS UNDERGOING PERITONEAL DIALYSIS

RAMSEY, N.J., Nov. 7 /PRNewswire/ -- Alteon Inc. (Amex: ALT) announced today that it has expanded the clinical testing of ALT-711, its lead A.G.E. Crosslink Breaker, into patients with end-stage renal disease (ESRD) who are undergoing peritoneal dialysis (PD). ESRD is a condition in which the kidneys no longer function, resulting in an increase of waste products in the body that cause a number of cardiovascular complications, including left ventricular hypertrophy (enlarged heart). PD is a method of dialysis that uses the patient's peritoneum (a membrane in the abdomen) to filter out waste products.

The new Phase I study is an important component of Alteon's clinical strategy in developing ALT-711 for cardiovascular disease, and will provide data necessary for Alteon to evaluate further development of ALT-711 in the critically ill peritoneal dialysis population. ALT-711 is concurrently in two Phase IIb trials, the SAPPHIRE (Systolic And Pulse Pressure Hemodynamic Improvement by Restoring Elasticity) and SILVER (Systolic Hypertension Interaction with Left VEntricular

Remodeling) trials, evaluating its effectiveness on systolic hypertension in individuals with or without left ventricular hypertrophy.

The Phase I safety and pharmacokinetic study, which has been initiated at Wake Forest University Medical Center in Winston-Salem, NC, will evaluate the way ALT-711 is metabolized in PD patients with ESRD. Recruited patients will receive drug or placebo in tablet form once a day. The dosage amount will be increased over a 4-week treatment period.

Peritoneal dialysis works on the same principle as hemodialysis, but the blood is cleaned while inside the body rather than through a machine. In most cases, this treatment can be performed without assistance, at home or at work. The peritoneal cavity is filled with dialysis fluid through a permanently implanted catheter. Excess water and waste pass through the peritoneum into the dialysis fluid. The fluid is then drained from the body and discarded.

Latest statistics show that almost 25,000 of the 400,000 Americans living with ESRD are undergoing peritoneal dialysis. This patient population has a limited 5-year survival (less than 30%) and significant cardiovascular complications, which are the primary cause of death.

ALT-711 is the most clinically advanced drug in a new class of compounds, known as Advanced Glycosylation 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, ALT-711 has demonstrated the ability to reverse certain age-related and diabetes-related conditions. In a 93-patient Phase IIa clinical trial, treatment with ALT-711 resulted in statistically significant and clinically meaningful effects of

increasing vascular wall elasticity and lowering pulse pressure, each major contributing factors in cardiovascular disease.

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 process that lead to a loss of flexibility and function in body tissues, organs and vessels. The company 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 developed for the treatment of cardiovascular disorders. ALT-711 is being evaluated in the Phase IIb SAPPHIRE clinical trial focused on isolated systolic hypertension, and the Phase IIb SILVER trial in systolic hypertension with left ventricular hypertrophy. The compound is also under 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, as well as additional human indications and animal health. For more information on Alteon, visit the company's web site at http://www.alteonpharma.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/ Kenneth I. Moch

Kenneth I. Moch
President and Chief Executive Officer

Dated: November 9, 2001