ALTEON INC /DE
Form 8-K
October 25, 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) October 23, 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 October 23, 2001 Alteon Inc. issued the following press release:

ALTEON INITIATES SECOND PHASE IIb TRIAL OF ALT-711 IN SYSTOLIC HYPERTENSION

RAMSEY, N.J., Oct. 23 /PRNewswire/ -- Alteon Inc. (Amex: ALT) announced today that it has initiated a second Phase IIb trial of ALT-711, an orally active drug that has demonstrated a broad beneficial effect in reversing cardiovascular disease. The SILVER (Systolic Hypertension Interaction with Left VEntricular Remodeling) trial will evaluate the blood pressure lowering effects of ALT-711 in patients who have systolic hypertension and

left ventricular hypertrophy (LVH), a thickening of the heart tissue that results from hypertension. LVH can lead to decreased cardiac output, the inability to meet the circulatory needs of the body, and to heart failure itself.

ALT-711 is concurrently being tested in humans with systolic hypertension alone in the Phase IIb SAPPHIRE (Systolic And Pulse Pressure Hemodynamic Improvement by Restoring Elasticity) trial, which was initiated in July 2001. Patients who are excluded as patients in the SAPPHIRE trial because of LVH will be target candidates for the SILVER trial. The SAPPHIRE and SILVER trials collectively will enroll 630 patients, with data expected in the second half of 2002.

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.

"The SILVER trial is an important addition to our overall clinical strategy," said Robert C. deGroof, Senior Vice President, Scientific Affairs. "Evaluating the interaction between systolic hypertension and LVH in the SILVER trial will help us build a solid foundation for a subsequent pivotal Phase III program."

"The results from these trials are critical in providing further proof of the value of A.G.E. compounds and ALT-711 in treating cardiovascular disease," said Kenneth I. Moch, Chairman and CEO. "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, as in our Phase IIa trial, the ongoing SAPPHIRE and SILVER trials will use ALT-711 in addition to currently prescribed hypertension medications. Market estimates indicate that 15-20 million patients in the U.S. suffer from systolic hypertension."

Additional background information on systolic hypertension follows this press release.

The SILVER and SAPPHIRE Trials

The SILVER trial will test ALT-711 in 180 patients at the approximately 40 sites

throughout the United States that are also conducting the ongoing 450 patient SAPPHIRE trial. Recruited patients will be randomized to one of two treatment arms and receive ALT-711 or placebo tablets once a day for three months, in addition to their existing medications. Patients enrolled in the trial must be older than 50 years of age, have a systolic blood pressure of greater than 160 mmHg and diastolic blood pressure of less than 90 mmHg, and have thickening of the left ventricle of the heart as measured by echocardiography. The trial will include males and female, non-diabetic and diabetic patients. As with the SAPPHIRE trial, the primary endpoints of the study will be the change in systolic blood pressure, and change in pulse pressure (the difference between the systolic and diastolic blood pressure). In addition, secondary endpoints will include additional blood pressure measurements and change in certain urological characteristics.

ALT-711: Consistent Beneficial Data in Cardiovascular Disease

Through its unique mechanism of action, ALT-711 is the first compound in development that breaks A.G.E.-derived crosslinks between proteins, potentially restoring flexibility and function to tissues, vessels and organs throughout the body. Normal structure and function is preserved while abnormal crosslinking is reduced. Evidence of the positive effect of ALT-711 on the cardiovascular system continues to grow. In a Phase IIa human trial, ALT-711 was shown to restore the cardiovascular system to a younger state by reversing the stiffening of the arteries that occurs in aging patients, increasing the ability of the diseased large arteries to stretch by 11-18%, and bringing them approximately 30% back to normal. The study was designated as "breakthrough information" and selected for "Rapid Track" publication in Circulation: Journal of the American Heart Association, and was published in the September 25, 2001, issue of the journal. Earlier in 2001, the ALT-711 Phase IIa data was featured at the March 2001 American College of Cardiology (ACC) meeting in a "Late Breaking Clinical Trials Special Scientific Session" and further chosen as one of four highlights of the Hypertension Section of the ACC meeting.

Evidence that ALT-711 may be effective for improving cardiovascular remodeling in hypertension was presented by University of Minnesota researchers at the American Heart Association's 55th Annual Fall Conference and Scientific Sessions of the Council for High Blood Pressure Research on September 23, 2001. This preclinical study demonstrated the ability of ALT-711 to decrease the thickening of the heart and improve the function of the endothelium in rats with hypertension. The research team tested ALT-711's ability to selectively break the cross-linking of collagen that contributes to cardiovascular disease in aging and diabetes. ALT-711 normalized left ventricular fibrosis, or the thickening of the left ventricle of the heart, and improved the function of the endothelium, the part of the cardiovascular system that regulates both the relaxation and contraction of blood vessels and contributes to the maintenance of the vascular structure.

Preclinical studies of ALT-711 conducted by researchers from The National Institute on Aging and Johns Hopkins Geriatric Center demonstrated the ability of the compound to significantly reduce arterial stiffness in elderly monkeys. Another study, in aged dogs, found that administration of ALT-711 for one month resulted in an approximate 40% decrease in age-related ventricular stiffness. This decrease was accompanied by an overall improvement in cardiac function. Reductions in blood pressure have also been observed in preclinical

models of diabetic hypertension.

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 evaluated in two Phase IIb trials, SAPPHIRE and SILVER, for cardiovascular diseases. The compound is also under investigation for end-stage renal disease patients undergoing peritoneal

dialysis, and is serving as a clinical prototype in other conditions where A.G.E. crosslinking is a cause of disease, such as uropathy and diabetic retinopathy. 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.

BACKGROUNDER

Systolic Hypertension: An Unmet Medical Need in Aging

Systolic hypertension is the most common form of hypertension in people over age 50, with an estimated prevalence of 15-20 million people in the U.S. alone. Yet it is the type of hypertension least likely to be well treated, according to a recent study published in the March 16, 2001 edition of Hypertension, a journal of the American Heart Association.

Systolic hypertension is a consequence of the age-related stiffening of the large arteries, and it is defined as elevated systolic blood pressure (above 140 mmHg) in conjunction with normal diastolic blood pressure (below 90 mmHg). It is characterized by an increased pulse pressure, defined as the difference between systolic and diastolic blood pressures. The

prevalence of hypertension increases with age, with systolic hypertension becoming far more common than diastolic hypertension.

Traditionally, treatment of hypertension has focused on controlling diastolic pressure. Current hypertension therapies, including diuretics, ACE inhibitors, beta blockers, calcium channel blockers and angiotensin receptor blockers have an effect on lowering both systolic and diastolic pressures. Treatment is therefore limited, as a patient may become hypotensive with too low a diastolic pressure.

A recent editorial in The New England Journal of Medicine [August 16, 2001] stated that the control of hypertension is an important national priority, and that clinical practice needs to shift focus to the management of systolic rather than diastolic hypertension. As documented in this issue of the Journal, most cases of uncontrolled hypertension are in persons with elevated systolic blood pressure, particularly in elderly adults. The epidemiological data indicate that systolic blood pressure is significantly more important than diastolic blood pressure as a determinant of cardiovascular risk in this group of patients.

The focus on systolic pressure began to increase in the 1990's with the results from the Systolic Hypertension in the Elderly Program (SHEP) trial and other epidemiological data that demonstrated that the level of systolic blood pressure is a better predictor of cardiovascular events including

stroke, coronary heart disease, and heart failure. A systolic blood pressure higher than 160 mmHg has been shown to double all-cause mortality, triple cardiovascular mortality, particularly in women, and more than double cardiovascular morbidity in both sexes. Similarly, elevated pulse pressure is increasingly being recognized as a risk factor for cardiovascular disease. The Framingham Study and others have demonstrated that a reduction in pulse pressure is associated with a significant risk reduction in cardiovascular death.

However, these findings have not yet been reflected in clinical practice due in part to the fact that there are no approved agents that selectively lower systolic blood pressure. The NEJM editorial states that physicians are often reluctant to treat systolic hypertension for fear of doing harm.

Alteon's proprietary class of A.G.E. Crosslink Breakers, and lead compound ALT-711, may specifically address this treatment issue by directly targeting the stiffening of the arteries that contributes to systolic hypertension. ALT-711 is currently 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 in patients with systolic hypertension, with data expected in the second half of 2002.

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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: October 23, 2001