ALTEON INC /DE
Form 8-K
January 05, 2001

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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) January 3, 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)

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Item 5. Other Events

On January 3, 2001 Alteon Inc. issued the following press release:

ALTEON'S ALT-711 DEMONSTRATES POTENTIAL AS NOVEL TREATMENT FOR ISOLATED SYSTOLIC HYPERTENSION

RAMSEY, N.J., Jan. 3 /PRNewswire/ -- Alteon Inc. (Amex: ALT) today announced positive results from a Phase IIa clinical trial evaluating the safety, efficacy and pharmacology of ALT-711, a first of its kind Advanced Glycosylation End-product Crosslink Breaker (A.G.E. Crosslink Breaker). The

formation of A.G.E. Crosslinks is a natural part of the aging process that can lead to stiffening and loss of function in tissues, organs and vessels including large arteries.

Study results show that patients who received ALT-711 experienced a statistically significant reduction in the arterial pulse pressure, defined by the difference between systolic and diastolic blood pressures. Results also show a clinically relevant increase in large artery compliance, an indicator of greater vascular flexibility and volume capacity, using a traditional measurement of the ratio of stroke volume to pulse pressure. Additionally, the drug was well-tolerated.

The ability to decrease pulse pressure and increase large artery compliance offers an opportunity to provide a treatment option specifically for isolated systolic hypertension (ISH), a currently unmet medical need. ISH, defined as elevated systolic blood pressure (greater than 160 mmHg) accompanied by normal diastolic blood pressure (less than 90 mmHg), can result in a substantially increased risk of cardiovascular disease and death. ISH affects nearly eight million Americans and is primarily a consequence of stiffening of the large arteries. ALT-711 is the first drug to show activity against ISH by targeting stiff vessel disease that contributes to this form of hypertension.

"These study results are important because currently available cardiovascular treatments do not directly target vascular stiffening and, as a result, are not optimal for the treatment of isolated systolic hypertension," said Edward G. Lakatta, M.D., Chief of the Laboratory of Cardiovascular Science at The National Institute on Aging and an investigator in this study. "The ALT-711 results are exciting in that selective enhancement of large artery distensibility with reduced pressure pulsation was achieved, providing a novel approach for the treatment of isolated systolic hypertension."

The Phase IIa human clinical trial was a double-blinded, placebo-controlled study evaluating the safety, efficacy and pharmacology of ALT-711. The trial included 93 patients over the age of 50 with measurably stiffened cardiovasculature including systolic blood pressure of at least 140 mmHg and pulse pressure of at least 60 mmHg. Patients were randomized to receive 56 consecutive daily oral doses of either 210 mg of ALT-711 (n=62) or placebo (n=31) during an 8-week period. During the study, which was conducted at nine

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U.S. clinical sites, patients were evaluated for cardiovascular elasticity and function as measured by pulse pressure, cardiovascular compliance, pulse wave velocity and cardiac output. Treatment with ALT-711 was in addition to all other medications.

"The results of this study represent a significant milestone for Alteon. The trial was designed to provide us with a better understanding of ALT-711's potential therapeutic benefits to the cardiovascular system and, as a result, impart meaningful guidance for the clinical direction of this compound," said Kenneth I. Moch, President and Chief Executive Officer of Alteon. "Based on these results, during 2001 Alteon plans to initiate Phase IIb efficacy trials to further assess ALT-711's activity in isolated systolic hypertension. Additionally, the Company will continue to evaluate the compound for other therapeutic applications."

Preclinical testing showed that ALT-711 reversed aging- and diabetes-related cardiovascular disease and restored function to the cardiovascular system. In preclinical evaluations, ALT-711 reversed stiffening of the aorta in rodents, canines and non-human primates. Although a statistically significant effect was not seen in cardiac output and pulse wave velocity as observed in preclinical trials, Alteon will continue to evaluate these measures in larger populations over longer periods of time as part of the Phase IIb program in ISH.

"Alteon was founded on the belief that by targeting the A.G.E. pathway, we can treat the cause of certain aging- and diabetes-related pathologies and reduce the severity and incidence of resulting diseases," said Robert C. deGroof, Ph.D., Senior Vice President, Scientific Affairs of Alteon. "This trial was an important step in proving our technology platform and demonstrating the potential to reverse cardiovascular disease caused by pathologies of diabetes and aging and, as a result, we believe that ALT-711 may represent a new frontier in cardiovascular medicine."

A.G.E. Crosslink Breakers

Advanced Glycosylation End-products (A.G.E.s) are permanent glucose structures that form when glucose binds to the surface of proteins. These structures interact with adjacent proteins to form pathological links called A.G.E. Crosslinks. Diabetic individuals form excessive amounts of A.G.E.s earlier in life than non-diabetic individuals. The formation of A.G.E. Crosslinks leads to increased stiffness of tissues, abnormal protein accumulation and organ dysfunction, which result in many complications of aging and diabetes.

Structural proteins, such as collagen and elastin, play an integral role in the maintenance of cardiovascular elasticity function and vascular wall integrity and are prime targets for A.G.E. crosslinking. This mechanical process can impair the normal function of contractile organs, such as blood vessels and cardiac muscle, which depend on flexibility for normal function. Loss of flexibility of the vasculature leads to isolated systolic hypertension, which creates increased workload for the heart and may lead to myocardial hypertrophy and heart failure.

Cardiovascular Disease and Isolated Systolic Hypertension

According to the American Heart Association, nearly 60 million Americans have one or



more types of cardiovascular disease. Cardiovascular disease has been the number one killer of Americans since the early 1900's. Isolated systolic hypertension is associated with a significantly increased risk of overall mortality, cardiovascular mortality and congestive heart failure. The latest World Health Organization - International Society of Hypertension guidelines for the management of hypertension emphasize the importance of pulse pressure and arterial stiffness as predictors of cardiovascular risk.

About Alteon

Alteon is a leader in the discovery and development of novel pharmaceuticals for the treatment of pathologies of aging and diabetes, with an initial emphasis on cardiovascular disease. The Company's proprietary technology is based on reversing or slowing or 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 is an inevitable part of the aging process that leads to a loss of flexibility and function in body tissues, organs and vessels.

Alteon has created a library of novel classes of compounds based on 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 drug candidate, ALT-711, is an A.G.E. Crosslink Breaker currently in Phase II clinical trials for the treatment of cardiovascular disorders including isolated systolic hypertension.

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.

Alteon is holding an analyst/investor conference call today, January 3, 2001, at 2:00 PM, Eastern Time. To access this call live, please dial 1-888-222-2994. Callers outside of the United States, please call +973-694-6836. This call will be archived on the Company's website at http://www.alteonpharma.com and will be rebroadcast until January 10, 2001, at 1-800-428-6051, passcode 151696. Callers outside of the United States, please call +973-709-2089, passcode 151696.

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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
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Kenneth I. Moch
Chief Executive Officer

Dated: January 3, 2001