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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 is initially developing therapies for cardiovascular diseases.

*Any statements contained in this annual report 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 report 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.*

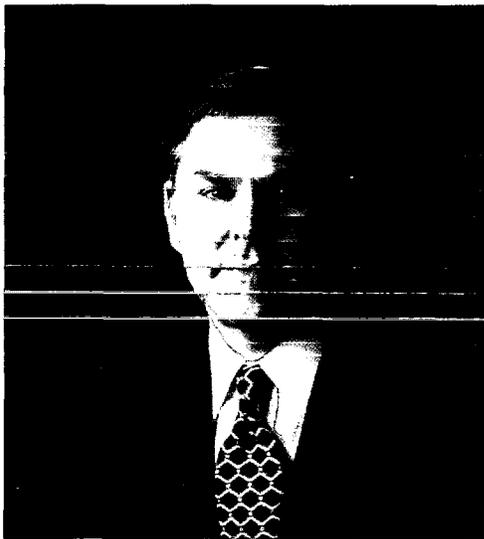
2003 was a year marked by significant progress for Alteon and alagebrium (formerly known as ALT-711), as well as by product development hurdles often encountered in pharmaceutical development.

During 2003, our primary focus was on the clinical development of alagebrium, our lead Advanced Glycation End-product (A.G.E.) Crosslink Breaker. Early in the year, we announced positive Phase 2a data on alagebrium's efficacy in patients with diastolic heart failure. In mid-year, and on several subsequent occasions, we announced data from the Phase 2b SAPPHIRE/SILVER trial of alagebrium in systolic hypertension which demonstrated alagebrium's activity in a traditionally difficult-to-treat patient population of people with systolic blood pressures not controlled by one or more medications.

The growing body of clinical and preclinical data on alagebrium has been evaluated against five key criteria for development of a successful pharmaceutical. As highlighted in the table on the next page, alagebrium continues to meet all of these characteristics. In uncontrolled systolic hypertension, the data support the potential for alagebrium as a novel, first-in-class anti-hypertensive agent with characteristics that are clearly differentiated from existing blood pressure agents. In diastolic dysfunction in heart failure, the drug has demonstrated exciting early results. Importantly, alagebrium has been safe and well tolerated in all clinical trials to date; I can't emphasize enough the importance of this finding.

Based on the cumulative body of scientific evidence, Alteon is moving aggressively ahead with the development of alagebrium. Systolic hypertension and diastolic dysfunction have become major areas of focus of the medical community because they affect very large patient populations that are not adequately treated by existing therapies. These medical conditions result, in part, from the stiffening of the cardiovascular system as we age.

Already, 2004 has been marked by a great deal of clinical activity. As discussed in more detail below, we have initiated SPECTRA, a Phase 2b trial in patients with uncontrolled systolic hypertension. We expect to initiate a second Phase 2 trial in diastolic dysfunction in the near future, and recently initiated a Phase 2 trial of alagebrium in endothelial function.



**Kenneth I. Moch**  
Chairman of the Board  
President and Chief Executive Officer

*“In persons older than 50 years, systolic blood pressure of more than 140 mm Hg is a much more important cardiovascular disease risk factor than diastolic blood pressure.”*

**The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure, May 2003.**

**Key Attributes of a Successful Pharmaceutical**

**Alagebrium Findings**

**Efficacy**

Drug has potential to meet regulatory and clinical hurdles against established endpoints.

In hypertension, ambulatory blood pressure measurements in the SAPPHIRE/SILVER (S/S) trial showed significant lowering of systolic blood pressure (SBP) in patients with baseline readings exceeding 140mm Hg

In heart failure, patients experienced a statistically significant reduction of left ventricular (LV) mass, in addition to a marked improvement in LV diastolic fillin and statistically significant effects on quality-of-life measures.

**Safety**

Drug is safe and well-tolerated in a significant number of patients, with a clean toxicity profile.

Alagebrium has demonstrated a clean safety profile in over 800 patients who have received active drug (of ~1,100 total patients in clinical trials).

**Responders**

Drug addresses a substantial proportion of potential candidates; responders have identifiable characteristics.

In the S/S trial of alagebrium, the responder rate was higher in all treatment arms; in certain groups, the responder rate was 2 to 2.5x that of placebo. Treatment effects were greater in patients with higher starting SBPs.

**Targets Unmet Medical Need**

Drug has potential to address patient populations with conditions not sufficiently treated with existing therapies.

Alagebrium targets underlying disease, not just symptoms. No optimal therapy currently exists for systolic hypertension or diastolic dysfunction in heart failure.

**Consistent Data**

Data is consistent across species, across human studies and mechanistically.

Alagebrium has shown consistency across preclinical and clinical studies conducted to date.

**Alagebrium Chloride, ALT-711’s USAN Generic Name**

In March 2004, we received notification from the United States Adopted Names (USAN) Council that the generic name *alagebrium chloride* was approved for our drug candidate, formerly known as ALT-711. We will be using the name alagebrium in all future communications.

**Alagebrium, Alteon’s Lead A.G.E. Crosslink Breaker**

Alagebrium works in part by “cleaving” the glucose/protein bonds, known as A.G.E. crosslinks, which accumulate in our body as part of the normal aging process and at an accelerated rate in diabetes. A.G.E.s are responsible for the progressive loss of flexibility and function of body tissues, vessels and organs. Alagebrium is the first compound in the A.G.E. Crosslink Breaker class that has been shown to “break” A.G.E. crosslinks, thereby restoring more normal function to organs, tissues and vessels that have lost flexibility. Its mechanism is new and novel, and we believe that it is unrelated to any existing anti-hypertensive agent.



In addition to restoring elasticity of stiffened tissues by breaking pathological crosslinks, there is a growing body of evidence that alagebrium has a beneficial effect on certain cellular responses that are negatively altered by advanced glycation. Data has already been published that show alagebrium's 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 may result from a combination of breaking A.G.E. crosslinks and restoring control of gene function.

**Alagebrium in Uncontrolled Systolic Hypertension:**

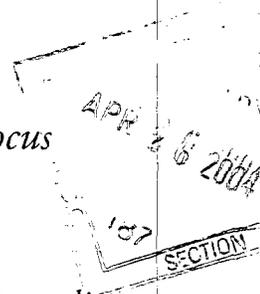
*The Phase 2b SAPPHIRE/SILVER Clinical Trials*

During the year, we announced results from the multi-center Phase 2b SAPPHIRE/SILVER clinical trial of alagebrium in the treatment of patients with uncontrolled systolic hypertension. The SAPPHIRE/SILVER trial evaluated alagebrium's effectiveness in a total of 768 patients having elevated systolic blood pressure (systolic hypertension) without or with enlargement of the left ventricle of the heart. The trials were dose-ranging, double-blind, placebo-controlled and conducted at over 60 sites nationwide. All patients were maintained on background hypertension medication.

Based in large part on a blood pressure drop across all arms and dosing groups including placebo, alagebrium did not demonstrate statistical significance as compared to placebo against the pre-specified primary endpoint of reduction of systolic blood pressure by office cuff pressure measurement at the highest of the four active dose levels, 210 mg per day. However, patients in the SAPPHIRE "intent-to-treat" population demonstrated efficacy net of placebo, in the 2-3 mm Hg range by cuff pressure, at the lower end of the alagebrium dosing range. We noted that in patients who completed their dosing regimen in the SAPPHIRE study, this effect at lower doses was amplified and strengthened to about 4 mm Hg net of placebo by ambulatory blood pressure measurements (ABPM). Importantly, the ABPM measurements were not affected by a placebo drop.

Subsequent in-depth analyses of the ABPM data further supported the meaningful activity of alagebrium. We found that treatment with alagebrium resulted in a significant lowering of systolic blood pressures in patients with a baseline systolic ABPM of 140 mm Hg or greater, with little concurrent effect on diastolic blood pressure readings. Trends were similar for both three and six months. The treatment effects were greatest in patients with higher starting systolic blood pressure readings. Furthermore, alagebrium's effect was persistent in the presence of increasing numbers of background medicines, rather than reduced, as is generally seen with current incremental therapies.

*"[We] need to focus more on the management of systolic rather than diastolic hypertension..."*



*Control of Hypertension  
An Important National Priority  
The New England Journal of Medicine,  
August 2001.*

*“...heart failure with preserved ejection fraction [diastolic dysfunction] confers a considerable burden on patients, with the risk of readmission, disability, and symptoms subsequent to hospital discharge, comparable to that of heart failure patients with depressed ejection fraction.”*

*Outcomes in Heart Failure Patients  
With Preserved Ejection Fraction  
Journal of the American College  
of Cardiology, May 2003.*

These data further support the hypothesis that alagebrium works best in patients with more serious baseline hypertension via a mechanism of action unlike any currently marketed high blood pressure drug. The data from SAPPHIRE/SILVER have helped us identify the patients who might best benefit from treatment with alagebrium, and have helped us design the protocol for our new Phase 2b trial in systolic hypertension SPECTRA.

*SPECTRA: The Next Phase 2b Trial of Alagebrium in Uncontrolled Systolic Hypertension*

Recently, we announced the initiation of a new Phase 2b clinical trial of alagebrium chloride in patients with systolic hypertension. SPECTRA (Systolic Pressure Efficacy and Safety Trial of Alagebrium) is designed to evaluate alagebrium's ability to lower systolic blood pressure in patients with elevated systolic blood pressures. In SPECTRA alagebrium will be tested in approximately 390 patients at over 50 clinical sites throughout the United States. The trial will include male and female patients at least 45 years of age. Recruited patients will undergo a wash-out period, during which they are weaned from their existing anti-hypertensive treatment, followed by a run-in phase during which they will receive a diuretic. They will then receive alagebrium tablets or placebo once a day for 12 weeks.

SPECTRA further extends the range of effective dosing defined in previous Phase 2 testing. The study consists of four treatment arms, comprising three different dose levels of alagebrium (10, 50 or 150 mg) or placebo. Patients enrolled in the trial must have a systolic blood pressure of greater or equal to 140 mm Hg as measured by ABPM, as well as additional qualifications. Automated office blood pressures (oscillometric) as well as ABPM pressures will be taken at scheduled time points. Change from baseline in mean 24-hour systolic ABPM pressure after 12 weeks of dosing (as compared to placebo) will be evaluated as the primary measure of efficacy. Secondary endpoints will include changes in diastolic, pulse and arterial pressures.

**Alagebrium in Heart Failure:**

*The Phase 2a DIAMOND Trial*

Early in 2003, we announced positive findings from the Phase 2a DIAMOND (Distensibility Improvement and Remodeling in Diastolic Heart Failure) trial in patients with diastolic heart failure (DHF). DHF is characterized by the inability of the heart to fill properly due to the stiffening of the heart tissue and impaired relaxation of the left ventricle. The DIAMOND study was 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 DHF.



In the DIAMOND trial, the 21 patients who completed the 16 weeks of alagebrium therapy experienced a statistically significant reduction in left ventricular (LV) mass; to the best of our knowledge, this kind of reduction is unprecedented in such a short treatment timeframe. Furthermore, 15 of 21 patients showed an improvement in their heart failure classification during the course of the study. DIAMOND patients also had a marked improvement in LV diastolic filling, and a statistically significant effect on three key quality-of-life measurements, as determined by the Minnesota Living With Heart Failure Questionnaire, a well-established heart failure/quality-of-life questionnaire.

These results were reported at the 9<sup>th</sup> Annual Scientific Sessions of the Society of Geriatric Cardiology in March 2003 and again at the European Society of Cardiology (ESC) Congress 2003 meeting in September. We were pleased by the enthusiasm generated by this pilot study and the presentation of the data at these scientific meetings.

The DIAMOND results suggest that alagebrium can have a direct effect on the remodeling of the enlarged heart, and that the drug warrants further investigation as a potential treatment for diastolic dysfunction, a disorder for which no optimal therapy currently exists. We have an approved protocol for our next trial, which will be in heart failure patients with diastolic dysfunction.

*Phase 2 Trial of Alagebrium in Endothelial Function*

In February 2004, we announced that a Phase 2 clinical trial of alagebrium in endothelial function was initiated at Johns Hopkins University School of Medicine. This Phase 2 study is an additional component to Alteon's ongoing Phase 2 programs in systolic hypertension and heart failure and is being funded under grants from the National Heart, Lung and Blood Institute and the Society of Geriatric Cardiology.

The Hopkins endothelial function study will enroll approximately 25 patients, 50 years of age or greater, who have systolic hypertension. The primary purpose of the trial is to determine whether increasing arterial elasticity by breaking A.G.E. crosslinks improves endothelial function as assessed by evaluating vessel relaxation and biomarkers of endothelial function. The study will help us further define the beneficial effects of alagebrium on the entire cardiovascular system, and will give us additional insights into the drug's mechanism of action.

*“These findings...lend support to a potential role of increased vascular stiffness in the pathogenesis of diastolic heart failure.”*

*Pathophysiological Characterization of Isolated Diastolic Heart Failure in Comparison to Systolic Heart Failure*  
**The Journal of the American Medical Association, November 2002.**

*“Realizing our goal of seeing alagebrium through development to approval takes diligence and commitment, and I believe we have a team that can make this happen.”*

### **Building a Company and a Culture**

During January 2004, Alteon completed the move into its new corporate headquarters in Parsippany, New Jersey. The key reason for this move was to facilitate our recruitment activities and attract the highest caliber personnel. I am truly pleased by the progress that we have made in bringing talented professionals to our organization at this critical time. Even more importantly, we have built a strong and positive culture, operating with clear standards of teamwork and performance. As we further expand the infrastructure of Alteon, this group will be the core of our success.

### **Finance**

In October 2003, we entered into an agreement to raise up to \$10.7 million in the sale of common stock, structured as two tranches. In the first closing in October, net proceeds were approximately \$7.8 million. We began 2004 with approximately \$16.7 million in cash, enabling us to begin our aggressive Phase 2 programs.

### **Looking Forward**

We are at a pivotal juncture in Alteon’s corporate life, and I would like to thank the entire Alteon team for its efforts and enthusiasm, especially as we progress with our important clinical initiatives. Realizing our goal of seeing alagebrium through development to approval takes diligence and commitment, and I believe we have a team that can make this happen. I also thank you, our shareholders, for your continued support.



Kenneth I. Moch  
*Chairman of the Board*  
*President and Chief Executive Officer*

April 10, 2004

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
 WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2003, or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-16043

**ALTEON INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
 (State or other jurisdiction of  
 incorporation or organization)

**13-3304550**  
 (I.R.S. Employer Identification No.)

**6 Campus Drive, Parsippany, New Jersey 07054**

(Address of principal executive offices)  
 (Zip Code)

**(201) 934-5000**

(Registrant's telephone number, including area code)

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class  
 Common Stock, Par Value \$.01 per share

Name of Each Exchange  
On Which Registered  
 American Stock Exchange

Securities Registered Pursuant to Section 12(g) of the Act:

**None**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined by Rule 12b-2 of the Act). Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the American Stock Exchange closing price of the common stock (\$4.85 per share), as of June 30, 2003, was \$173,745,192.

At March 5, 2004, 40,472,898 shares of the registrant's common stock, par value \$.01 per share, were outstanding.

## PART I

### Item 1. Business.

#### Overview

We are a product-based biopharmaceutical company engaged in the discovery and development of small molecule drugs to reverse or slow down diseases of aging and complications of diabetes. Our product candidates represent novel approaches to some of the largest pharmaceutical markets. Our lead compound is in clinical development; several others are in earlier development stages. These pharmaceutical candidates were developed as a result of our research on the Advanced Glycation End-Product ("A.G.E.") pathway, a fundamental pathological process and inevitable consequence of aging that causes or contributes to many medical disorders, including cardiovascular, kidney and eye diseases.

A.G.E.s are glucose/protein complexes that form as a result of circulating blood glucose reacting with proteins. These A.G.E. complexes subsequently interact and bond (crosslink) with other proteins, resulting in "hardened" (stiffened) arteries, toughened tissues and impaired flexibility and function of many body organs. In healthy individuals, this pathological A.G.E.-formation process occurs slowly as the body ages. In diabetic patients, the rate of A.G.E. accumulation and the extent of protein crosslinking are accelerated because of high glucose levels.

Our research and drug development activities targeting the A.G.E. pathway have taken three directions: the breaking of A.G.E. crosslinks between proteins in order to reverse damage ("A.G.E. Crosslink Breakers"); the prevention or inhibition of A.G.E. formation ("A.G.E.-Formation Inhibitors") and the reduction of the A.G.E. burden through a novel class of anti-hyperglycemic agents, Glucose Lowering Agents ("GLA"). We believe that we were the first company to focus on the development of compounds to treat diseases caused by A.G.E. formation and crosslinking. Since our inception, we have created an extensive library of novel compounds targeting the A.G.E. pathway, and have actively pursued patent protection for these discoveries.

The primary focus of our research and development activities is alagebrium chloride (formerly ALT-711), which is our lead product candidate and we believe the only A.G.E. Crosslink Breaker in advanced clinical development. In February, the United States Adopted Name (USAN) Council approved alagebrium chloride as the generic name of the chemical compound formerly known as ALT-711. Alagebrium offers the possibility of the first therapeutic approach to "breaking" A.G.E. crosslinks, the benefit of which may be to reverse tissue damage caused by aging and diabetes, thereby restoring flexibility and function to tissues, blood vessels and organs of the body. Alagebrium has demonstrated safety and efficacy in three Phase 2 trials and several Phase 1 studies in which over 800 patients received alagebrium. We are actively developing the compound for the treatment of cardiovascular diseases including systolic hypertension and heart failure. In July 2003, we announced initial results from the Phase 2b SAPPHIRE (**S**ystolic **A**nd **P**ulse **P**ressure **H**emodynamic **I**mprovement by **R**estoring **E**lasticity) and SILVER (**S**ystolic Hypertension Interaction with **L**eft **V**entricular **R**emodeling) trial that focused on patients with systolic hypertension. Alagebrium was safe and well tolerated at all doses tested. Results from this 768 patient, six-month, placebo-controlled, dose-ranging study showed that although the pre-specified primary endpoint of reduction of systolic blood pressure by office cuff pressure measurement did not demonstrate statistical significance as compared to placebo, pre-specified secondary analysis of ambulatory blood pressure measurements ("ABPM") in all patients who completed the study demonstrated a blood pressure lowering effect at lower doses of approximately 4 mm Hg net of placebo. In February 2004, we announced the partial results of a *post hoc* analysis which showed that alagebrium treatment resulted in significant lowering of systolic blood pressures in patients with a baseline systolic ABPM of  $\geq 140$  mm Hg, with little concurrent effect on diastolic blood pressure readings. The treatment effects were greatest in patients with higher starting systolic blood pressure readings.

The DIAMOND (**D**istensibility **I**mprovement **a**nd **R**emodeling in **D**iaastolic Heart Failure) open-label, single dose trial of alagebrium was conducted in 23 patients with diastolic heart failure ("DHF"). Treatment with alagebrium over 16 weeks demonstrated a statistically significant reduction in left ventricular mass and a marked improvement in left ventricular diastolic filling. The trial also showed statistically significant improvements in multiple quality of life measurements. Pre-specified primary endpoint data was not evaluable. Patients with Class III heart failure at baseline, the sickest patients in the study, appeared to benefit the most from alagebrium treatment. Side effects were as expected for a similar patient population of this size and severity. In 2001, we conducted a Phase 2a clinical trial, in which 93 patients received alagebrium or placebo tablets once daily for eight weeks. Study results showed that alagebrium patients experienced a statistically significant and clinically meaningful reduction in pulse pressure ( $p < 0.02$ ), defined as the difference between systolic and diastolic blood pressures. Results also showed a statistically significant increase in large artery compliance ( $p < 0.03$ ), an indicator of greater vascular flexibility and volume capacity. Additionally, the drug was well tolerated. This Phase 2a data was published as "breakthrough information" in the September 26, 2001 issue of the peer-reviewed journal, *Circulation: Journal of the American Heart Association*.

In March 2004, we initiated SPECTRA (**S**ystolic **P**ressure **E**fficacy and Safety **T**rial of **A**lagebrium), a Phase 2b trial in patients with systolic hypertension. An additional Phase 2 trial in diastolic dysfunction in heart failure is expected to be initiated in the first half of 2004.

We continue to evaluate potential pre-clinical studies and clinical trials in other cardiovascular and therapeutic indications where A.G.E. Crosslink Breaker compounds may address significant unmet needs. In addition, we plan to continue to explore the use of topical A.G.E. Crosslink Breakers in skin and photoaging, following our recent evaluation of ALT-744. We intend to identify other crosslink breaker compounds in our research and development portfolio with more attractive characteristics than those of ALT-744 to further explore the pharmaceutical applications of our compounds for skin and photoaging.

We were incorporated in Delaware in October 1986 under the name Geritech Inc. Our name was changed to Alteon Inc. in August 1991. We recently moved our headquarters to 6 Campus Drive, Parsippany, New Jersey 07054. Our web address is [www.alteon.com](http://www.alteon.com), and our telephone number is (201) 934-5000. We make available free of charge through our internet website our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with the United States Securities and Exchange Commission ("SEC").



## Our Business Strategy

Our strategy is to develop drug candidates from our proprietary portfolio of new chemical entities. Because of their novel mechanism of action, these compounds address large medical needs that are unmet by existing therapies. We will seek, as appropriate, to selectively out-license or co-develop our drug candidates with corporate partners. As we continue clinical development of alagebrium, we may elect to retain development and marketing rights for one or several indications in North America, while at the same time continuing to evaluate potential corporate partnerships for the further development and ultimate marketing of the compound. In addition to alagebrium, we have identified compounds in multiple chemical classes that may warrant further evaluation and potential development.

## Markets of Opportunity

Our research and development efforts have led us to an initial focus on cardiovascular diseases, including hypertension and heart failure, as well as complications of diabetes. Targeting the A.G.E. pathway may have an impact on a number of medical disorders related to aging and diabetes and the progressive stiffening of tissues, vessels and organs, thus potentially broadening our markets of opportunity. Importantly, there are no currently marketed cardiovascular drugs that work directly on the stiffening of the vasculature that leads to systolic hypertension and heart failure. Angiotensin converting enzyme (ACE) inhibitors and aldosterone antagonists indirectly affect these pathways.

The pre-clinical and clinical data generated to date on our A.G.E. Crosslink Breakers and A.G.E.-Formation Inhibitors demonstrate clear and consistent findings across several species, including rats, dogs, non-human primates and man.

### Cardiovascular Disease

According to the American Heart Association, more than 64 million Americans have one or more types of cardiovascular disease, with 50 million Americans estimated to have high blood pressure. Cardiovascular disease has been the number one killer of Americans since the early 1900's. The latest World Health Organization – International Society of Hypertension guidelines for the management of hypertension emphasize the importance of pulse pressure (the difference between systolic and diastolic pressures) and arterial stiffness as predictors of overall cardiovascular risk. Currently available antihypertensive agents commonly reduce pressure on the vessel wall in such a manner as to lower both systolic and diastolic blood pressures and may not significantly affect pulse pressure. Pharmacologic intervention targeting the stiffness of the cardiovascular system may decrease the incidence and severity of complications such as left ventricular hypertrophy (“LVH”), a thickening and stiffening of the heart tissue, and congestive heart failure. Published studies have shown that a 10 mm Hg reduction in pulse pressure correlates with approximately a 35% reduction in cardiovascular mortality.

#### Systolic Hypertension

Systolic hypertension, defined as elevated systolic blood pressure greater than 140 mm Hg, is the most common form of hypertension in those over the age of 50, with an estimated prevalence of nearly 25 million Americans. It is associated with a significantly increased risk of overall mortality, cardiovascular mortality and congestive heart failure. According to the American Heart Association, it is the type of hypertension least likely to be well treated. The potential ability of alagebrium to decrease pulse pressure and increase large artery compliance offers an opportunity to provide a treatment option specifically for systolic hypertension. See “—A.G.E. Crosslink Breakers – Alagebrium.” Although currently marketed antihypertensive agents are being used to treat the disease, it is not adequately treated by these therapies. We believe that alagebrium is the first drug to show direct activity by targeting the stiff vessels that are associated with systolic hypertension. We believe that alagebrium will provide additional benefit because it exerts its activity by a mechanism unique from currently marketed anti-hypertension drugs, and it appears to be well tolerated in patients with hypertension.

#### Diastolic Dysfunction in Heart Failure

Diastolic dysfunction is the impaired ability of the heart to relax and fill properly after a contraction, in part due to the stiffening of the myocardial tissue. When the ventricles (the heart's lower pumping chambers) do not relax and fill normally, increased pressure and fluid in the blood vessels of the lungs may be a result (pulmonary congestion), resulting in shortness of breath. Diastolic dysfunction can also cause increased pressure and fluid in the blood vessels returning to the heart (systemic congestion). Diastolic dysfunction is common to both systolic and diastolic heart failure in a group that collectively numbers about five million in the United States alone. DHF, which is estimated to account for 30-50% of all heart failure cases, is an especially poorly treated medical condition. Alagebrium offers promise as a novel therapy for cardiovascular diseases related to diastolic dysfunction because currently available therapies do not specifically target the stiffening heart and vessel walls.

#### Left Ventricular Hypertrophy

LVH refers to the thickening of the left ventricle that can occur progressively with hypertension. It can lead to decreased cardiac output, the inability to meet the circulatory needs of the body and to heart failure itself. It is a condition associated with many cardiovascular diseases, including systolic hypertension and DHF. In the DIAMOND trial, a statistically significant reduction of left ventricular mass was noted in DHF patients treated with alagebrium. Additionally, in several pre-clinical studies, alagebrium has been shown to reduce the thickening of the left ventricle and induce reverse remodeling of the heart.

### Complications of Diabetes

The Diabetes Control and Complications Trial, a multi-center clinical trial conducted by the National Institutes of Health, demonstrated that elevated blood glucose levels significantly increase the rate of progression of eye, kidney, blood vessel and nerve complications from diabetes. More than 50% of people with diabetes in the United States develop diabetic complications that range from mild to severe.

#### Overt Nephropathy and ESRD

Kidney disease is a significant cause of morbidity and mortality in patients with Type 1 and Type 2 diabetes. It is a chronic and progressive disease that affects approximately one third of patients with Type 1 diabetes. Approximately 10-15% of patients with Type 2 diabetes develop nephropathy. One of the early signs of kidney damage is microalbuminuria (characterized by leakage of small amounts of protein into the urine), which progresses to overt nephropathy (characterized by leakage of large amounts of protein into the urine) and ultimately to End-Stage Renal Disease (“ESRD”).

In addition, we have conducted a Phase 1 safety study of alagebrium in the critically ill ESRD patient population undergoing peritoneal dialysis, and are evaluating the next steps as part of this Phase 1 program.

In the Phase 2/3 ACTION (A Clinical Trial In Overt Nephropathy) trial in Type 1 diabetic patients with overt nephropathy, therapy with our first A.G.E.-Formation Inhibitor, pimagedine, showed a statistically significant reduction in 24-hour total urinary protein excretion ( $<0.001$ ), although it did not reach statistical significance in its primary endpoint, the time to doubling of serum creatinine. In addition, glomerular filtration rate decreased more slowly in pimagedine patients ( $p=0.04$  to  $0.03$ ), and fewer patients experienced a progression in retinopathy. See “—Retinopathy.” Though pimagedine is no longer in active clinical development, the ACTION trial provided the first clinical proof-of-concept that inhibiting A.G.E. formation can result in clinically important attenuation of the serious complications of diabetes mellitus Type 1. ALT-946, another A.G.E.-Formation Inhibitor, has demonstrated the ability to slow the progression of overt nephropathy in a pre-clinical study.

#### **Cardiovascular Complications**

A significant portion of diabetic individuals develops cardiovascular diseases and complications due to the high levels of blood glucose and A.G.E.s within the body. According to the American Diabetes Association, heart disease is the leading cause of diabetes-related deaths. Heart disease death rates are two to four times higher in adults with diabetes than adults without diabetes. The risk of stroke is also two to four times higher in those with diabetes.

#### **Retinopathy**

Approximately nine out of 10 people with diabetes eventually develop retinopathy, a complication that affects the blood vessels inside the eye and can lead to blindness. Each year, approximately 12,000 to 24,000 people lose their sight because of diabetes. The incidence and severity of retinopathy increases with the duration of diabetes. Pre-clinical evidence suggests that alagebrium and other compounds from the A.G.E. Crosslink Breaker class may have a positive impact on retinopathy. In a secondary endpoint in the Phase 2/3 ACTION trial, pimagedine therapy did result in a statistically significant reduction in the progression of retinopathy. Fewer pimagedine patients ( $p=0.03$ ) experienced a three-step or greater progression of retinopathy (Early Treatment of Diabetic Retinopathy Study).

#### **Skin Aging**

We plan to continue to explore the use of topical A.G.E. Crosslink Breakers in skin and photoaging, following our recent evaluation of ALT-744. We intend to identify other compounds in our research and development portfolio with more attractive characteristics than those of ALT-744 to further explore the pharmaceutical applications for our compounds in skin and photoaging.

#### **Other Diseases**

A.G.E.s have been shown to cause or contribute to many disorders beyond cardiovascular diseases and complications of diabetes, such as arthritis/inflammation, ophthalmic diseases, respiratory diseases, stroke and urological diseases, among others. We continue to evaluate potential indications for our compounds.

#### **Our Technology: The A.G.E. Pathway in Aging and Diabetes**

The harmful consequences of A.G.E. formation in man was proposed in the 1980's by our scientific founders as an outgrowth of a research effort focused on diabetes. The foundation for our technology is the experimental evidence that intervention along the A.G.E. pathway provides significant benefit in slowing or reversing the development of serious diseases in the diabetic and aging populations. We are the pioneers in A.G.E. technology, and we have built an extensive patent estate covering our discoveries and compounds.

A.G.E.s are permanent structures that form when simple sugars such as glucose bind to the surface of proteins. As the body ages, A.G.E. complexes form on proteins continuously and naturally, though slowly throughout life, at a rate dependent upon glucose levels and on the body's natural ability to clear these pathological structures. A.G.E. complexes subsequently crosslink to other proteins, causing a progressive loss of flexibility and function in various tissues, blood vessels and organs.

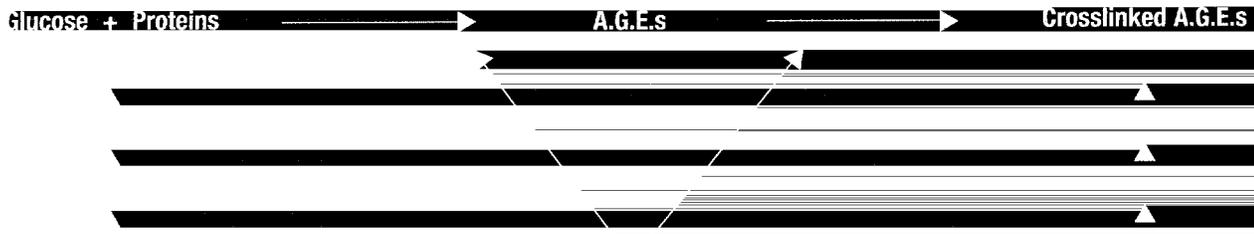
The formation and crosslinking of A.G.E.s is a well-known process in food chemistry, where it is called the Maillard Reaction. The browning and toughening of food during the cooking process occurs, in part, as a result of the formation of A.G.E. complexes between sugars and the amino acids of proteins. The A.G.E. crosslink has been found to be unique in biology and is prevalent in animal models of aging and diabetes. Scientific literature suggests that the formation and subsequent crosslinking of A.G.E.s is an inevitable part of the aging process and diabetes that leads to a loss of flexibility and function in body tissues, organs and vessels.

The A.G.E. pathway may provide the scientific explanation for how and why many of the medical complications of the aging process occur with higher frequency and earlier in life in diabetic patients. Diabetic individuals form excessive amounts of A.G.E.s earlier in life than do non-diabetic individuals, due primarily to higher levels of blood sugar. For this reason, diabetes may be viewed as an accelerated form of aging.

A.G.E.s and A.G.E. crosslinks are considered to be likely causative factors in the development of many age-related and diabetic disorders, including those associated with the cardiovascular and renal systems. For example, proteins in the body, such as collagen and elastin, which play an important role in maintaining the elasticity of the cardiovascular system, are prime targets for A.G.E. crosslinking. This stiffening process can impair the normal function of contractile organs, such as blood vessels, which depend on flexibility for normal function. A loss of flexibility of the vasculature is associated with a number of cardiovascular disorders, including systolic hypertension, diastolic dysfunction and LVH, and ultimately may lead to heart failure.

Studies conducted in animal models of diabetes and aging at numerous independent institutions worldwide demonstrate that A.G.E.s are a major factor contributing to many of the disorders of aging and diabetes, including cardiovascular, kidney and eye diseases, as well as atherosclerosis. Recent human clinical studies we performed confirm that targeting the A.G.E. pathway can have beneficial effects on these diseases.

The following chart illustrates the process of A.G.E. formation and crosslinking and is qualified by the more detailed description in the text. It also highlights those areas within the A.G.E. pathway where we are developing pharmaceutical agents to intervene therapeutically.



Glucose Lowering Agents	A.G.E. Formation and Crosslink Inhibitors	A.G.E. Crosslink Breakers
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Chemical Class	> 9 Chemical Classes	> 17 Chemical Classes
Compounds	(852 Compounds)	(675 Compounds)

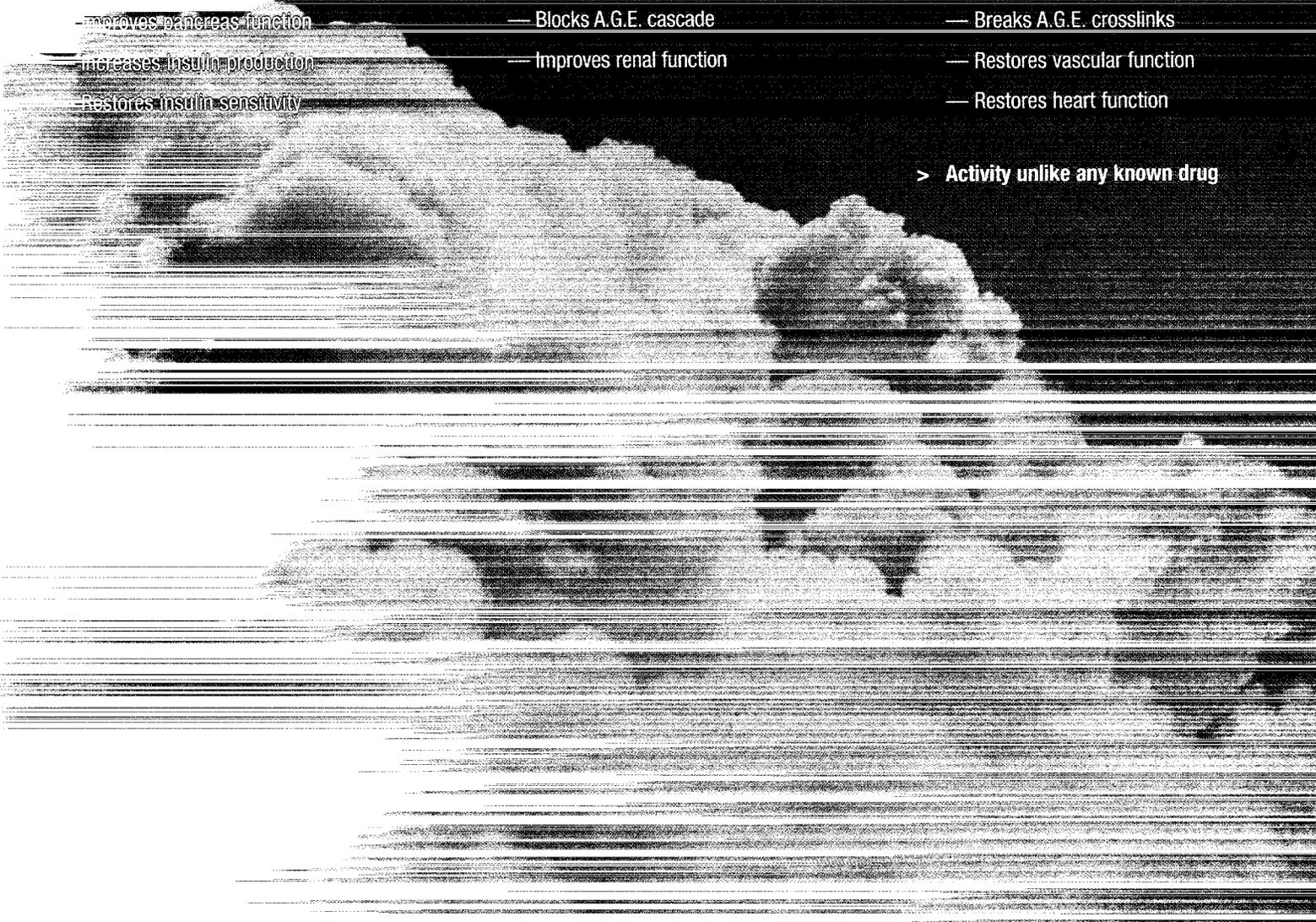
Mechanism	> Mechanism	> Mechanism
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- Improves pancreas function
- Increases insulin production
- Restores insulin sensitivity

- Blocks A.G.E. cascade
- Improves renal function

- Breaks A.G.E. crosslinks
- Restores vascular function
- Restores heart function

> Activity unlike any known drug



We incurred research and development expenditures of approximately \$9,930,000, \$14,992,000 and \$8,461,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

### **A.G.E. Crosslink Breakers**

By "breaking" A.G.E. crosslinks, these novel classes of compounds may have an impact on a number of medical disorders where loss of flexibility or elasticity leads to a loss in function. Our lead clinical candidate, alagebrium, has demonstrated the ability to reverse tissue damage and restore function to the cardiovascular system in Phase 2 clinical trials in cardiovascular compliance and diastolic heart failure.

Additionally, we are evaluating the development of several compounds in the breaker class for other indications where A.G.E. crosslinking leads to abnormal function. The scientific literature also points to the possible utility of breaker compounds in ophthalmic and dermatological conditions, stiff joint disorders and treatment of complications in patients undergoing peritoneal dialysis.

We have identified 17 potential chemical classes of A.G.E. Crosslink Breakers, and have a library of more than 650 compounds.

#### **Alagebrium**

Through its unique mechanism of action, alagebrium is the first compound that breaks A.G.E. crosslinks between proteins, both *in vitro* and *in vivo*. Alagebrium is a small, easily synthesized compound with a rapid mode of action. It is well absorbed from an oral tablet formulation. The compound is under Phase 2 clinical evaluation in cardiovascular diseases and is being evaluated in various pre-clinical models to assess its potential in a number of other disease states.

In July 2003, we announced the initial results of the SAPPHIRE and SILVER trial, a 768 patient, six-month, placebo-controlled, dose-ranging study. The pre-specified primary endpoint of reduction of systolic blood pressure by office cuff pressure measurement at the highest of the four active dose levels, 210 mg per day, did not demonstrate statistical significance as compared to placebo. The data analysis was confounded by a 6-10 mm Hg drop in systolic blood pressures in all arms of the SAPPHIRE and SILVER trial, including placebo, during the first two weeks after patient randomization. However, patients in the SAPPHIRE "intent-to-treat" population demonstrated efficacy, net of placebo, in the 2-3 mm Hg range by cuff pressure at the lower end of the alagebrium dosing range. As reported at that time, a pre-specified secondary analysis of ABPM measurements in all patients who completed the study demonstrated a blood pressure lowering effect of approximately 4 mm Hg net of placebo at lower doses. There was no significant placebo effect noted in the ABPM measurements.

In February 2004, we announced the partial results of a *post hoc* analysis which showed that alagebrium treatment resulted in significant lowering of systolic blood pressures in patients with a baseline systolic ABPM of  $\geq 140$  mm Hg, with little concurrent effect on diastolic blood pressure readings. Trends were similar for both three and six months. The treatment effects were greatest in patients with higher starting systolic blood pressure readings, with no statistically meaningful effect in patients with a systolic blood pressure below 140 mm Hg. In patients with starting blood pressures of  $\geq 140$  mm Hg on multiple medications, systolic blood pressure was reduced by an average of 6 mm Hg ( $p \leq 0.01$ ). In patients who were on two or more medications with starting systolic blood pressures of  $\geq 150$  mm Hg, a difficult to treat group of patients, clinically significant systolic pressure reductions were maintained. Furthermore, alagebrium's effect was persistent in the presence of increasing numbers of background medicines, rather than reduced as is generally seen with current incremental therapies. These findings further support the hypothesis that alagebrium works best in patients with more serious baseline hypertension via a mechanism of action unlike any currently marketed high blood pressure drug.

In January 2003, we announced positive results from an analysis of the first 17 patients in the Phase 2a DIAMOND clinical trial evaluating alagebrium in DHF patients. The trial was 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 DHF. In the DIAMOND trial, 23 patients received 210 mg of alagebrium twice daily on an open-label outpatient basis for 16 weeks in addition to their current medications. Primary endpoints included changes in exercise tolerance and aortic stiffness; effects on LVH, diastolic filling and quality of life were also assessed. Patients who received alagebrium for 16 weeks experienced a statistically significant reduction in left ventricular mass, as well as a marked improvement in left ventricular diastolic filling. Additionally, the drug was well tolerated and had a positive effect on patients' quality of life. Measurements of exercise tolerance and aortic distensibility proved to be more variable than anticipated for a study of this size and were not reportable.

In January 2001, we announced successful results from a Phase 2a clinical trial of alagebrium evaluating the effects of the compound on the cardiovascular system. This trial, conducted at nine United States clinical sites, was a double-blind, placebo-controlled study evaluating the safety, efficacy and pharmacology of alagebrium. The trial enrolled 93 patients over the age of 50 with measurably stiffened large vessels, including systolic blood pressure of at least 140 mm Hg and pulse pressure of at least 60 mm Hg. Patients were randomized to receive oral doses of either 210 mg of alagebrium or placebo once daily for eight weeks. Patients were evaluated for cardiovascular elasticity and function as measured by pulse pressure, cardiovascular compliance, pulse wave velocity, a measure of vascular stiffness and cardiac output. Under this protocol, alagebrium treatment was in addition to the best available therapeutic regimen chosen by the treating physicians. Study results showed that patients who received alagebrium experienced a statistically significant ( $p < 0.02$ ) and clinically meaningful reduction in the arterial pulse pressure, defined as the difference between systolic and diastolic blood pressure. Results also showed a statistically significant increase in large artery compliance ( $p < 0.03$ ), 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. This Phase 2a data was presented at the Special Sessions Presentation of "Late Breaking Clinical Trials" at the American College of Cardiology Annual Scientific Session in March 2001, and published as "breakthrough information" in the September 26, 2001 issue of the peer-reviewed journal, *Circulation: Journal of the American Heart Association*.



In March 2004, we initiated SPECTRA, a Phase 2b clinical trial in patients with systolic hypertension. SPECTRA is designed to evaluate alagebrium's ability to lower systolic blood pressure in patients with a systolic blood pressure reading of  $\geq 140$  mm Hg, building upon positive data from previous Phase 2 trials. Alagebrium's activity in prior clinical trials demonstrated the drug's safety and ability to lower systolic blood pressure and pulse pressure in aging and diabetic patients, especially in the difficult-to-treat hypertensive patient population.

In SPECTRA, alagebrium will be tested in approximately 390 patients at over 50 clinical sites throughout the United States. The trial will include male and female patients of at least 45 years of age. Recruited patients will undergo a wash-out period, when they are weaned from their existing antihypertensive treatment, followed by a run-in phase during which they will be stabilized on a diuretic. They will then receive alagebrium tablets or placebo once a day for 12 weeks.

SPECTRA is designed to further extend the range of effective dosing defined in previous Phase 2 testing. The study will consist of four treatment arms, comprising three different dose levels of alagebrium (10, 50 or 150 mg) or placebo. Patients enrolled in the trial must have systolic blood pressure of  $\geq 140$  mm Hg as measured by ABPM, as well as additional qualifications. Automated office blood pressures (oscillometric), as well as ABPM pressures, will be taken at scheduled time points. Change from baseline in mean 24-hour systolic ABPM pressure after 12 weeks of dosing (as compared to placebo) will be evaluated as the primary measure of efficacy. Secondary endpoints will include changes in diastolic, pulse and arterial pressures.

An additional Phase 2 trial in diastolic dysfunction in heart failure is expected to be initiated in the first half of 2004.

We have also completed a Phase 1 trial assessing the safety of alagebrium and the way the drug is metabolized in ESRD patients undergoing peritoneal dialysis. This patient population has a limited five-year survival (less than 30%) and significant cardiovascular complications, which are the primary cause of death. We are evaluating next steps as part of this Phase 1 program.

Alagebrium data is consistent across species. Studies in animal models in several laboratories around the world have demonstrated rapid reversal of impaired cardiovascular functions with alagebrium. In these pre-clinical models, alagebrium reverses the stiffening of arteries, as well as the stiffening of the heart, that accompanies the development of aging and diabetes. Pre-clinical studies of alagebrium 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 Rhesus monkeys. In a pre-clinical study of alagebrium in aged dogs, administration of alagebrium for one month resulted in an approximate 40% decrease in age-related ventricular stiffness, or hardening of the heart, with an overall improvement in cardiac function. Reductions in blood pressure that have been observed in animal models of diabetic hypertension suggest that alagebrium may prove beneficial in the treatment of systolic hypertension in the elderly or in the diabetic. Additionally, in several pre-clinical studies, alagebrium has been shown to normalize the thickening of the left ventricle and to reduce remodeling of the heart.

In addition to several Phase 2 human trials, a series of Phase 1 safety and dose escalation studies were conducted. These trials have shown the drug to be safe and well tolerated.

#### **A.G.E.-Formation Inhibitors**

A.G.E.-Formation Inhibitors are designed to prevent glucose/protein formation and crosslinking. This class of compounds may have broad applications in slowing down the key complications of diabetes.

We have identified nine distinct chemical classes of A.G.E.-Formation Inhibitors, encompassing a library in excess of 850 compounds.

#### ***Pimagedine***

Pimagedine was the lead compound in the A.G.E.-Formation Inhibitor class, but is not in active clinical development.

In November 1998, we announced results of an analysis of data from the ACTION 1 trial of pimagedine in diabetic patients with overt nephropathy. Although the results showed that pimagedine reduced the risk of doubling of serum creatinine, the study's primary endpoint, the data did not reach statistical significance. However, pimagedine therapy did result in a statistically significant and clinically meaningful reduction of urinary protein excretion. Pimagedine also reduced, to a statistically significant extent, cholesterol and triglycerides, as well as the progression of retinopathy. Additional data suggested a trend toward improvements in other measures of kidney function, including estimated creatinine clearance and glomerular filtration rate. The drug was generally well tolerated. Though pimagedine is no longer in active clinical development because of resource allocation priorities, the ACTION trial served as a proof-of-concept study demonstrating the potential of compounds that target the A.G.E. pathway in the treatment of diabetic kidney disease and a broad range of diabetic complications. The study also suggests that other pharmacologic compounds that target the A.G.E. pathway could have an impact on diabetic conditions. A.G.E. Crosslink Breakers have the potential to reverse damage caused by A.G.E.s and potentially are much faster acting than pimagedine and other A.G.E. Inhibitors.

We are continuing to evaluate the A.G.E. Inhibitors in our patent portfolio in order to identify pre-clinical leads for further development.

#### ***Glucose Lowering Agents***

High glucose levels (hyperglycemia of diabetes) accelerate the rate of A.G.E. formation and crosslinking. Controlling glucose levels has been shown to slow the rate of progression of diabetic complications. The GLA program arose from a search of plant-derived natural products that would exhibit a beneficial profile of glucose and lipid lowering of Type 2 diabetes. Several pre-clinical candidates that display these beneficial properties have been evaluated. They have demonstrated the ability to lower glucose and lipids, restore insulin sensitivity and stimulate increased insulin production.

We have identified one chemical class of GLA, which includes more than 50 compounds.

## Manufacturing

We have no manufacturing facilities for either production of bulk chemicals or the manufacturing of pharmaceutical dosage forms. We rely on third-party contract manufacturers to produce the raw materials and chemicals used as the active drug ingredients in our products used in clinical trials, and we expect to rely on third parties to perform the tasks necessary to process, package and distribute these products in finished form.

We will inspect third-party contract manufacturers and their consultants to confirm compliance with current Good Manufacturing Practice ("cGMP") required for pharmaceutical products. We believe we will obtain sufficient quantities of bulk chemicals at reasonable prices to satisfy anticipated needs. There can be no assurance, however, that we can continue to meet our needs for supply of bulk chemicals or that manufacturing limitations will not delay clinical trials or possible commercialization.

## Marketing and Sales

We retain worldwide marketing rights to our A.G.E. Crosslink Breaker compounds. We believe that alagebrium may address the cardiovascular, diabetes and primary care physician markets. We plan to market and sell our products, if successfully developed and approved, directly or through co-promotion or other licensing arrangements with third parties. Such arrangements may be exclusive or nonexclusive and may provide for marketing rights worldwide or in a specific market.

## Patents, Trade Secrets and Licenses

Proprietary protection for our product candidates, processes and know-how is important to our business. We aggressively file and prosecute patents covering our proprietary technology, and, if warranted, will defend our patents and proprietary technology. As appropriate, we seek patent protection for our proprietary technology and products in the United States and Canada and in key commercial European and Asia/Pacific countries. We also rely upon trade secrets, know-how, continuing technological innovation and licensing opportunities to develop and maintain our competitive position. In addition to our own patent filings, we have licensed or obtained technology and patent portfolios from others relating to the A.G.E.-formation and crosslinking technology currently under development by us.

As of the date of this report, our patent estate of owned and/or licensed patent rights consisted of 85 issued United States patents, none of which expire prior to 2005, and 24 pending patent applications in the United States, the majority of which are A.G.E.-related. We also own or have exclusive rights to 68 issued patents in Europe, Japan, Australia and Canada. These patents and additional patent applications cover compounds, compositions and methods of treatment for several chemical classes of crosslink breaker compounds, including alagebrium.

Effective as of August 5, 2002, we entered into a letter agreement with Yamanouchi Pharmaceutical Co, Ltd. ("Yamanouchi"), which terminated its License Agreement dated as of June 16, 1989. Pursuant to the letter agreement, for a period of fifteen years, we will pay Yamanouchi royalties on any sales of pimagedine or pimagedine products in Japan, South Korea, Taiwan and The People's Republic of China covered by the License Agreement.

In 1987, we acquired an exclusive, royalty-free, worldwide license (including the right to sub-license to others) to Rockefeller University's issued patents, patent applications and trade secrets relating to A.G.E.-formation and crosslinking technology currently under development by us. In addition, we previously exclusively licensed from The Picower Institute for Medical Research ("The Picower Institute") certain patentable inventions and discoveries relating to A.G.E. technology. This license agreement was terminated as of April 15, 2002, when we entered into a Termination Agreement, pursuant to which The Picower Institute assigned to us all of its patents, patent applications and other technology related to A.G.E.s. We agreed to prosecute and maintain the patents and patent applications and will pay to the trustee for The Picower Institute royalties on any sales of products falling within the claims of these patents and patent applications until they expire or are allowed to lapse.

We have entered into an exclusive licensing arrangement with Roche Diagnostics GmbH for our technology for diagnostic applications, and we have also entered into clinical testing and distribution agreements with Gamida for Life ("Gamida"), which grant Gamida the exclusive right to distribute pimagedine, if successfully developed and approved for marketing, in Israel, Bulgaria, Cyprus, Jordan and South Africa.

We believe that our licensed and owned patents provide a substantial proprietary base that will allow us and our collaborative partners to commercialize products in this field. We believe our research and development plans will expand and broaden our rights within our technological and patent base. We are also prepared to in-license additional technology that may be useful in building our proprietary position. There can be no assurance, however, that pending or future applications will issue, that the claims of any patents which do issue will provide any significant protection of our technology or that our directed discovery research will yield compounds and products of therapeutic and commercial value.

Where appropriate, we utilize trade secrets and unpatentable improvements to enhance our technology base and improve our competitive position. We require all employees, scientific consultants and contractors to execute confidentiality agreements as a condition of engagement. There can be no assurance, however, that we can limit unauthorized or wrongful disclosures of unpatented trade secret information.

We believe that our estate of licensed and owned issued patents, if upheld, and pending applications, if granted and upheld, will be a substantial factor in our success. The patent positions of pharmaceutical firms, including ours, are generally uncertain and involve complex legal and factual questions. Consequently, even though we are currently prosecuting such patent applications in the United States and foreign patent offices, we do not know whether any of such applications will result in the issuance of any additional patents or, if any additional patents are issued, whether the claims thereof will provide significant proprietary protection or will be circumvented or invalidated.

Competitors or potential competitors have filed for or have received United States and foreign patents and may obtain additional patents and proprietary rights relating to compounds or processes competitive with those of ours. Accordingly, there can be no assurance that our patent applications will result in patents being issued or that, if issued, the claims of the patents will afford protection against competitors with similar technology; nor can there be any assurance that others will not obtain patents that we would need to license or circumvent. See “—Competition.”

Our success will depend, in part, on our ability to obtain patent protection for our products, preserve our trade secrets and operate without infringing on the proprietary rights of third parties. There can be no assurance that our current patent estate will enable us to prevent infringement by third parties or that competitors will not develop competitive products outside the protection that may be afforded by the claims of such patents. To the extent we rely on trade secrets and unpatented know-how to maintain our competitive technological position, there can be no assurance that others may not develop independently the same or similar technologies. Failure to maintain our current patent estate or to obtain requisite patent and trade secret protection, which may become material or necessary for product development, could delay or preclude us or our licensees or marketing partners from marketing their products and could thereby have a material adverse effect on our business, financial condition and results of operations.

### **Government Regulation**

We and our products are subject to comprehensive regulations by the United States Food and Drug Administration (“FDA”) and by comparable authorities in other countries. These national agencies and other federal, state and local entities regulate, among other things, the pre-clinical and clinical testing, safety, effectiveness, approval, manufacturing, labeling, marketing, export, storage, record keeping, advertising and promotion of our products.

The process required by the FDA before our products may be approved for marketing in the United States generally involves (i) pre-clinical new drug laboratory and animal tests, (ii) submission to the FDA of an investigational new drug application (“IND”), which must become effective before clinical trials may begin, (iii) adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for its intended indication, (iv) submission to the FDA of a new drug application (“NDA”), and (v) FDA review of the NDA in order to determine, among other things, whether the drug is safe and effective for its intended uses. There is no assurance that the FDA review process will result in product approval on a timely basis, if at all.

Pre-clinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies to assess the potential safety and efficacy of the product. Certain pre-clinical tests are subject to FDA regulations regarding current Good Laboratory Practices. The results of the pre-clinical tests are submitted to the FDA as part of an IND and are reviewed by the FDA prior to the commencement of clinical trials or during the conduct of the clinical trials, as appropriate.

Clinical trials are conducted under protocols that detail such matters as the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, each protocol must be reviewed and approved by an institutional review board.

Clinical trials are typically conducted in three sequential phases, which may overlap. During Phase 1, when the drug is initially given to human subjects, the product is tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase 2 involves studies in a limited patient population to (i) evaluate preliminarily the efficacy of the product for specific targeted indications, (ii) determine dosage tolerance and optimal dosage, and (iii) identify possible adverse effects and safety risks. Phase 3 trials are undertaken in order to further evaluate clinical efficacy and to further test for safety within an expanded patient population. The FDA may suspend clinical trials at any point in this process if it concludes that clinical subjects are being exposed to an unacceptable health risk.

We will need FDA approval of our products, including a review of the manufacturing processes and facilities used to produce such products, before such products may be marketed in the United States. The process of obtaining approvals from the FDA can be costly, time-consuming and subject to unanticipated delays. There can be no assurance that the FDA will grant approvals of our proposed products, processes or facilities on a timely basis, if at all. Any delay or failure to obtain such approvals would have a material adverse effect on our business, financial condition and results of operations. Moreover, even if regulatory approval is granted, such approval may include significant limitations on indicated uses for which a product could be marketed.

Among the conditions for NDA approval is the requirement that the prospective manufacturer’s operating procedures conform to cGMP requirements, which must be followed at all times. In complying with those requirements, manufacturers (including a drug sponsor’s third-party contract manufacturers) must continue to expend time, money and effort in the area of production and quality control to ensure compliance. Domestic manufacturing establishments are subject to periodic inspections by the FDA in order to assess, among other things, cGMP compliance. To supply a product for use in the United States, foreign manufacturing establishments must comply with cGMP and are subject to periodic inspection by the FDA or by regulatory authorities in certain of such countries under reciprocal agreements with the FDA.

Both before and after approval is obtained, a product, its manufacturer and the holder of the NDA for the product are subject to comprehensive regulatory oversight. Violations of regulatory requirements at any stage, including the pre-clinical and clinical testing process, the approval process, or thereafter (including after approval) may result in various adverse consequences, including the FDA’s delay in approving or refusal to approve a product, withdrawal of an approved product from the market and/or the imposition of criminal penalties against the manufacturer and/or NDA holder. In addition, later discovery of previously unknown problems may result in restrictions on such product, manufacturer or NDA holder, including withdrawal of the product from the market. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

The FDA has implemented accelerated approval procedures for certain pharmaceutical agents that treat serious or life-threatening diseases and conditions, especially where no satisfactory alternative therapy exists. We cannot predict the ultimate impact, however, of the FDA's accelerated approval of procedures on the timing or likelihood of approval of any of our potential products or those of any competitor. In addition, the approval of a product under the accelerated approval procedures may be subject to various conditions, including the requirement to verify clinical benefit in post-marketing studies, and the authority on the part of the FDA to withdraw approval under streamlined procedures if such studies do not verify clinical benefit.

For marketing outside the United States, we will have to satisfy foreign regulatory requirements governing human clinical trials and marketing approval for drugs and diagnostic products. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. We do not currently have any facilities or personnel outside of the United States.

## Competition

A.G.E.s have been shown to contribute to many of the disorders of aging and diabetes, including cardiovascular, kidney and eye diseases. We are aware of several companies that have research and development activities in the A.G.E. field. Many companies are pursuing research and development of compounds for cardiovascular and kidney diseases and the lowering of glucose levels.

Many of our potential competitors have substantially greater financial, technical and human resources than ours and may be better equipped to develop, manufacture and market products. In addition, many of these companies have extensive experience in pre-clinical testing and human clinical trials. These companies may develop and introduce products and processes competitive with or superior to ours.

Our competition will be determined, in part, by the potential indications for which our compounds are developed and ultimately approved by regulatory authorities. For certain of our potential products, an important factor in competition may be the timing of market introduction of our or our competitors' products. Accordingly, the relative speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market are important competitive factors. We expect that competition among products approved for sale will be based on, among other things, product efficacy, safety, reliability, availability, price and patent position. Our competitive position also depends upon our ability to attract and retain qualified personnel, obtain protection or otherwise develop proprietary products or processes and secure sufficient capital resources.

We are competing in an industry in which technologies can become obsolete over time, thereby reducing or eliminating the market for any pharmaceutical product. For example, competitive drugs based on other therapeutic mechanisms may be efficacious in treating cardiovascular disease or diabetic complications. The development by others of non-A.G.E.-related treatment modalities could render our products non-competitive. Therapeutic approaches being pursued by others include curing cardiovascular disease or diabetic complications via gene therapy or cell transplantation, as well as pharmaceutical intervention with agents such as the aldose reductase inhibitors.

Angiotensin converting enzyme inhibitors, angiotensin receptor blockers, calcium channel blockers,  $\alpha$ -2 agonists,  $\alpha_1$  blocker, aldosterone inhibitors, beta-blockers and diuretics are effective treatments for essential hypertension, a disease characterized by increased peripheral vascular resistance (essential hypertension closely related to diastolic blood pressure). Systolic hypertension, characterized by increased stiffness of the large arteries, is not usually associated with increased peripheral vascular resistance. In the absence of any marketed products that address the underlying pathology of systolic hypertension patients, treatments approved for essential hypertension are currently being prescribed to treat hypertension in these patients.

## Medical and Clinical Advisors

Our Medical and Clinical Advisors consist of individuals with recognized expertise in the medical and pharmaceutical science and related fields who advise us about present and long-term scientific planning, research and development. These advisors consult and meet with our management informally on a frequent basis. All advisors are employed by employers other than us, who may also be competitors of ours, and may have commitments to, or consulting or advisory agreements with, other entities that may limit their availability to us. The advisors have agreed, however, not to provide any services to any other entities that might conflict with the activities that they provide us. Each member also has executed a confidentiality agreement for our benefit.

The following persons are Medical and Clinical Advisors:

**George L. Bakris, M.D., F.A.C.P., F.C.P.**, Professor of Preventive and Internal Medicine, Vice Chairman, Department of Preventive Medicine and Director, Hypertension/Clinical Research Center, Rush University Medical Center; immediate Past-President, American College of Clinical Pharmacology.

**Leslie Z. Benet, Ph.D.**, Professor, University of California San Francisco, School of Pharmacy, Department of Biopharmaceutical Sciences; Chairman of the Board, AvMax, Inc.; Past-Chairman, Department of Biopharmaceutical Sciences of the University of California San Francisco.

**Edward D. Frohlich, M.D.**, Alton Ochsner Distinguished Scientist of the Ochsner Clinic Foundation; Professor of Medicine and Physiology at Louisiana State University; Clinical Professor of Medicine and Adjunct Professor of Pharmacology at Tulane University; President, Society of Geriatric Cardiology; Past-President, American Society for Clinical Pharmacology and Therapeutics; Past-Chairman, Council for High Blood Pressure Research (American Heart Association); immediate Past-Editor-in-Chief of the journal *Hypertension*.

**Norman K. Hollenberg, M.D., Ph.D.**, Professor of Medicine, Harvard Medical School; Director of Physiologic Research, Brigham and Women's Hospital, Boston; served as an Editor of the *New England Journal of Medicine*.

**Peter R. Kowey, M.D.**, Full Professor, Medicine and Clinical Pharmacology, Jefferson Medical College; President and Chief of the Division of Cardiovascular Diseases, Main Line Health Heart Center, Lankenau Hospital; Fellow of the American Heart Association, the American College of Cardiology, the American College of Physicians, the College of Physicians of Philadelphia, the American College of Chest Physicians and the American College of Clinical Pharmacology.

**Craig M. Pratt, M.D.**, Professor of Medicine, Baylor College of Medicine; Director of Research, Methodist DeBakey Heart Center; Director, Coronary Intensive Care Unit, The Methodist Hospital; Member, Continuing Medical Education Advisory Board, Discovery International; Fellow, American College of Cardiology.

## Employees

As of February 29, 2004, we employed 34 persons; 23 were engaged in research and development, and 11 were engaged in administration and management. Five of those employed held a Ph.D., M.D. or other advanced degree. We believe that we have been successful in attracting skilled and experienced personnel. Our employees are not covered by collective bargaining agreements, but all employees are covered by confidentiality agreements. We believe that our relationship with our employees is good.

## Forward-Looking Statements and Cautionary Statements

Statements in this Form 10-K that are not statements or descriptions of historical facts are "forward-looking" statements under Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and are subject to numerous risks and uncertainties. These forward-looking statements and other forward-looking statements made by us or our representatives are based on a number of assumptions. The words "believe," "expect," "anticipate," "intend," "estimate" or other expressions, which are predictions of or indicate future events and trends and which do not relate to historical matters, identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, as they involve risks and uncertainties, and actual results could differ materially from those currently anticipated due to a number of factors, including those set forth in this section and elsewhere in this Form 10-K. These factors include, but are not limited to, the risks set forth below.

The forward-looking statements represent our judgment and expectations as of the date of this Report. We assume no obligation to update any such forward-looking statements.

***If we do not obtain sufficient additional funding to meet our needs, we may have to curtail or discontinue the research, product development, pre-clinical testing and clinical trials of some or all of our product candidates.***

As of December 31, 2003, we had working capital of \$15,033,000, including \$16,679,000 of cash and cash equivalents. Our cash used in operations for the year ended December 31, 2003 was \$15,906,000.

We believe that our lead compound, alagebrium, is the only A.G.E. Crosslink Breaker in advanced human testing. Several Phase 2 clinical trials have been completed: the DIAMOND, the SAPPHIRE and SILVER trial in systolic hypertension and a trial in cardiovascular compliance. Based on evidence of alagebrium's demonstrated efficacy and biological activity in these Phase 2 trials, as well as a strong and consistent safety profile, we are proceeding with Phase 2 development of alagebrium in two major cardiovascular indications, systolic hypertension and heart failure. We continue to work with our external advisors to determine the appropriate clinical development strategy and timeline.

We expect to utilize cash to fund our operations and to initiate new Phase 2 trials in systolic hypertension and diastolic dysfunction in heart failure during the first half of 2004. The first of the Phase 2 trials was initiated in March 2004, SPECTRA, a Phase 2b trial in patients with systolic hypertension. Based on our projected spending levels, including these trials, which are expected to continue into 2005, we do not currently have adequate cash and cash equivalents to complete the trials or complete the 2004 fiscal year and therefore will require additional funding during 2004. As a result, throughout 2004 and 2005, we will monitor our liquidity position and the status of our clinical trials. If we are unsuccessful in our efforts to raise additional funds through the sale of additional equity securities, we will be required to significantly reduce or curtail our research and product development activities, including the number of patients enrolled in our trials, and other operations if our level of cash and cash equivalents fall below pre-determined levels. We have the intent and ability to quickly and significantly reduce the cash burn rate, if necessary, as we have limited fixed commitments. We believe that such curtailment actions, if needed, will enable us to fund our operations into early 2005.

The amount and timing of our future capital requirements will depend on numerous factors, including the progress of our research and development programs, the conduct of pre-clinical tests and clinical trials, the development of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the development of marketing and sales capabilities and the availability of third-party funding.

We will require, over the long-term, substantial new funding to pursue development and commercialization of alagebrium and our other product candidates to continue our operations. We believe that satisfying these capital requirements over the long-term will require successful commercialization of our product candidates, particularly alagebrium. However, it is uncertain whether any products will be approved or will be commercially successful.

Because of our near-term and long-term capital requirements, we will seek access to the public or private equity markets whenever conditions are favorable. This may have the effect of materially diluting the current holders of our outstanding stock. We may also seek additional funding through corporate collaborations and other financing vehicles, potentially including off-balance sheet financing through limited partnerships or corporations. There can be no assurance that such funding will be available at all or on terms acceptable to us. If adequate funds are not available, we may be required to curtail significantly one or more of our research or development programs. If we obtain funds through arrangements with collaborative partners or others, we may be required to relinquish rights to certain of our technologies or product candidates. If we are unable to obtain the necessary funding, we may need to cease operations.

***If we do not successfully develop any products, we may not derive any revenues.***

We have not yet requested or received regulatory approval for any product from the FDA or any other regulatory body. All of our product candidates, including our lead candidate, alagebrium, are still in research or clinical development. We may not succeed in the development and marketing of any therapeutic or diagnostic product. We do not have any product other than alagebrium in active clinical development, and there can be no assurance that we will be able to bring any other compound into clinical development. To achieve profitable operations, we must, alone or with others, successfully identify, develop, introduce and market proprietary products. Such products will require significant additional investment, development and pre-clinical and clinical testing prior to potential regulatory approval and commercialization.

The development of new pharmaceutical products is highly uncertain and subject to a number of significant risks. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. Potential products may be found ineffective or cause harmful side effects during pre-clinical testing or clinical trials, fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical, fail to achieve market acceptance or be precluded from commercialization by proprietary rights of third parties. We may not be able to undertake additional clinical trials. In addition, our product development efforts may not be successfully completed, we may not obtain regulatory approvals, and our products, if introduced, may not be successfully marketed or achieve customer acceptance. We do not expect any of our products, including alagebrium, to be commercially available for a number of years, if at all.

***Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is uncertain.***

Before obtaining regulatory approvals for the commercial sale of any of our products under development, we must demonstrate through pre-clinical studies and clinical trials that the product is safe and effective for use in each target indication. The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Factors which can cause delay or termination of our clinical trials include: (i) slower than expected patient enrollment due to the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the study, competition with clinical trials for other drug candidates or other factors; (ii) lower than expected retention rates of patients in a clinical trial; (iii) inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials; (iv) delays in approvals from a study site's review board; (v) longer treatment time required to demonstrate effectiveness or determine the appropriate product dose; (vi) lack of sufficient supplies of the product candidate; (vii) adverse medical events or side effects in treated patients; (viii) lack of effectiveness of the product candidate being tested, and (ix) regulatory changes.

Even if we obtain positive results from pre-clinical or clinical trials for a particular product, we may not achieve the same success in future trials of that product. In addition, some or all of the clinical trials we undertake may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals, which could prevent the creation of marketable products. Our product development costs will increase if we have delays in testing or approvals, if we need to perform more or larger clinical trials than planned or if our trials are not successful. Delays in our clinical trials may harm our financial results and the commercial prospects for our products.

***If we are unable to derive revenues from product sales, we may never be profitable.***

All of our revenues to date have been generated from collaborative research agreements and financing activities or interest income earned on these funds. We have not received any revenues from product sales. We may not realize product revenues on a timely basis, if at all.

At December 31, 2003, we had an accumulated deficit of \$187,619,000. We anticipate that we will incur substantial, potentially greater, losses in the future. Our products under development may not be successfully developed and our products, if successfully developed, may not generate revenues sufficient to enable us to earn a profit. We expect to incur substantial additional operating expenses over the next several years as our research, development and clinical trial activities continue. We do not expect to generate revenues from the sale of products, if any, for a number of years. Our ability to achieve profitability depends, in part, on our ability to enter into agreements for product development, obtain regulatory approval for our products and develop the capacity, or enter into agreements, for the manufacture, marketing and sale of any products. We may not obtain required regulatory approvals, or successfully develop, manufacture, commercialize and market product candidates, and we may never achieve product revenues or profitability.

***Prior stock option repricing may have an adverse effect on our future financial performance.***

Based on the performance of our stock and in order to bolster employee retention, we repriced certain employee stock options on February 2, 1999. As a result of this repricing, options to purchase 1.06 million shares of stock were repriced and certain vesting periods related to these options were modified or extended. This repricing may have a material adverse impact on future financial performance based on the Financial Accounting Standards Board ("FASB") Interpretation No. 44 ("FIN 44"), "Accounting for Certain Transactions Involving Stock Compensation, An Interpretation of APB Opinion No. 25." This interpretation requires us to record compensation expense or benefit, which is adjusted every quarter, for increases or decreases in the fair value of the repriced options based on changes in our stock price from the value at July 1, 2000, until the repriced options are exercised, forfeited or expire. The options expire at various dates through January 2008.



***If we are unable to form the collaborative relationships that our business strategy requires, then our programs will suffer and we may not be able to develop products.***

Our strategy for developing and deriving revenues from our products depends, in large part, upon entering into arrangements with research collaborators, corporate partners and others. We are seeking to establish these relationships to provide the funding necessary for continuation of our product development, but if such efforts may not be successful, our programs may suffer and we may be unable to develop products.

***If we are able to form our collaborative relationships, but are unable to maintain them, our product development may be delayed and disputes over rights to technology may result.***

We may form collaborative relationships that will, in some cases, make us dependent upon outside partners to conduct pre-clinical testing and clinical trials and to provide adequate funding for our development programs. Such corporate partners, if any, may have all or a significant portion of the development and regulatory approval responsibilities. Failure of the corporate partners to develop marketable products or to gain the appropriate regulatory approvals on a timely basis, if at all, would have a material adverse effect on our business, financial condition and results of operations.

In most cases, we will not be able to control the amount and timing of resources that our corporate partners devote to our programs or potential products. If any of our corporate partners breached or terminated its agreement with us or otherwise failed to conduct its collaborative activities in a timely manner, the pre-clinical or clinical development or commercialization of product candidates or research programs could be delayed, and we would be required to devote additional resources to product development and commercialization or terminate certain development programs.

Disputes may arise in the future with respect to the ownership of rights to any technology we develop with third parties. These and other possible disagreements between us and collaborators could lead to delays in the collaborative research, development or commercialization of product candidates, or could require or result in litigation or arbitration, which would be time-consuming and expensive and would have a material adverse effect on our business, financial condition and results of operations.

Any corporate partners we have may develop, either alone or with others, products that compete with the development and marketing of our products. Competing products, either developed by the corporate partners or to which the corporate partners have rights, may result in their withdrawal of support with respect to all or a portion of our technology, which would have a material adverse effect on our business, financial condition and results of operations.

***If we cannot successfully develop a marketing and sales force or maintain suitable arrangements with third parties to market and sell our products, our ability to deliver products may be impaired.***

We currently have no experience in marketing or selling pharmaceutical products. In order to achieve commercial success for any approved product, we must either develop a marketing and sales force or, where appropriate or permissible, enter into arrangements with third parties to market and sell our products. We might not be successful in developing marketing and sales capabilities. Further, we may not be able to enter into marketing and sales agreements with others on acceptable terms, and any such arrangements, if entered into, may be terminated. If we develop our own marketing and sales capability, it will compete with other companies that currently have experienced, well funded and larger marketing and sales operations. To the extent that we enter into co-promotion or other sales and marketing arrangements with other companies, revenues will depend on the efforts of others, which may not be successful.

***If we cannot successfully form and maintain suitable arrangements with third parties for the manufacturing of the products we may develop, our ability to develop or deliver products may be impaired.***

We have no experience in manufacturing products and do not have manufacturing facilities. Consequently, we are dependent on contract manufacturers for the production of products for development and commercial purposes. The manufacture of our products for clinical trials and commercial purposes is subject to cGMP regulations promulgated by the FDA. In the event that we are unable to obtain or retain third-party manufacturing for our products, we will not be able to commercialize such products as planned. We may not be able to enter into agreements for the manufacture of future products with manufacturers whose facilities and procedures comply with cGMP and other regulatory requirements. Our current dependence upon others for the manufacture of our products may adversely affect our profit margin, if any, on the sale of future products and our ability to develop and deliver such products on a timely and competitive basis.

***If we are not able to protect the proprietary rights that are critical to our success, the development and any possible sales of our product candidates could suffer and competitors could force our products completely out of the market.***

Our success will depend on our ability to obtain patent protection for our products, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others, both in the United States and abroad.

The degree of patent protection afforded to pharmaceutical inventions is uncertain and our potential products are subject to this uncertainty. Competitors may develop competitive products outside the protection that may be afforded by the claims of our patents. We are aware that other parties have been issued patents and have filed patent applications in the United States and foreign countries with respect to other agents that have an effect on A.G.E.s. or the formation of A.G.E. crosslinks. In addition, although we have several patent applications pending to protect proprietary technology and potential products, these patents may not be issued, and the claims of any patents, which do issue, may not provide significant protection of our technology or products. In addition, we may not enjoy any patent protection beyond the expiration dates of our currently issued patents.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to maintain, develop and expand our competitive position, which we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and certain, but not all, corporate partners and consultants. Relevant inventions may be developed by a person not bound by an invention assignment agreement. Binding agreements may be breached, and we may not have adequate remedies for such breach. In addition, our trade secrets may become known to or be independently discovered by competitors.

***If we fail to obtain regulatory approvals for our products, the commercial use of our products will be limited.***

Our research, pre-clinical testing and clinical trials of our product candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous regulation by numerous governmental authorities in the United States and in other countries where we intend to test and market our product candidates.

Prior to marketing, any product we develop must undergo an extensive regulatory approval process. This regulatory process, which includes pre-clinical testing and clinical trials and may include post-marketing surveillance of each compound to establish its safety and efficacy, can take many years and can require the expenditure of substantial resources. Data obtained from pre-clinical and clinical activities is susceptible to varying interpretations that could delay, limit or prevent regulatory approval. In addition, we may encounter delays or rejections based upon changes in FDA policy for drug approval during the period of product development and FDA regulatory review of each submitted NDA. We may encounter similar delays in foreign countries. We may not obtain regulatory approval for the drugs we develop. Moreover, regulatory approval may entail limitations on the indicated uses of the drug. Further, even if we obtain regulatory approval, a marketed drug and its manufacturer are subject to continuing review and discovery of previously unknown problems with a product or manufacturer which may have adverse effects on our business, financial condition and results of operations, including withdrawal of the product from the market. Violations of regulatory requirements at any stage, including pre-clinical testing, clinical trials, the approval process or post-approval, may result in various adverse consequences, including the FDA's delay in approving, or its refusal to approve a product, withdrawal of an approved product from the market and the imposition of criminal penalties against the manufacturer and NDA holder. None of our products has been approved for commercialization in the United States or elsewhere. We may not be able to obtain FDA approval for any products. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude our licensees or marketing partners from marketing our products or limit the commercial use of such products and will have a material adverse effect on our business, financial condition and results of operations.

***If we are not able to compete successfully with other companies in the development and marketing of cures and therapies for cardiovascular diseases, diabetes and the other conditions for which we seek to develop products, we may not be able to continue our operations.***

We are engaged in pharmaceutical fields characterized by extensive research efforts and rapid technological progress. Many established pharmaceutical and biotechnology companies with resources greater than ours are attempting to develop products that would be competitive with our products. Other companies may succeed in developing products that are safer, more efficacious or less costly than any we may develop and may also be more successful than us in production and marketing. Rapid technological development by others may result in our products becoming obsolete before we recover a significant portion of the research, development or commercialization expenses incurred with respect to those products.

Certain technologies under development by other pharmaceutical companies could result in better treatments for cardiovascular disease, or diabetes and its related complications. Several large companies have initiated or expanded research, development and licensing efforts to build pharmaceutical franchises focusing on these medical conditions. It is possible that one or more of these initiatives may reduce or eliminate the market for some of our products. In addition, other companies have initiated research in the inhibition or crosslink breaking of A.G.E.s.

***If governments and third-party payers continue their efforts to contain or decrease the costs of healthcare, we may not be able to commercialize our products successfully.***

In certain foreign markets, pricing and/or profitability of prescription pharmaceuticals are subject to government control. In the United States, we expect that there will continue to be federal and state initiatives to control and/or reduce pharmaceutical expenditures. In addition, increasing emphasis on managed care in the United States will continue to put pressure on pharmaceutical pricing. Cost control initiatives could decrease the price that we receive for any products we may develop and sell in the future and have a material adverse effect on our business, financial condition and results of operations. Further, to the extent that cost control initiatives have a material adverse effect on our corporate partners, our ability to commercialize our products may be adversely affected.

Our ability to commercialize pharmaceutical products may depend, in part, on the extent to which reimbursement for the products will be available from government health administration authorities, private health insurers and other third-party payers. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and third-party payers, including Medicare, are increasingly challenging the prices charged for medical products and services. Third-party insurance coverage may not be available to patients for any products developed by us. Government and other third-party payers are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing in some cases to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. If adequate coverage and reimbursement levels are not provided by government and other third-party payers for our products, the market acceptance of these products would be adversely affected.



***If the users of the products we develop claim that our products have harmed them, we may be subject to costly and damaging product liability litigation, which could have a material adverse effect on our business, financial condition and results of operations.***

The use of any of our potential products in clinical trials and the sale of any approved products, including the testing and commercialization of alagebrium or other compounds, expose us to liability claims resulting from the use of products or product candidates. Claims could be made directly by participants in our clinical trials, consumers, pharmaceutical companies or others. We maintain product liability insurance coverage for claims arising from the use of our products in clinical trials. However, coverage is becoming increasingly expensive, and we may not be able to maintain or acquire insurance at a reasonable cost or in sufficient amounts to protect us against losses due to liability that could have a material adverse effect on our business, financial condition and results of operations. We may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future and insurance coverage, and our resources may not be sufficient to satisfy any liability resulting from product liability claims. A successful product liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

***If we are unable to attract and retain the key personnel on whom our success depends, our product development, marketing and commercialization plans could suffer.***

We are highly dependent on the principal members of our management and scientific staff. The loss of services of any of these personnel could impede the achievement of our development objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future will also be critical to our success. We may not be able to attract and retain personnel on acceptable terms given the competition between pharmaceutical and healthcare companies, universities and non-profit research institutions for experienced scientists. In addition, we rely on consultants to assist us in formulating our research and development strategy. All of our consultants are employed outside of us and may have commitments to or consulting or advisory contracts with other entities that may limit their availability to us.

**Item 2. Properties.**

Our lease for office and laboratory space in Ramsey, New Jersey, expired on November 1, 2003, but was extended through January 31, 2004. We signed a three-year lease, commencing December 1, 2003, for 10,800 square feet of office space in Parsippany, New Jersey.

**Item 3. Legal Proceedings.**

Not applicable.

**Item 4. Submission of Matters to a Vote of Security Holders.**

Not applicable.

**PART II**

**Item 5. Market for the Company's Common Equity and Related Stockholder Matters.**

Our common stock has traded on the American Stock Exchange since August 7, 2000, under the symbol "ALTI."

<b>2003</b>	<b>High</b>	<b>Low</b>
First Quarter .....	\$ 4.37	\$ 1.95
Second Quarter .....	5.65	3.17
Third Quarter .....	7.50	1.25
Fourth Quarter .....	2.18	1.41
<b>2002</b>	<b>High</b>	<b>Low</b>
First Quarter .....	\$ 5.90	\$ 3.40
Second Quarter .....	3.84	1.77
Third Quarter .....	2.25	1.38
Fourth Quarter .....	2.45	1.00

As of February 27, 2004, there were 337 holders of the common stock. On February 27, 2004, the last sale price reported on the American Stock Exchange for the common stock was \$2.09 per share.

We have neither paid nor declared dividends on our common stock since our inception and do not plan to pay dividends in the foreseeable future. Any earnings that we may realize will be returned to finance our growth.

The market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors, such as fluctuations in our operating results, announcements of technological innovations or new therapeutic products by us or others, clinical trial results, developments concerning agreements with collaborators, governmental regulation, developments in patent or other proprietary rights, public concern as to the safety of drugs developed by us or others, future sales of substantial amounts of common stock by existing stockholders and general market conditions, can have an adverse effect on the market price of the common stock.

The information called for by Item 201(d) of Regulation S-K is provided in response to Item 12 of this Annual Report on Form 10-K, which is incorporated herein by reference.

**Item 6. Selected Financial Data.**

The selected financial data set forth below should be read in conjunction with the audited financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The selected financial data for the five years ended December 31, 2003 has been derived from our audited financial statements.

Year Ended December 31,	2003	2002	2001	2000	1999
	(in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Revenues:					
Investment income .....	\$ 179	\$ 410	\$ 452	\$ 570	\$ 835
Other income .....	—	—	—	—	600
Total revenues .....	179	410	452	570	1,435
Expenses:					
Research and development (which includes non-cash variable stock compensation expense/(benefit) in 2003, 2002, 2001 and 2000 of \$20, \$(94), \$165 and \$353, respectively) ...	9,930	14,992	8,461	6,375	10,598
General and administrative (which includes non-cash variable stock compensation expense/(benefit) in 2003, 2002, 2001 and 2000 of \$0, \$(1,316), \$657 and \$891, respectively) ...	5,046	2,946	4,761	5,313	4,357
Total expenses .....	14,976	17,938	13,222	11,688	14,955
Loss before income tax benefit .....	(14,797)	(17,528)	(12,770)	(11,118)	(13,520)
Income tax benefit .....	345	647	1,187	1,548	2,588
Net loss .....	(14,452)	(16,881)	(11,583)	(9,570)	(10,932)
Preferred stock dividends .....	3,791	3,485	3,204	2,945	2,707
Common stock warrant deemed dividends .....	—	—	210	—	—
Net loss applicable to common stockholders .....	\$ (18,243)	\$ (20,366)	\$ (14,997)	\$ (12,515)	\$ (13,639)
Basic/diluted net loss per share applicable to common stockholders .....					
	\$ (0.50)	\$ (0.64)	\$ (0.61)	\$ (0.63)	\$ (0.72)
Weighted average common shares used in computing basic/diluted net loss per share ...					
	36,190	31,793	24,556	19,861	19,055

**Balance Sheet Data:**

Cash, cash equivalents and short-term investments ..	\$ 16,679	\$ 17,439	\$ 10,726	\$ 9,955	\$ 12,370
Working capital .....	15,033	13,786	9,758	9,754	10,425
Total assets .....	17,255	18,099	13,233	13,389	15,021
Accumulated deficit .....	(187,619)	(169,376)	(149,009)	(134,011)	(121,496)
Total stockholders' equity .....	15,384	14,303	10,871	11,453	12,827

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.****Overview**

We are a product-based biopharmaceutical company primarily engaged in the discovery and development of small molecule drugs to reverse or slow down diseases of aging and complications of diabetes. Our product candidates represent novel approaches to some of the largest pharmaceutical markets. Our lead compound is in clinical development; several others are in earlier development stages. These pharmaceutical candidates were developed as a result of our research on the A.G.E. pathway, a fundamental pathological process and inevitable consequence of aging that causes or contributes to many medical disorders, including cardiovascular, kidney and eye diseases.

Alagebrium chloride (formerly ALT-711) is our lead product candidate and we believe the only A.G.E. Crosslink Breaker in advanced human testing. In February, the United States Adopted Name (USAN) Council approved alagebrium chloride as the generic name of the chemical compound formerly known as ALT-711. Several Phase 2 clinical trials have been completed: the DIAMOND trial in diastolic heart failure, the SAPPHIRE and SILVER trial in systolic hypertension and a trial in cardiovascular compliance. Based on evidence of alagebrium's demonstrated efficacy and biological activity in these Phase 2 trials, as well as a strong and consistent safety profile, additional Phase 2 trials are planned in two major cardiovascular indications, systolic hypertension and diastolic dysfunction in heart failure in the first half of 2004. The first of the Phase 2 trials was initiated in March 2004, SPECTRA, a Phase 2b trial in patients with systolic hypertension. Importantly, there are no currently marketed cardiovascular drugs that can work directly on the stiffening of the vasculature that leads to systolic hypertension and heart failure.

Our primary priorities are to continue the clinical development of alagebrium in systolic hypertension and diastolic dysfunction in heart failure and to ensure that we have the funding and personnel necessary to accomplish this objective.



As we continue clinical development of alagebrium, we will determine if it is appropriate to retain development and marketing rights for one or several indications in North America, while at the same time continuing to evaluate potential corporate partnerships for the further development and ultimate marketing of the compound in other territories throughout the world. We believe that alagebrium may address the cardiovascular, diabetes and primary care physician markets.

We plan to continue to explore the use of topical A.G.E. Crosslink Breakers in skin and photoaging, as a result of our recent evaluation of ALT-744. We will focus efforts on bringing forward other crosslink breaker compounds with more attractive formulation characteristics than those of ALT-744 to address the pharmaceutical market for skin and photoaging.

Since our inception in October 1986, we have devoted substantially all of our resources to research, drug discovery and development programs. To date, we have not generated any revenues from the sale of products and do not expect to generate any such revenues for a number of years, if at all. We have incurred an accumulated deficit of \$187,619,000 as of December 31, 2003, and expect to incur operating losses, potentially greater than losses in prior years, for a number of years.

We have financed our operations through proceeds from an initial public offering of common stock in 1991, public offerings of common stock, private placements of common and preferred equity securities, revenue from former collaborative relationships, reimbursement of certain of our research and development expenses by our collaborative partners, investment income earned on cash balances and short-term investments and the sale of a portion of our New Jersey State net operating loss carryforwards.

Our business is subject to significant risks including, but not limited to, (i) the ability to obtain funding, (ii) the risks inherent in our research and development efforts, including clinical trials, (iii) uncertainties associated with obtaining and enforcing our patents and with the patent rights of others, (iv) the lengthy, expensive and uncertain process of seeking regulatory approvals, (v) uncertainties regarding government healthcare reforms and product pricing and reimbursement levels, (vi) technological change and competition, (vii) manufacturing uncertainties, and (viii) dependence on collaborative partners and other third parties. Even if our product candidates appear promising at an early stage of development, they may not reach the market for numerous reasons. Such reasons include the possibilities that the products will prove ineffective or unsafe during clinical trials, will fail to receive necessary regulatory approvals, will be difficult to manufacture on a large scale, will be uneconomical to market or will be precluded from commercialization by proprietary rights of third parties. These risks and others are discussed under the heading "Forward-Looking Statements and Cautionary Statements."

## Results of Operations

### Years Ended December 2003, 2002, 2001

#### Revenues

Total revenues for 2003, 2002 and 2001 were \$179,000, \$410,000 and \$452,000, respectively. Revenues were derived from interest earned on cash and cash equivalents and short-term investments. The decrease in revenues in 2003 over 2002 was attributed to decreased investment balances and decreased interest rates. The decrease in revenues in 2002 over 2001 was attributed to decreased interest rates, partially offset by larger investment balances.

#### Operating Expenses

Total expenses decreased to \$14,976,000 in 2003 from \$17,938,000 in 2002, and increased from \$13,222,000 in 2001, and in each year consisted primarily of research and development expenses. Research and development expenses were \$9,930,000 in 2003, \$14,992,000 in 2002 and \$8,461,000 in 2001, and included non-cash variable stock compensation expense/(benefit) of \$20,000, \$(94,000) and \$165,000, respectively. Research and development expenses consisted primarily of third-party expenses associated with clinical and pre-clinical studies, manufacturing costs, including the development and preparation of clinical supplies, personnel and personnel-related expenses and an allocation of facility expense.

Research and development expenses decreased in 2003 from 2002 by \$5,062,000, or 33.8%. This was primarily related to decreased clinical trial costs associated with the crosslink breaker program. In 2003, approximately \$1,788,000 of total research and development expenditures was related to the Phase 2b SAPPHIRE and SILVER trial. The equivalent amount in 2002 was \$6,631,000. This reduction is a result of the completion of the Phase 2b SAPPHIRE and SILVER trial in July 2003. The 2003 results also included approximately \$4,147,000 in personnel and personnel-related costs, \$1,279,000 in facility allocation, \$751,000 in pre-clinical expenses, \$672,000 of manufacturing costs (tableting, drug stability studies and active pharmaceutical ingredient development) and \$432,000 in consulting expense.

Research and development expenses increased in 2002 from 2001 by \$6,531,000, or 77.2%. This was primarily related to increased clinical trial costs associated with the crosslink breaker program. In 2002, approximately \$6,631,000 of total research and development expenditures was related to the Phase 2b SAPPHIRE and SILVER trial and the Phase 2a DIAMOND trial, as compared to approximately \$971,000 in 2001, the year the trials were initiated. The 2002 results also included approximately \$3,250,000 in personnel and personnel-related costs, \$683,000 in pre-clinical expenses and approximately \$1,872,000 of manufacturing costs. These manufacturing costs included finalizing the development of manufacturing processes for the production of clinical trial supplies and potential commercialization of alagebrium, drug stability studies and drug packaging.

General and administrative expenses were \$5,046,000 in 2003, increased from \$2,946,000 in 2002 and from \$4,761,000 in 2001. The changes in general and administrative expenses consisted primarily of non-cash variable stock compensation expense/(benefit) of \$0, \$(1,316,000) and \$657,000 in 2003, 2002 and 2001, respectively. Excluding the non-cash variable stock compensation, general and administrative expenses were \$5,046,000, \$4,262,000 and \$4,104,000 in 2003, 2002 and 2001, respectively. The increase in 2003 over 2002 is primarily related to \$550,000 of business development and marketing costs incurred during the first half of 2003 associated with the unblinding of data from the SAPPHIRE and SILVER trial in July 2003.

At December 31, 2003, we had available federal net operating loss carryforwards, which expire in various amounts from the years 2006 through 2023, of approximately \$144,952,000 and State net operating loss carryforwards, which expire in the years 2004 through 2010, of approximately \$91,343,000. In addition, at December 31, 2003, we had federal research and development credit carryforwards of approximately \$6,401,000 and State research and development tax credit carryforwards of approximately \$1,600,000.

#### **Net Loss**

We had net losses of \$14,452,000 in 2003, \$16,882,000 in 2002 and \$11,584,000 in 2001. Included in our net loss in 2003, 2002 and 2001 was the sale of approximately \$2,083,000, \$1,839,000 and \$6,243,000, respectively, of our gross State net operating loss carryforwards and approximately \$209,000, \$578,000 and \$802,000, respectively, of our State research and development tax credit carryforwards. The proceeds from the sale in 2003, 2002 and 2001 were approximately \$345,000, \$647,000 and \$1,187,000, respectively.

Included in the net loss applicable to common stockholders for 2003, 2002 and 2001 were preferred stock dividends of approximately \$3,791,000, \$3,485,000 and \$3,204,000, respectively, and common stock deemed dividends of \$210,000 in 2001.

#### **Liquidity and Capital Resources**

We had cash and cash equivalents and short-term investments at December 31, 2003, of \$16,679,000 compared to \$17,439,000 at December 31, 2002, a decrease of \$760,000. Cash used in operations for the year ended December 31, 2003, totaled \$15,906,000 (net of \$345,000 of cash received for the sales of our New Jersey State net operating loss carryforwards and State research and development tax credit carryforwards) and consisted primarily of research and development expenses, personnel and related costs, and facility expenses. Cash used in investing activities for the year ended December 31, 2003, included approximately \$86,000 of capital expenditures and restricted cash of \$250,000 associated with our new facility lease. This was partially offset by \$15,484,000 of cash provided by financing activities for the year ended December 31, 2003, related to public offerings of common stock and proceeds from stock option exercises. In October 2003, we completed a public offering of 4,457,146 shares of common stock at \$1.75 per share, which provided net proceeds of approximately \$7,772,000. The Stock Purchase Agreement, as amended, provides that we could sell up to a total of 1,559,456 additional shares of common stock at \$1.85 per share for approximately \$2,885,000 in gross proceeds to such of the investors who elect to purchase shares on April 20, 2004, which is 120 business days after the initial closing. The investors are not obligated and at their discretion may elect not to purchase additional shares. In March 2003, we completed a public offering of 2,300,000 shares of common stock at \$3.50 per share, which provided net proceeds of \$7,656,000.

In 2003, 2002 and 2001, we sold \$2,083,000, \$1,839,000 and \$6,243,000, respectively, of our gross State net operating loss carryforwards and \$209,000, \$578,000 and \$802,000, respectively, of our State research and development tax credit carryforwards under the State Program. The proceeds from the sale in 2003, 2002 and 2001 were \$345,000, \$647,000 and \$1,187,000, respectively, and such amounts were recorded as a tax benefit in the statements of operations. As of December 31, 2003, we had State net loss carryforwards and State research and development tax credit carryforwards available for sale of approximately \$92,944,000. The State renews the Program annually and limits the aggregate benefit to \$10,000,000. We cannot be certain if we will be able to sell any or all of these carryforwards under the Program.

We do not have any approved products and currently derive cash from sales of our securities, sales of our New Jersey operating loss carryforwards and interest on cash and cash equivalents. We are highly susceptible to conditions in the global financial markets and in the pharmaceutical industry. Positive and negative movement in those markets will continue to pose opportunities and challenges to us. Previous downturns in the market valuations of biotechnology companies and of the equity markets more generally have restricted our ability to raise additional capital on favorable terms.

We expect to utilize cash to fund our operations and to initiate new Phase 2 trials in systolic hypertension and diastolic dysfunction in heart failure during the first half of 2004. The first of the Phase 2 trials was initiated in March 2004, SPECTRA, a Phase 2b trial in patients with systolic hypertension. The cost of these trials, exclusive of our internal cost, is currently estimated to be approximately \$8.2 million for the systolic hypertension trial and \$0.5 million for the first phase of the diastolic dysfunction trial. The cost includes executed, but cancelable, agreements with outside organizations. Based on our projected spending levels, including these trials, which are expected to continue into 2005, we do not currently have adequate cash and cash equivalents to complete the trials or complete the 2004 fiscal year and therefore will require additional funding during 2004. As a result, throughout 2004 and into 2005, we will monitor our liquidity position and the status of our clinical trials. If we are unsuccessful in our efforts to raise additional funds through the sale of additional equity securities, we will be required to significantly reduce or curtail our research and product development activities, including the number of patients enrolled in our trials and other operations, if our level of cash and cash equivalents fall below pre-determined levels. We have the intent and ability to quickly and significantly reduce the cash burn rate, if necessary, as we have limited fixed commitments. We believe that such curtailment actions, if needed, will enable us to fund our operations into early 2005.

We will require, over the long-term, substantial new funding to pursue development and commercialization of alagebrum and our other product candidates and continue our operations. We believe that satisfying these capital requirements over the long-term will require successful commercialization of our product candidates. However, it is uncertain whether any products will be approved or will be commercially successful. The amount of our future capital requirements will depend on numerous factors, including the progress of our research and development programs, the conduct of pre-clinical tests and clinical trials, the development of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the development of marketing and sales capabilities and the availability of third-party funding.

Because of our short-term and long-term capital requirements, we, as stated above, may seek access to the public or private equity markets. This may have the effect of materially diluting the current holders of our outstanding stock. We may also seek additional funding through corporate collaborations and other financing vehicles, potentially including off-balance sheet financing through limited partnerships or corporations. There can be no assurance that such funding will be available at all or on terms acceptable to us. If we obtain funds through arrangements with collaborative partners or others, we may be required to relinquish rights to certain of our technologies or product candidates. If we are unable to obtain the necessary funding, we may need to cease operations.

Our current priorities and the focus of our resources are the evaluation and continued development of alagebrium and determining the optimal course for the development of other compounds in our patent estate. As we continue clinical development of alagebrium, we will determine if it is appropriate to retain development and marketing rights for one or several indications in North America, while at the same time, continuing to evaluate potential corporate partnerships for the further development and ultimate marketing of the compound throughout the world. As described above, we believe that additional development of this compound and other product candidates will require us to obtain additional funding.

### Commitments

The table below presents our contractual obligations as of December 31, 2003:

	Payments Due by Period				
	Total	Within 1 Year	1-3 Years	4-5 Years	After 5 Years
<b>Contractual Obligations:</b>					
Operating lease commitments	\$ 946,870	\$ 303,377	\$ 639,244	\$ 4,249	\$ —
Employment agreements <sup>(1)</sup>	800,616	(1)	(1)	(1)	(1)
Total contractual obligations	\$ 1,747,486	\$ 303,377	\$ 639,244	\$ 4,249	\$ —

(1) We have employment agreements with key executives, which provide that either party may terminate the agreement upon 30 days' prior written notice. If we terminate all of the agreements without cause, we are subject to a salary continuation obligation totaling \$800,616.

### Critical Accounting Policies

In December 2001, the SEC issued a statement concerning certain views of the Commission regarding the appropriate amount of disclosure by publicly held companies with respect to their critical accounting policies. In particular, the Commission expressed its view that in order to enhance investor understanding of financial statements, companies should explain the effects of critical accounting policies as they are applied, the judgments made in the application of these policies and the likelihood of materially different reported results if different assumptions or conditions were to prevail. We have since carefully reviewed the disclosures included in our filings with the Commission, including, without limitation, our Annual Report on Form 10-K for the year ended December 31, 2003, and accompanying audited financial statements and related notes thereto, as well as our definitive Proxy Statement for the 2003 Annual Meeting. We believe the effect of the following accounting policy is significant to our results of operations and financial condition.

We account for options granted to employees and directors in accordance with Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. As such, compensation expense is recorded on fixed stock grants only if the current fair value of the underlying stock exceeds the exercise price of the option at the date of grant and it is recognized on a straight-line basis over the vesting period. Based on the performance of our stock, we repriced certain employee stock options on February 2, 1999. As a result of this repricing, options to purchase 1.06 million shares of stock were repriced and certain vesting periods related to these options were modified or extended. Financial Accounting Standards Board ("FASB") Interpretation No. 44 ("FIN 44"), "Accounting for Certain Transactions Involving Stock Compensation, An Interpretation of APB Opinion No. 25" requires us to record compensation expense or benefit, which is adjusted every quarter, for increases or decreases in the fair value of the repriced options based on changes in our stock price from the value at July 1, 2000, until the repriced options are exercised, forfeited or expire. As a result, net loss applicable to common stockholders and net loss per share applicable to common stockholders may be subject to volatility. Had we accounted for repricing of stock option grants in accordance with SFAS No. 123, "Accounting for Stock-Based Compensation," the expense related to the vested options would have been recorded at the repricing date, and the expense related to non-vested options would have been recorded over the vesting period.

### Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Our exposure to market risk for changes in interest rates relates primarily to our investment in marketable securities. We do not use derivative financial instruments in our investments. Our investments consist primarily of debt instruments of the United States government, government agencies, financial institutions and corporations with strong credit ratings. The table below presents principal amounts and related weighted average interest rates as of December 31, 2003 for our investment portfolio. There are no maturities after 2003, and our exposure is limited based on the short-term nature of these investments.

<u>Assets</u>	<u>December 31,</u> <u>2003</u>
Cash equivalents:	
Fixed Rate	\$16,678,582
Average interest rate	.96%

**Item 8. Financial Statements and Supplementary Data.**

(a) The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. A list of the financial statements filed herewith is found at "Index to Financial Statements and Schedules" on page 35.

(b) The unaudited quarterly financial data for the two-year period ended December 31, 2003 is as follows:

	Revenues	Expenses	Loss Before Income Tax Benefit	Net Loss Applicable to Common Stockholders	Basic/Diluted Loss Per Share
(in thousands, except per share amounts)					
<b>2003</b>					
First Quarter	\$ 49	\$ 5,272	\$ (5,223)	\$ (6,128)	\$ (0.18)
Second Quarter	55	5,117	(5,062)	(5,997)	(0.17)
Third Quarter	36	1,743	(1,707)	(2,672)	(0.07)
Fourth Quarter	39	2,844	(2,805)	(3,446)	(0.08)
Total Year	\$ 179	\$ 14,976	\$ (14,797)	\$ (18,243)	\$ (0.50)
<b>2002</b>					
First Quarter	\$ 136	\$ 3,878	\$ (3,742)	\$ (4,574)	\$ (0.15)
Second Quarter	117	4,961	(4,844)	(5,703)	(0.18)
Third Quarter	93	5,307	(5,214)	(6,101)	(0.19)
Fourth Quarter	64	3,792	(3,728)	(3,988)	(0.12)
Total Year	\$ 410	\$ 17,938	\$ (17,528)	\$ (20,366)	\$ (0.64)

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

On May 30, 2002, we dismissed Arthur Andersen LLP ("Andersen") as our principal independent accountants and engaged KPMG LLP ("KPMG") to serve as our principal independent accountants for the fiscal year ending December 31, 2002.

Andersen's reports on our financial statements, as of and for the years ended December 31, 2001 and 2000, did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles.

During the years ended December 31, 2001 and 2000 and the period from December 31, 2001 to the date of dismissal of Andersen, (i) there were no disagreements with Andersen on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to Andersen's satisfaction, would have caused Andersen to make reference to the subject matter of the disagreement(s) in connection with its report, and (ii) there were no "reportable events," as such term is defined in Item 304(a)(1)(v) of Regulation S-K.

**Item 9A. Controls and Procedures.**

(a) Evaluation of Disclosure Controls and Procedures. Our Chief Executive Officer and our Vice President, Finance, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e)) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of the end of the fiscal year covered by this Annual Report on Form 10-K. Based upon that evaluation, the Chief Executive Officer and the Vice President, Finance, have concluded that as of the end of such fiscal year, our current disclosure controls and procedures are adequate and effective to ensure that information required to be disclosed in the reports we file under the Exchange Act is recorded, processed, summarized and reported on a timely basis.

(b) Changes in Internal Controls. There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the last quarter of the year ended December 31, 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART III

### Item 10. Directors and Executive Officers of the Registrant.

Pursuant to our certificate of incorporation, the Board of Directors is divided into three classes, each of which serves a term of three years. Class A consists of Ms. Breslow, Mr. Dalby and Mr. Moore, whose terms will expire at the Annual Meeting of Stockholders in 2004. Class B consists of Mr. Moch, Dr. Bransome and Dr. Naimark, whose terms will expire at the Annual Meeting of Stockholders in 2005. Class C consists of Mr. McCurdy and Dr. Novitch, whose terms will expire at the Annual Meeting of Stockholders in 2006.

The current Board of Directors, including the nominees, is comprised of the following persons:

Name	Age	Served as a Director Since	Positions with Alteon
Kenneth I. Moch	49	1998	Chairman of the Board, President and Chief Executive Officer
Edwin D. Bransome, Jr., M.D.	70	1999	Director
Marilyn G. Breslow	59	1988	Director
Alan J. Dalby	67	1994	Director
David K. McCurdy	53	1997	Director
Thomas A. Moore	53	2001	Director
George M. Naimark, Ph.D.	79	1999	Director
Mark Novitch, M.D.	71	1994	Director

The principal occupations and business experience, for at least the past five years, of each director are as follows:

Kenneth I. Moch, Chairman of the Board, President and Chief Executive Officer, joined the Company in February 1995, as Senior Vice President, Finance and Business Development and Chief Financial Officer. Mr. Moch became President, Chief Executive Officer and a director of the Company in December 1998. In June 2001, he was named Chairman of the Board. From 1990 to 1995, Mr. Moch served as President and Chief Executive Officer of Biocyte Corporation, a cellular therapy company that pioneered the use of cord blood stem cells in transplantation therapy. Mr. Moch was a founder and the Managing General Partner of Catalyst Ventures, a seed venture capital partnership, and was a founder of The Liposome Company, Inc. in Princeton, New Jersey, where he served as Vice President from 1982 to 1988. Previously, he was a management consultant with McKinsey & Company, Inc. and a biomedical technology consultant with Channing, Weinberg & Company, Inc. Mr. Moch received an A.B. in Biochemistry from Princeton University, and an M.B.A. with emphasis in Finance and Marketing from the Stanford Graduate School of Business.

Edwin D. Bransome, Jr., M.D., has been a Director of the Company since July 1999. He is a Professor of Medicine and Physiology Emeritus at the Medical College of Georgia. He retired as Chief of the Section of Endocrinology and Metabolism in 2000, is the Past-President of the United States Pharmacopoeial Convention and has been a member of the USP Board of Trustees since 1990. He served on the Georgia Department of Medical Assistance (Medicaid) Drug Utilization Board from 1992 to 2000 and was its first Chairman. Currently, Dr. Bransome is in medical practice as a consultant in Endocrinology. He is a member of the editorial board of the journal, *Diabetes Care*. Dr. Bransome has had faculty positions at the Scripps Clinic and Research Foundation, MIT and the Harvard University School of Medicine. He received his A.B. in 1954 from Yale University and received his M.D. from Columbia University College of Physicians and Surgeons in 1958. His post-graduate training in Internal Medicine and Clinical Endocrinology fellowship was at the Peter Bent Brigham Hospital in Boston and in Biochemistry at Columbia University College of Physicians and Surgeons.

Marilyn G. Breslow has been a Director of the Company since June 1988. She has been a Portfolio Manager/Analyst for W. P. Stewart & Co., Inc., the research subsidiary of W. P. Stewart & Co., Ltd., an investment advisory firm, since 1990, and is President of the New York office of WPS, Inc. She was a General Partner of Concord Partners and a Vice President of Dillon, Read & Co., Inc. from 1984 to 1990. Prior to Dillon, Read & Co., she worked at Polaroid Corporation from 1973 to 1984 and was with Peat, Marwick, Mitchell and Company from 1970 to 1972 and ICE, Inc. from 1972 to 1973. Ms. Breslow holds a B.S. degree from Barnard College and an M.B.A. from the Harvard Graduate School of Business Administration.

Alan J. Dalby has been a Director of the Company since December 1994. He is the former Chairman of Reckitt Benckiser plc, a household products company, and former Chairman, Chief Executive Officer and a founder of Cambridge NeuroScience, Inc. He was Executive Vice President and member of the Board of Directors for SmithKline Beckman Corporation, retiring in 1987. Mr. Dalby is a Director of Acambis plc.

David K. McCurdy, has been a Director of the Company since June 1997. He is currently the President of Electronic Industries Alliance ("EIA"), the premier trade organization representing more than 2,100 of the world's leading electronics manufacturers. Before becoming President of EIA in November 1998, Mr. McCurdy was Chairman and Chief Executive Officer of the McCurdy Group L.L.C., a business consulting and investment firm focused on high-growth companies in the fields of healthcare, high technology and international business, which he formed in 1995. Prior to forming the McCurdy Group, Mr. McCurdy served for 14 years in the United States House of Representatives from the fourth district of Oklahoma. He attained numerous leadership positions, including Chairman of the House Intelligence Committee and subcommittee chairs in both the House Armed Services Committee and the Science and Space Committee. He held a commission in the United States Air Force Reserve attaining the rank of major and serving as a Judge Advocate General (JAG). A 1972 graduate of the University of Oklahoma, Mr. McCurdy received his J.D. in 1975 from Oklahoma's Law School. He also studied international economics at the University of Edinburgh, Scotland, as a Rotary International Graduate Fellow.

Thomas A. Moore has been a Director of the Company since October 2001. He was President and Chief Executive Officer of Biopure Corporation, a leading developer, manufacturer and marketer of oxygen therapeutics for the treatment of anemia and other applications, from 2002 to 2004. Prior to joining Biopure in 2002, Mr. Moore was President and Chief Executive Officer of Nelson Communications Worldwide, one of the largest providers of healthcare marketing services globally. Mr. Moore was President of Procter & Gamble's worldwide prescription and over-the-counter healthcare products business, and Group Vice President of the Procter & Gamble Company. He is a trustee of the Institute for Cancer Prevention, a non-profit organization that researches the nutritional and environmental factors in cancer and other diseases. Mr. Moore holds a B.A. in History from Princeton University.

George M. Naimark, Ph.D., has been a Director of the Company since July 1999. He is President of Naimark & Barba, Inc., a management consultancy, since September 1966, and Naimark & Associates, Inc. a private healthcare consulting organization, since February 1994. Dr. Naimark has more than 30 years of experience in the pharmaceutical, diagnostic and medical device industries. His experience includes management positions in research and development, new product development and quality control. In addition, Dr. Naimark has authored books on patent law, communications and business, as well as many articles that appeared in general business, marketing, scientific and medical journals and was the editor of a medical journal. He received his Ph.D. from the University of Delaware in 1951, and received a B.S. and M.S. from Bucknell University in 1947 and 1948, respectively.

Mark Novitch, M.D., has been a Director of the Company since June 1994. He retired as Vice Chairman and Chief Compliance Officer of the Upjohn Company in December 1993. Prior to joining Upjohn in 1985, he was Deputy Commissioner of the United States Food and Drug Administration. Dr. Novitch is a Director of Guidant Corporation, a supplier of cardiology and minimally invasive surgery products; Neurogen Corporation, a biopharmaceutical firm focused on central nervous system disorders; and Kos Pharmaceuticals, Inc., a developer of pharmaceutical products for cardiovascular and respiratory conditions. He graduated from Yale University and received his M.D. from New York Medical College.

#### **Audit Committee of the Board**

In 2003, the Audit Committee of the Board of Directors was comprised of Marilyn G. Breslow, Edwin D. Bransome, Jr., M.D., Alan J. Dalby, David K. McCurdy, Thomas A. Moore, George M. Naimark, Ph.D., and Mark Novitch, M.D. All of the members of the Audit Committee are independent, as such term is defined by Section 121A of the American Stock Exchange listing standards. The Board of Directors does not have an "audit committee financial expert," within the meaning of applicable regulations of the SEC, serving on its Audit Committee. The Board of Directors believes that one or more members of the Audit Committee satisfy the financial sophistication requirement of the American Stock Exchange and are capable of (i) understanding generally accepted accounting principles ("GAAP") and financial statements, (ii) assessing the application of GAAP in connection with our accounting for estimates, accruals and reserves, (iii) analyzing and evaluating our financial statements, (iv) understanding our internal controls and procedures for financial reporting, and (v) understanding audit committee functions, all of which are attributes of an audit committee financial expert. However, the Board of Directors believes that these members may not have obtained these attributes through the experience specified, and therefore may not qualify as an "audit committee financial expert."

#### **Executive Officers**

The following table identifies our current executive officers:

<b>Name</b>	<b>Age</b>	<b>Capacities In Which Served</b>	<b>In Current Positions Since</b>
Kenneth I. Moch	49	Chairman of the Board, President and Chief Executive Officer	June 2001 December 1998
Robert C. deGroof, Ph.D. <sup>(1)</sup>	59	Senior Vice President Scientific Affairs	March 2000
Judith S. Hedstrom <sup>(2)</sup>	47	Senior Vice President Corporate Development	February 2002
Elizabeth A. O'Dell <sup>(3)</sup>	43	Vice President, Finance Secretary and Treasurer	October 1993

(1) Robert C. deGroof, Ph.D., joined Alteon as Senior Vice President, Scientific Affairs, in March 2000. From April 1990 to February 2000, he was the President of Keystone Scientific Management. Dr. deGroof previously served as Director of Regulatory Affairs, World Wide Development Operations, for Bristol-Myers Squibb from July 1987 to March 1990. From November 1979 to July 1987, he served in various medical and regulatory positions within Johnson & Johnson. Prior to joining the industry, Dr. deGroof was an Assistant Professor of Pharmacology at Jefferson Medical College, Thomas Jefferson University, was the recipient of a National Institutes of Health postdoctoral fellowship at the University of Pennsylvania and was a Grass Fellow in Neurophysiology at the Marine Biological Laboratory, Woods Hole. Dr. deGroof received his B.S. at the University of Florida in 1967 and his Ph.D. in Physiology and Pharmacology from Duke University in 1973.

(2) Judith S. Hedstrom was appointed Senior Vice President, Corporate Development, in February 2002. From January 1996 to February 2002, she was a leader of the Pharmaceuticals and Medical Products Practice at McKinsey & Company, Inc., a global consulting firm, where she provided strategic advice on R&D, marketing, sales and business development matters to many biotechnology and pharmaceutical clients. Prior to that, Ms. Hedstrom was Vice President of Business Development at APACHE Medical Systems from April 1993 to January 1996. From June 1988 to April 1993, she was a Senior Consultant with The Wilkerson Group, formerly a leading healthcare consulting firm. Ms. Hedstrom received her B.A. and M.B.A. degrees from the University of Chicago.

(3) Elizabeth A. O'Dell has been Vice President, Finance, Secretary and Treasurer since October 1993. She served as Alteon's Director of Finance from February 1993 to September 1993 and as Controller of Alteon from February 1992 to February 1993. Ms. O'Dell was the Controller of Radiodetection Corporation from November 1991 to January 1992. From March 1987 to November 1991, she held various positions at Kratos Analytical, Inc. Prior to that, she served for five years in public accounting at PricewaterhouseCoopers LLP and Deloitte & Touche LLP. Ms. O'Dell received her B.B.A. and M.B.A. from Pace University. She is also a CPA in New Jersey.

Executive officers are elected annually and serve at the pleasure of the Board of Directors.

### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of ownership and changes in ownership on Forms 3, 4 and 5 with the SEC. Officers, directors and greater than 10% stockholders are required by SEC regulation to furnish us with copies of all Forms 3, 4 and 5 they file.

Based solely on our review of the copies of such forms we have received and written representations from certain reporting persons that they were not required to file Forms 5 for specified fiscal years, we believe that all of our officers, directors, and greater than 10% beneficial owners complied with all filing requirements applicable to them with respect to transactions during fiscal 2003.

### Code of Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller. We have posted this Code on our website at [www.alteon.com](http://www.alteon.com).

### Item 11. Executive Compensation.

The following table sets forth certain information concerning the annual and long-term compensation for the fiscal years ended December 31, 2003, 2002 and 2001, of our Chief Executive Officer and three other highly compensated executive officers of Alteon who were serving as executive officers at December 31, 2003, or who served as executive officers during the fiscal year ended December 31, 2003 (collectively, the "Named Officers"):

**Summary Compensation Table**

Name and Principal Position	Year	Annual Compensation		Long-Term Compensation Stock Option Awards	All Other Compensation
		Salary	Bonus	(Number of Shares)	
Kenneth I. Moch President and Chief Executive Officer	2003	\$ 353,600	\$ 200,000 <sup>(1)</sup>	100,000	\$ 3,000 <sup>(2)</sup>
	2002	340,000	—	100,000	2,750 <sup>(2)</sup>
	2001	326,025	100,000 <sup>(3)</sup>	500,000	2,625 <sup>(2)</sup>
Robert C. deGroof, Ph.D. Senior Vice President Scientific Affairs	2003	\$ 234,780	\$ 68,333	75,000	\$ 41,385 <sup>(4)</sup>
	2002	225,750	—	175,000	43,514 <sup>(5)</sup>
	2001	215,000	50,000 <sup>(3)</sup>	75,000	35,253 <sup>(6)</sup>
Judith S. Hedstrom <sup>(7)</sup> Senior Vice President Corporate Development	2003	\$ 223,600	\$ 78,333 <sup>(8)</sup>	150,000	\$ 3,000 <sup>(2)</sup>
	2002	188,125	15,000 <sup>(9)</sup>	275,000	2,750 <sup>(2)</sup>
Elizabeth A. O'Dell Vice President, Finance Secretary and Treasurer	2003	\$ 176,800	\$ 30,000 <sup>(10)</sup>	150,000	\$ 3,000 <sup>(2)</sup>
	2002	170,000	—	30,000	2,750 <sup>(2)</sup>
	2001	150,800	15,000 <sup>(3)</sup>	11,667	2,625 <sup>(2)</sup>

(1) Includes a \$100,000 deferred performance bonus relating to the year ended December 31, 2003, paid in 2004.

(2) Represents matching 401(k) contributions we paid on behalf of the executive officer.

(3) Represents a deferred performance bonus relating to the year ended December 31, 2001, paid in 2002.

(4) Includes a housing allowance of \$30,000, medical premiums of \$7,885 and matching 401(k) contributions of \$3,500.

(5) Includes a housing allowance of \$30,000, medical premiums of \$10,514 and matching 401(k) contributions of \$3,000.

(6) Includes a housing allowance of \$30,000, medical premiums of \$2,628 and matching 401(k) contributions of \$2,625.

(7) Ms. Hedstrom began serving as Senior Vice President, Corporate Development, in February 2002.

(8) Includes a \$45,000 deferred performance bonus relating to the year ended December 31, 2003, paid in 2004.

(9) Represents a deferred performance bonus relating to the year ended December 31, 2002, paid in 2003.

(10) Includes a \$20,000 deferred performance bonus relating to the year ended December 31, 2003, paid in 2004.

The following tables set forth certain information concerning grants and exercises of stock options during the fiscal year ended December 31, 2003, to and by the Named Officers:

#### Option Grants in Last Fiscal Year

Name	Number of Securities Underlying Options Granted	Percentage of Total Options Granted to Employees in Fiscal 2003	Exercise or Base Price Per Share	Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term <sup>(1)</sup>	
					5%	10%
					Kenneth I. Moch	100,000
Robert C. deGroof, Ph.D.	75,000	10.2%	1.56	12/10/13	73,581	186,468
Judith S. Hedstrom	150,000	20.5%	1.56	12/10/13	147,161	372,936
Elizabeth A. O'Dell	150,000	20.5%	1.56	12/10/13	147,161	372,936

(1) The dollar amounts under these columns are the result of calculations assuming that the price of common stock on the date of the grant of the option increases at the hypothetical 5% and 10% rates set by the Securities and Exchange Commission and therefore are not intended to forecast possible future appreciation, if any, of our stock price over the option term of 10 years.

#### Aggregated Option Exercises In Last Fiscal Year and Fiscal Year-End Option Values

Name	Shares Acquired on Exercise (#)	Value Realized	Number of Securities Underlying Unexercised Options at December 31, 2003		Value of Unexercised in-the-Money Options at December 31, 2003 <sup>(1)</sup>	
			Exercisable	Unexercisable	Exercisable	Unexercisable
			Kenneth I. Moch	—	\$ —	605,308
Robert C. deGroof, Ph.D.	—	—	309,583	340,417	—	750
Judith S. Hedstrom	—	—	70,833	354,167	—	1,500
Elizabeth A. O'Dell	15,500	13,439	343,667	180,000	99,031	1,500

(1) Based on the closing price on the American Stock Exchange at December 31, 2003 (\$1.57).

#### Director Compensation

All of the directors are reimbursed for their expenses for each Board and committee meeting attended. Directors who are not compensated as Alteon employees receive \$1,500 per meeting attended in person and \$1,000 for each meeting attended by telephone for their service to the Board. Non-compensated directors also receive, upon the date of their election or re-election to the Board and on the dates of the next two Annual Meetings of Stockholders (subject to their continued service on the Board of Directors), a stock option to purchase 20,000 shares of common stock (subject to adjustment if they received stock options upon appointment to the Board between Annual Meetings of Stockholders to fill a vacancy or newly created directorship) at an exercise price equal to the fair market value of the common stock on the date of grant. Each of these options will vest and become exercisable on the date of Alteon's first Annual Meeting of Stockholders following the date of grant, subject to the director's continued service on the Board.

#### Compensation Committee Interlocks and Insider Participation

The persons who served as members of the Compensation Committee of the Board of Directors during 2003 were Alan J. Dalby, Edwin D. Bransome, Jr., M.D., Marilyn G. Breslow, David K. McCurdy, Thomas A. Moore, George M. Naimark, Ph.D., and Mark Novitch, M.D. None of the members of the Compensation Committee was an officer, former officer or employee of Alteon or had any relationship with Alteon requiring disclosure under Item 404 of Regulation S-K under the Securities Exchange Act of 1934, as amended. No executive officer has served as a director or member of the compensation committee (or other committee serving an equivalent function) of any other entity whose executive officers served as a director of Alteon or a member of our Compensation Committee.

#### Employment Agreements and Termination of Employment Arrangements with Executive Officers

Kenneth I. Moch entered into a three-year amended and restated employment agreement with Alteon as of December 15, 1998. By letter agreement dated December 3, 2001, the term of Mr. Moch's amended and restated employment agreement was extended for an additional three years to December 15, 2004. Pursuant to this letter agreement, Mr. Moch received stock options to purchase an aggregate of 500,000 shares of our common stock. Under the amended and restated employment agreement, Mr. Moch serves as our Chief Executive Officer and is entitled to an annual salary of \$300,000 (subject to annual review by the Board of Directors) plus an annual bonus awarded at the discretion of the Board of Directors. Based on the provisions of his agreement, in December 2003, the Board of Directors approved an increase in Mr. Moch's base salary to \$367,744.



Robert C. deGroof, Ph.D., entered into a three-year employment agreement with Alteon as of March 14, 2000. By letter agreement dated March 14, 2003, the term of Dr. deGroof's amended and restated employment agreement was extended for an additional three years to March 14, 2006. Pursuant to this letter agreement, Dr. deGroof received stock options to purchase an aggregate of 100,000 shares of our common stock and is entitled to an annual salary of \$234,780 (subject to annual review by the Board of Directors) plus an annual bonus awarded at the discretion of the Board of Directors. Based on the provisions of his agreement, in December 2003, the Board of Directors approved an increase in Dr. deGroof's base salary to \$250,000.

Judith S. Hedstrom entered into a three-year employment agreement with Alteon as of February 11, 2002. Under the employment agreement, Ms. Hedstrom is entitled to an annual salary of \$215,000 (subject to annual review by the Board of Directors) plus an annual bonus awarded at the discretion of the Board of Directors. Ms. Hedstrom received stock options to purchase 200,000 shares of our common stock. Pursuant to the agreement, in December 2003, the Board of Directors approved an increase in Ms. Hedstrom's base salary to \$250,000.

Elizabeth A. O'Dell, by letter agreement dated December 22, 2003, entered into an amended and restated employment agreement for an additional three years to December 31, 2006. Pursuant to this letter agreement, Ms. O'Dell received stock options to purchase an aggregate of 100,000 shares of our common stock and is entitled to an annual salary of \$182,872 (subject to annual review by the Board of Directors) plus an annual bonus awarded at the discretion of the Board of Directors.

In addition to provisions in the above-described agreements requiring each individual to maintain the confidentiality of our information and assign inventions to us, such executive officers have agreed that during the terms of their agreements and for one year thereafter, they will not compete with us by engaging in any capacity in any business that is competitive with our business. The employment agreements of Mr. Moch, Dr. deGroof, Ms. Hedstrom and Ms. O'Dell provide that either party may terminate the agreement upon 30 days' prior written notice, subject to a salary continuation obligation of Alteon if it terminates the agreements without cause. Mr. Moch and Ms. O'Dell will receive a 12-month salary continuation and Dr. deGroof and Ms. Hedstrom will receive a six-month salary continuation under such circumstances.

All employment agreements between Alteon and its Vice Presidents provide that all unvested stock options held by such Vice Presidents will vest and become exercisable immediately in the event of a change in control of Alteon.

***Change in Control Severance Benefits Plan***

In February 1996, we adopted the Alteon Inc. Change in Control Severance Benefits Plan to protect and retain qualified employees and to encourage their full attention, free from distractions caused by personal uncertainties and risks in the event of a pending or threatened change in control of Alteon. The Severance Plan provides for severance benefits to employees upon certain terminations of employment after or in connection with a change in control of Alteon as defined in the Severance Plan. Following a qualifying termination that occurs as a result of a change in control, officers of Alteon will be entitled to continuation of (i) their base salary for a period of 24 months, and (ii) all benefit programs and plans providing for health and insurance benefits for a period of up to 18 months. In addition, upon a change in control of Alteon, all outstanding unexercisable stock options held by employees will become exercisable.

***401(k) Plan***

We have a tax-qualified employee savings and retirement plan (the "401(k) Plan") covering all of our employees. Pursuant to the 401(k) Plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit (\$13,000 in 2004) and have the amount of such reduction contributed to the 401(k) Plan. The 401(k) Plan does not require that we make additional matching contributions to the 401(k) Plan on behalf of participants in the 401(k) Plan. However, in 1998, we began making discretionary contributions at a rate of 25% of employee contributions up to a maximum of 5% of their base salary. Contributions by employees to the 401(k) Plan and income earned on such contributions are not taxable to employees until withdrawn from the 401(k) Plan. The Trustees under the 401(k) Plan, at the direction of each participant, invest the assets of the 401(k) Plan.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

**Principal Stockholder Information**

The following table sets forth certain information regarding the beneficial ownership of our common stock as of February 23, 2004, except as otherwise set forth below, by each (i) person who is known to Alteon to own beneficially more than 5% of the common stock, and (ii) current director and Named Officer, including the nominees, and by all current directors and officers as a group:

Name of Beneficial Owner <sup>(1)</sup>	Amount and Nature of Beneficial Ownership <sup>(1)</sup>	Percent of Class <sup>(2)</sup>
Charles Livingston Grimes P.O. Box 136 Mendenhall, PA 19357	2,500,000 <sup>(3)</sup>	6.2%
William Harris Investors, Inc. 2 North LaSalle Street, Suite 400 Chicago, IL 60602	2,083,400 <sup>(4)</sup>	5.1%
Kenneth I. Moch	649,097 <sup>(5)</sup>	1.5%
Edwin D. Bransome, Jr., M.D.	72,500 <sup>(6)</sup>	*
Marilyn G. Breslow**	128,467 <sup>(7)</sup>	*
Alan J. Dalby**	134,998 <sup>(8)</sup>	*
David K. McCurdy	106,067 <sup>(9)</sup>	*
Thomas A. Moore**	59,000 <sup>(10)</sup>	*
George M. Naimark, Ph.D.	82,337 <sup>(11)</sup>	*
Mark Novitch, M.D.	394,667 <sup>(12)</sup>	*
Robert C. deGroof, Ph.D.	330,416 <sup>(13)</sup>	*
Judith S. Hedstrom	91,666 <sup>(14)</sup>	*
Elizabeth A. O'Dell	403,667 <sup>(15)</sup>	*
All current directors and officers as a group (11 persons)	2,452,882 <sup>(16)</sup>	5.7%

\* Less than one percent.

\*\* Nominee for election to the Board of Directors.

(1) Beneficial ownership is determined in accordance with the rules of the SEC, and generally includes voting or investment power with respect to securities. Shares of common stock subject to stock options and warrants currently exercisable or exercisable within 60 days are deemed outstanding for computing the percentage ownership of the person holding such options and the percentage ownership of any group of which the holder is a member, but are not deemed outstanding for computing the percentage ownership of any other person. Except as indicated by footnote, and subject to community property laws where applicable, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them.

(2) Applicable percentage of ownership is based on 40,472,898 shares of common stock outstanding.

(3) As set forth in Schedule 13D/A, dated August 20, 2003, filed by Mr. Grimes with the SEC.

(4) As set forth in Schedule 13G, dated February 17, 2004, filed by William Harris Investors, Inc. with the SEC.

(5) Includes 2,023 shares of common stock and 646,974 shares of common stock subject to options which were exercisable as of February 23, 2004, or which will become exercisable within 60 days after February 23, 2004, and 100 shares held by Mr. Moch's sons. Does not include options to purchase 425,001 shares of common stock which will become exercisable more than 60 days after February 23, 2004, nor options to purchase 1,150,025 shares of common stock held in trust for Mr. Moch's minor children, for which Mr. Moch's wife is the trustee and Mr. Moch disclaims beneficial ownership.

(6) Includes 10,000 shares of common stock held directly by Dr. Bransome, 2,500 shares held by his wife and 60,000 shares of common stock subject to options that were exercisable as of February 23, 2004, or which will become exercisable within 60 days after February 23, 2004. Does not include an option to purchase 20,000 shares of common stock which will become exercisable more than 60 days after February 23, 2004.

(7) Includes 128,467 shares of common stock subject to options that were exercisable as of February 23, 2004, or which will become exercisable within 60 days after February 23, 2004. Does not include an option to purchase 20,000 shares of common stock which will become exercisable more than 60 days after February 23, 2004.

(8) Includes 12,467 shares of common stock and 122,531 shares of common stock subject to options which were exercisable as of February 23, 2004, or which will become exercisable within 60 days after February 23, 2004. Does not include an option to purchase 20,000 shares of common stock which will become exercisable more than 60 days after February 23, 2004.

(9) Includes 106,067 shares of common stock subject to options which were exercisable as of February 23, 2004, or which will become exercisable within 60 days after February 23, 2004. Does not include an option to purchase 20,000 shares of common stock which will become exercisable more than 60 days after February 23, 2004.

(10) Includes 24,000 shares of common stock held directly by Mr. Moore and 35,000 shares of common stock subject to options which were exercisable as of February 23, 2004, or which will become exercisable within 60 days after February 23, 2004. Does not include an option to purchase 20,000 shares of common stock which will become exercisable more than 60 days after February 23, 2004.

(11) Includes 5,000 shares of common stock held directly by Dr. Naimark, 4,000 shares held jointly by Dr. Naimark and his wife and 73,337 shares of common stock subject to options which were exercisable as of February 23, 2004, or which will become exercisable within 60 days after February 23, 2004. Does not include an option to purchase 20,000 shares of common stock which will become exercisable more than 60 days after February 23, 2004.

(12) Includes 5,000 shares of common stock held jointly by Dr. Novitch and his wife and 389,667 shares of common stock subject to options that were exercisable as of February 23, 2004, or which will become exercisable within 60 days after February 23, 2004. Does not include an option to purchase 20,000 shares of common stock which will become exercisable more than 60 days after February 23, 2004.

(13) Includes 330,416 shares of common stock subject to options which were exercisable as of February 23, 2004, or which will become exercisable within 60 days after February 23, 2004. Does not include options to purchase 319,584 shares of common stock which will become exercisable more than 60 days after February 23, 2004.

(14) Includes 91,666 shares of common stock subject to options that were exercisable as of February 23, 2004, or which will become exercisable within 60 days after February 23, 2004. Does not include options to purchase 333,334 shares of common stock which will become exercisable more than 60 days after February 23, 2004.

(15) Includes 35,500 shares of common stock held directly by Ms. O'Dell, 2,000 shares of common stock held by Ms. O'Dell's husband and 366,167 shares of common stock subject to options which were exercisable as of February 23, 2004, or which will become exercisable within 60 days after February 23, 2004. Does not include options to purchase 167,500 shares of common stock which will become exercisable more than 60 days after February 23, 2004.

(16) Includes 2,350,292 shares of common stock subject to options which were exercisable as of February 23, 2004, or which will become exercisable within 60 days after February 23, 2004.

**Equity Compensation Plan Information**

The following table sets forth information concerning the number of outstanding options, the weighted average exercise price of those securities and the number of securities remaining to be granted under existing equity plans, whether approved or not approved by security holders, as of December 31, 2003:

<b>Plan Category</b>	<b>Number of Securities To Be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>Weighted Average Exercise Price of Outstanding Options, Warrants and Rights</b>	<b>Number of Securities Remaining Available For Future Issuance Under Existing Equity Compensation Plans</b>
Equity compensation plans approved by security holders .....	5,979,318	\$2.93	2,178,370
Equity compensation plans not approved by security holders .....	N/A	N/A	N/A
<b>Total</b> .....	<b>5,979,318</b>	<b>\$2.93</b>	<b>2,178,370</b>

**Item 13. Certain Relationships and Related Transactions.**

Not applicable.

**PART IV**

**Item 14. Principal Accountant Fees and Services.**

**Audit fees**

The following table summarizes the fees paid or payable to KPMG for services rendered for the fiscal years ended December 31, 2003 and December 31, 2002:

<b>Type of Fees</b>	<b>Fiscal Year Ended December 31, 2003</b>	<b>Fiscal Year Ended December 31, 2002</b>
Audit Fees .....	\$82,700	\$53,500
Audit-Related Fees .....	—	—
Tax Fees .....	15,250	—
All other Fees .....	—	—
<b>Total Fees</b> .....	<b>\$97,950</b>	<b>\$53,500</b>

The caption “audit fees” are fees we paid KPMG for professional services for the audit of our financial statements included in our Form 10-K, review of our financial statements included in our Form 10-Qs and for the issuance of comfort letters and/or consents in connection with registration statements. “Tax fees” are fees for tax compliance, tax advice and tax planning.

**Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services by Independent Accountants**

The Audit Committee pre-approves all audit and legally permissible non-audit services provided by the independent accountants. The Audit Committee pre-approved all services performed by the independent accountants during 2003 and 2002.

**Item 15. Financial Statements, Reports on Form 8-K and Exhibits.**

*(a) Financial Statements.*

Our audited financial statements and the Independent Auditors’ Report are appended to this Annual Report on Form 10-K. Reference is made to the “Index to Financial Statements” on page 35.

*(b) Reports on Form 8-K.*

On November 14, 2003, we filed a current report on Form 8-K, dated November 13, 2003, regarding our financial condition and results of operations for the quarter ended September 30, 2003.

On November 12, 2003, we filed a current report on Form 8-K, dated November 10, 2003, reporting the results of a pre-clinical canine study of alagebrium.

On October 20, 2003, we filed a current report on Form 8-K, dated October 15, 2003, announcing that we entered into a Stock Purchase Agreement to sell 6,016,602 shares of common stock.

*(c) Exhibits.*

The exhibits required to be filed are listed on the “Exhibit Index” attached hereto, which is incorporated herein by reference.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized this 12th day of March 2004.

ALTEON INC.

By: /s/ Kenneth I. Moch

Kenneth I. Moch

President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ Kenneth I. Moch</u> Kenneth I. Moch	Chairman of the Board, President and Chief Executive Officer (principal executive officer)	March 12, 2004
<u>/s/ Elizabeth A. O'Dell</u> Elizabeth O'Dell	Vice President, Finance, Secretary and Treasurer (principal accounting officer)	March 12, 2004
<u>/s/ Edwin D. Bransome, Jr., M.D.</u> Edwin D. Bransome, Jr., M.D.	Director	March 12, 2004
<u>/s/ Marilyn G. Breslow</u> Marilyn G. Breslow	Director	March 12, 2004
<u>/s/ Alan J. Dalby</u> Alan J. Dalby	Director	March 12, 2004
<u>/s/ David K. McCurdy</u> David K. McCurdy	Director	March 12, 2004
<u>/s/ Thomas A. Moore</u> Thomas A. Moore	Director	March 12, 2004
<u>/s/ George M. Naimark, Ph.D.</u> George M. Naimark, Ph.D.	Director	March 12, 2004
<u>/s/ Mark Novitch, M.D.</u> Mark Novitch, M.D.	Director	March 12, 2004



# Independent Auditors' Report

Form 10-K – Item 14(a)(1)

Alteon Inc.

## Index to Financial Statements and Schedules

Page

Independent Auditors' Report – KPMG LLP .....	35
Report of Independent Public Accountants – Arthur Andersen LLP .....	36
Financial Statements:	
Balance Sheets at December 31, 2003 and 2002 .....	37
Statements of Operations for the years ended December 31, 2003, 2002 and 2001 .....	38
Statements of Stockholders' Equity for the years ended December 31, 2003, 2002 and 2001 .....	39
Statements of Cash Flows for the years ended December 31, 2003, 2002 and 2001 .....	40
Notes to Financial Statements .....	41

## INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders  
Alteon Inc.:

We have audited the accompanying balance sheets of Alteon Inc. as of December 31, 2003 and 2002, and the related statements of operations, stockholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The statements of operations, stockholders' equity and cash flows of Alteon Inc. for the year ended December 31, 2001 were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements in their report dated January 22, 2002.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Alteon Inc. as of December 31, 2003 and 2002, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP

Short Hills, New Jersey  
March 3, 2004

**INFORMATION REGARDING PREDECESSOR INDEPENDENT PUBLIC ACCOUNTANTS' REPORT**

**THE FOLLOWING REPORT IS A COPY OF A PREVIOUSLY ISSUED REPORT BY ARTHUR ANDERSEN LLP ("ANDERSEN"). THE REPORT HAS NOT BEEN REISSUED BY ANDERSEN NOR HAS ANDERSEN CONSENTED TO ITS INCLUSION IN THIS ANNUAL REPORT ON FORM 10-K. THE ANDERSEN REPORT REFERS TO THE CONSOLIDATED BALANCE SHEETS AS OF DECEMBER 31, 2001 AND 2000 AND THE CONSOLIDATED STATEMENTS OF OPERATIONS, STOCKHOLDERS' EQUITY AND CASH FLOWS FOR THE YEARS ENDED DECEMBER 31, 2000 AND 1999, WHICH ARE NO LONGER INCLUDED IN THE ACCOMPANYING FINANCIAL STATEMENTS.**

**REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

To the Stockholders and Board of Directors of Alteon Inc.:

We have audited the accompanying balance sheets of Alteon Inc. (a Delaware corporation) as of December 31, 2001 and 2000, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Alteon Inc. as of December 31, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

ARTHUR ANDERSEN LLP

Roseland, New Jersey  
January 22, 2002



# B a l a n c e   S h e e t s

December 31,	2003	2002
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents .....	\$ 16,678,582	\$ 14,452,413
Short-term investments .....	—	2,986,200
Other current assets .....	225,439	143,124
Total current assets .....	16,904,021	17,581,737
Property and equipment, net .....	100,964	517,623
Restricted cash .....	250,000	—
Total assets .....	\$ 17,254,985	\$ 18,099,360
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities:</b>		
Accounts payable .....	\$ 470,841	\$ 537,394
Accrued expenses .....	1,399,712	3,258,729
Total current liabilities .....	1,870,553	3,796,123
<b>Stockholders' Equity:</b>		
Preferred stock, \$.01 par value; 1,993,329 shares authorized, and 1,174 and 1,079 shares of Series G and 3,525 and 3,241 shares of Series H issued and outstanding, as of December 31, 2003 and December 31, 2002, respectively .....	47	43
Common stock, \$.01 par value; 80,000,000 shares authorized, and 40,467,148 and 33,600,841 shares issued and outstanding as of December 31, 2003 and December 31, 2002, respectively .....	404,671	336,008
Additional paid-in capital .....	202,598,573	183,341,416
Accumulated deficit .....	(187,618,859)	(169,375,594)
Accumulated other comprehensive income .....	—	1,364
Total stockholders' equity .....	15,384,432	14,303,237
Total liabilities and stockholders' equity .....	\$ 17,254,985	\$ 18,099,360

The accompanying notes are an integral part of these financial statements.

# S t a t e m e n t s   o f   O p e r a t i o n s

Year Ended December 31,	2003	2002	2001
Revenues:			
Investment income .....	\$ 179,006	\$ 409,853	\$ 451,518
Expenses:			
Research and development (which includes non-cash variable stock compensation expense/(benefit) in 2003, 2002 and 2001 of \$20,019, \$(93,516) and \$164,988, respectively) .....	9,929,704	14,992,418	8,461,476
General and administrative (which includes non-cash variable stock compensation expense/(benefit) in 2003, 2002 and 2001 of \$0, \$(1,315,635) and \$657,295, respectively) .....	5,046,357	2,945,846	4,760,747
Total expenses .....	14,976,061	17,938,264	13,222,223
Loss before income tax benefit .....	(14,797,055)	(17,528,411)	(12,770,705)
Income tax benefit .....	344,637	646,500	1,186,921
Net loss .....	(14,452,418)	(16,881,911)	(11,583,784)
Preferred stock dividends .....	3,790,847	3,485,042	3,203,906
Common stock warrant deemed dividends .....	—	—	209,528
Net loss applicable to common stockholders .....	<u>\$ (18,243,265)</u>	<u>\$ (20,366,953)</u>	<u>\$ (14,997,218)</u>
Basic/diluted net loss per share applicable to common stockholders .....	<u>\$ (0.50)</u>	<u>\$ (0.64)</u>	<u>\$ (0.61)</u>
Weighted average common shares used in computing basic/diluted net loss per share .....	<u>36,189,655</u>	<u>31,793,466</u>	<u>24,555,885</u>

The accompanying notes are an integral part of these financial statements.



**S t a t e m e n t s o f S t o c k h o l d e r s ' E q u i t y**

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income/(Loss)</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
Balances at								
DECEMBER 31, 2000	3,651	\$37	22,399,660	\$223,997	\$145,241,265	\$(134,011,423)	\$ (870)	\$ 11,453,006
Net loss	—	—	—	—	—	(11,583,784)	—	(11,583,784)
Change in unrealized gains/(losses)	—	—	—	—	—	—	10,335	10,335
Comprehensive loss	—	—	—	—	—	—	—	(11,573,449)
Issuance of Series G and H preferred stock dividends	321	3	—	—	3,203,903	(3,203,906)	—	—
Exercise of employee stock options	—	—	415,186	4,151	428,698	—	—	432,849
Public offering of common stock	—	—	4,500,000	45,000	9,365,080	—	—	9,410,080
Compensation expense related to variable plan employee stock options	—	—	—	—	822,283	—	—	822,283
Common stock warrant deemed dividends	—	—	—	—	209,528	(209,528)	—	—
Compensation expense in connection with the issuance of non-qualified stock options, stock option modifications and options granted to non-employees	—	—	—	—	326,177	—	—	326,177
DECEMBER 31, 2001	3,972	40	27,314,846	273,148	159,596,934	(149,008,641)	9,465	10,870,946
Net loss	—	—	—	—	—	(16,881,911)	—	(16,881,911)
Change in unrealized gains/(losses)	—	—	—	—	—	—	(8,101)	(8,101)
Comprehensive loss	—	—	—	—	—	—	—	(16,890,012)
Issuance of Series G and H preferred stock dividends	348	3	—	—	3,485,039	(3,485,042)	—	—
Exercise of employee stock options	—	—	121,710	1,217	120,797	—	—	122,014
Public offerings of common stock	—	—	6,164,285	61,643	21,513,373	—	—	21,575,016
Compensation benefit related to variable plan employee stock options	—	—	—	—	(1,409,151)	—	—	(1,409,151)
Compensation expense in connection with the issuance of non-qualified stock options granted to non-employees	—	—	—	—	34,424	—	—	34,424
DECEMBER 31, 2002	4,320	43	33,600,841	336,008	183,341,416	(169,375,594)	1,364	14,303,237
Net loss	—	—	—	—	—	(14,452,418)	—	(14,452,418)
Change in unrealized gains/(losses)	—	—	—	—	—	—	(1,364)	(1,364)
Comprehensive loss	—	—	—	—	—	—	—	(14,453,782)
Issuance of Series G and H preferred stock dividends	379	4	—	—	3,790,843	(3,790,847)	—	—
Exercise of employee stock options	—	—	51,688	517	54,937	—	—	55,454
Public offerings of common stock	—	—	6,757,146	67,571	15,360,705	—	—	15,428,276
Exercise of warrants	—	—	57,473	575	(575)	—	—	—
Compensation expense related to variable plan employee stock options	—	—	—	—	20,019	—	—	20,019
Compensation expense in connection with the issuance of non-qualified stock options granted to non-employees	—	—	—	—	31,228	—	—	31,228
DECEMBER 31, 2003	4,699	\$47	40,467,148	\$404,671	\$202,598,573	\$(187,618,859)	\$ —	\$ 15,384,432

The accompanying notes are an integral part of these financial statements.

# S t a t e m e n t s   o f   C a s h   F l o w s

Year Ended December 31,	2003	2002	2001
Cash flows from operating activities:			
Net loss .....	\$ (14,452,418)	\$ (16,881,911)	\$ (11,583,784)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	502,826	637,162	636,565
Stock compensation expense .....	31,228	34,424	326,177
Non-cash compensation expense/(benefit) related to variable plan employee stock options .....	20,019	(1,409,151)	822,283
Changes in operating assets and liabilities:			
Other assets .....	(82,315)	1,254,456	340,895
Accounts payable and accrued expenses .....	(1,925,570)	1,433,990	425,775
Net cash used in operating activities .....	(15,906,230)	(14,931,030)	(9,032,089)
Cash flows from investing activities:			
Capital expenditures .....	(86,167)	(45,109)	(50,159)
Purchases of marketable securities .....	(3,015,164)	(18,020,917)	(16,743,570)
Maturities of marketable securities .....	6,000,000	21,503,000	16,632,000
Restricted cash .....	(250,000)	—	—
Net cash provided by/(used in) investing activities .....	2,648,669	3,436,974	(161,729)
Cash flows from financing activities:			
Net proceeds from issuance of common stock .....	15,428,276	21,575,016	9,410,080
Net proceeds from exercise of employee stock options .....	55,454	122,014	432,849
Net cash provided by financing activities .....	15,483,730	21,697,030	9,842,929
Net increase in cash and cash equivalents .....	2,226,169	10,202,974	649,111
Cash and cash equivalents, beginning of year .....	14,452,413	4,249,439	3,600,328
Cash and cash equivalents, end of year .....	\$ 16,678,582	\$ 14,452,413	\$ 4,249,439

The accompanying notes are an integral part of these financial statements.

**NOTE 1 — Summary of Significant Accounting Policies**

*Organization and Business*

Alteon Inc. (“Alteon” or the “Company”) is a product-based biopharmaceutical company engaged in the discovery and development of small molecule drugs to reverse or slow down diseases of aging and complications of diabetes. The Company’s product candidates represent novel approaches to some of the largest pharmaceutical markets. The Company conducts its business in one operating segment. Alteon’s proprietary technology focuses on Advanced Glycation End-products (“A.G.E.s”). A.G.E.s ultimately form crosslinks with adjacent proteins, leading to a loss of flexibility and function in body tissues, vessels and organs. All of the Company’s products are in research or development, and no revenues have been generated from product sales.

Alagebrium chloride (formerly ALT-711) is our lead product candidate and we believe the only A.G.E. Crosslink Breaker in advanced human testing. In February, the United States Adopted Name (USAN) Council approved alagebrium chloride as the generic name of the chemical compound formerly known as ALT-711. Several Phase 2 clinical trials have been completed: the DIAMOND (**D**istensibility **I**mprovement and **R**emodeling in **D**ialstolic Heart Failure) trial in diastolic heart failure (“DHF”); the SAPPHIRE (**S**ystolic **A**nd **P**ulse **P**ressure **H**emodynamic **I**mprovement by **R**estoring **E**lasticity) and SILVER (**S**ystolic Hypertension **I**nteraction with **L**eft **V**entricular **R**emodeling) trial in systolic hypertension; and a trial in cardiovascular compliance. Based on evidence of alagebrium’s demonstrated efficacy and biological activity in these Phase 2 clinical trials, as well as a strong and consistent safety profile, Alteon is proceeding with Phase 2 development of alagebrium in two major cardiovascular indications, systolic hypertension and heart failure in the first half of 2004. The first of the Phase 2 trials was initiated in March 2004, SPECTRA (**S**ystolic **P**ressure **E**fficacy and **S**afety **T**rial of **A**lagebrium), a Phase 2b trial in patients with systolic hypertension. Importantly, there are no currently marketed cardiovascular drugs that can work directly on the stiffening of the vasculature that leads to systolic hypertension and heart failure.

As Alteon continues clinical development of alagebrium, it will determine if it is appropriate to retain development and marketing rights for one or several indications in North America, while at the same time continuing to evaluate potential corporate partnerships for the further development and ultimate marketing of the compound in other territories throughout the world. The Company believes that alagebrium may address the cardiovascular, diabetes and primary care physician markets.

Alteon plans to continue to explore the use of topical A.G.E. Crosslink Breakers in skin and photoaging, as a result of its recent evaluation of ALT-744’s positive activity in this area. The Company will focus efforts on bringing forward other crosslink breaker compounds with more attractive formulation characteristics than those of ALT-744 to address the pharmaceutical market for skin and photoaging.

The Company’s business is subject to significant risks including, but not limited to, (i) the ability to obtain funding, (ii) the risks inherent in its research and development efforts, including clinical trials, (iii) uncertainties associated with obtaining and enforcing its patents and with the patent rights of others, (iv) the lengthy, expensive and uncertain process of seeking regulatory approvals, (v) uncertainties regarding government healthcare reforms and product pricing and reimbursement levels, (vi) technological change and competition, (vii) manufacturing uncertainties, and (viii) dependence on collaborative partners and other third parties. Even if the Company’s product candidates appear promising at an early stage of development, they may not reach the market for numerous reasons. Such reasons include the possibilities that the products will prove ineffective or unsafe during clinical trials, will fail to receive necessary regulatory approvals, will be difficult to manufacture on a large scale, will be uneconomical to market or will be precluded from commercialization by proprietary rights of third parties.

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Estimates are used for, but not limited to: accrued expenses, income tax valuation allowances and assumptions utilized within the Black-Scholes options pricing model and the model itself. Accounting estimates require the use of judgment regarding uncertain future events and their related effects and, accordingly, may change as additional information is obtained.

*Cash and Cash Equivalents and Short-Term Investments*

Cash and cash equivalents include cash and highly liquid investments which have a maturity of less than three months at the time of purchase. Short-term investments are considered available-for-sale and are recorded at fair value, as determined by quoted market prices, with changes in fair value recorded as a component of accumulated other comprehensive income/(loss). As of December 31, 2002, short-term investments totaling \$2,986,200 were invested in debt instruments of the United States government and government agency funds. The cost of short-term investments was \$2,984,836 at December 31, 2002.

*Financial Instruments*

Financial instruments reflected in the Balance Sheets are recorded at cost which approximates fair value for cash equivalents, short-term investments, restricted cash, accounts payable and other current liabilities.

*Property and Equipment*

Property and equipment are stated at cost. Depreciation and amortization are computed using the straight-line method over the useful lives of owned assets, which range from three to five years.

**Impairment of Long-Lived Assets**

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the asset to the future undiscounted net cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets and would be charged to operations.

**Research and Development**

Expenditures for research and development are charged to operations as incurred.

**Stock-Based Compensation**

The Company accounts for employee stock-based compensation and awards issued to non-employee directors under APB Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations, under which no compensation cost (excluding those options granted below fair market value) has been recognized. Stock option awards issued to consultants and contractors are accounted for in accordance with SFAS No. 123, "Accounting for Stock-Based Compensation" and Emerging Issues Task Force Issue No. 96-18, "Accounting for Equity Instruments that are Issued To Other Than Employees for Acquiring or In Conjunction with Selling Goods or Services." In March 2000, the Financial Accounting Standards Board ("FASB") released Interpretation No. 44 ("FIN 44"), "Accounting for Certain Transactions Involving Stock Compensation, An Interpretation of APB Opinion No. 25." The interpretation became effective on July 1, 2000, but in some circumstances applies to transactions that occurred prior to the effective date. Under the interpretation, stock options that are repriced must be accounted for as variable-plan arrangements until the options are exercised, forfeited or expire. This requirement applies to any options repriced after December 15, 1998. (See Note 8.)

If the Company had applied the fair value recognition provisions of SFAS No. 123 to its employee and director option grants, the Company's pro forma net loss and net loss per share applicable to common stockholders for 2003, 2002 and 2001 would be as follows:

<b>Year Ended December 31,</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>
Net loss as reported .....	\$ (14,452,418)	\$ (16,881,911)	\$ (11,583,784)
Add: Variable non-cash employee and director stock compensation expense/(benefit) recognized in the Statements of Operations .....	20,019	(1,409,151)	822,283
Less: Total stock-based employee and director compensation expense determined under fair value method .....	(1,316,721)	(1,892,584)	(2,029,445)
Pro forma net loss .....	\$ (15,749,120)	\$ (20,183,646)	\$ (12,790,946)
Preferred stock dividends .....	3,790,847	3,485,042	3,203,906
Common stock warrant deemed dividends .....	—	—	209,528
Pro forma net loss applicable to common stockholders .....	\$ (19,539,967)	\$ (23,668,688)	\$ (16,204,380)
Net loss per share applicable to common stockholders:			
Basic/diluted as reported .....	\$ (0.50)	\$ (0.64)	\$ (0.61)
Basic/diluted pro forma .....	\$ (0.54)	\$ (0.74)	\$ (0.66)

The fair value of each stock option grant, for recognition or disclosure purposes, is calculated on the date of grant using the Black-Scholes option pricing model with the following assumptions used for grants in 2003, 2002 and 2001, respectively: weighted average risk free interest rate of 3.24%, 2.90% and 4.0%, respectively; weighted average expected life of 5.31, 4.49 and 4.75 years, respectively, and the contractual life for grants to consultants and contractors; expected dividend yield of 0%; and weighted average expected volatility of 132.35%, 108.98% and 110.39%, respectively.

**Income Taxes**

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and net operating loss and tax credit carryforwards. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date.

**Net Loss Per Share Applicable to Common Stockholders**

Basic net loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares outstanding during the year. Diluted net loss per share is the same as basic net loss per share applicable to common stockholders, since the assumed exercise of stock options and warrants and the conversion of preferred stock would be antidilutive. The amount of common stock equivalents excluded from the calculation as of December 31, 2003, 2002 and 2001, was 36,969,371, 28,870,120 and 15,135,350 shares, respectively.

**NOTE 2 — Liquidity**

The Company has devoted substantially all of its resources to research, drug discovery and development programs. To date, it has not generated any revenues from the sale of products and does not expect to generate any such revenues for a number of years, if at all. As a result, Alteon has incurred operating losses since inception, has an accumulated deficit of \$187,618,859 at December 31, 2003, and expects to incur operating losses, potentially greater than losses in prior years, for a number of years.

The Company has financed its operations through proceeds from the sale of common and preferred equity securities, revenue from former collaborative relationships, reimbursement of certain of our research and development expenses by collaborative partners, investment income earned on cash and cash equivalent balances and short-term investments and the sale of a portion of the Company's New Jersey state net operating loss carryforwards.

As of December 31, 2003, the Company had working capital of \$15,033,468, including \$16,678,582 of cash and cash equivalents. During 2003, the Company sold 6,757,146 shares of common stock, raising net proceeds of \$15,428,276. (See Note 8.) In connection with an October 2003 common stock offering, the Stock Purchase Agreement, as amended, provides that the Company could sell up to a total of 1,559,456 additional shares of common stock at \$1.85 per share for \$2,884,994 in gross proceeds to the investors who elect to purchase shares on April 20, 2004, which is 120 business days after the initial closing. The investors are not obligated and at their discretion may elect not to purchase additional shares. The Company's cash used in operations for the years ended December 31, 2003, 2002 and 2001 was \$15,906,230, \$14,931,030 and \$9,032,089, respectively. The Company expects to utilize cash to fund its operations and to initiate new Phase 2 trials in systolic hypertension and diastolic dysfunction in heart failure during the first half of 2004, which are expected to continue into 2005. The first of the Phase 2 trials was initiated in March 2004, SPECTRA, a Phase 2b trial in patients with systolic hypertension. Based on the projected spending levels for the Company, including these trials, the Company does not currently have adequate cash and cash equivalents to complete the trials or complete the 2004 fiscal year and therefore will require additional funding during 2004 and 2005. As a result, throughout 2004, the Company will monitor its liquidity position and the status of its clinical trials. If the Company is unsuccessful in its efforts to raise additional funds through the sale of additional equity securities, Alteon will be required to significantly reduce or curtail its research and product development activities, including the number of patients enrolled in the trials and other operations if its level of cash and cash equivalents fall below pre-determined levels. The Company has the intent and ability to quickly and significantly reduce the cash burn rate, if necessary, as it has limited fixed commitments. The Company believes that such curtailment actions, if needed, will enable Alteon to fund its operations into early 2005.

The Company will require, over the long-term, substantial new funding to pursue development and commercialization of alagebrium and its other product candidates and continue its operations. The Company believes that satisfying these capital requirements over the long-term will require successful commercialization of its product candidates. However, it is uncertain whether any products will be approved or will be commercially successful. The amount of the Company's future capital requirements will depend on numerous factors, including the progress of its research and development programs, the conduct of pre-clinical tests and clinical trials, the development of regulatory submissions, the costs associated with protecting patents and other proprietary rights, the development of marketing and sales capabilities and the availability of third-party funding.

Because of Alteon's short-term and long-term capital requirements, the Company, as stated above, may seek access to the public or private equity markets. This may have the effect of materially diluting the current holders of the Company's outstanding stock. The Company may also seek additional funding through corporate collaborations and other financing vehicles, potentially including off-balance sheet financing through limited partnerships or corporations. There can be no assurance that such funding will be available at all or on terms acceptable to Alteon. If Alteon obtains funds through arrangements with collaborative partners or others, the Company may be required to relinquish rights to certain of its technologies or product candidates. If the Company is unable to obtain the necessary funding, it may need to cease operations.

**NOTE 3 — Property and Equipment**

December 31,	2003	2002
Laboratory equipment .....	\$ 24,650	\$ 1,183,034
Furniture and equipment .....	140,561	699,020
Computer equipment .....	138,850	442,145
Leasehold improvements .....	—	5,215,069
	304,061	7,539,268
Less: Accumulated depreciation & amortization .....	(203,097)	(7,021,645)
	<u>\$ 100,964</u>	<u>\$ 517,623</u>

Depreciation and amortization expense was \$502,826, \$637,162 and \$636,565 for the years ended December 31, 2003, 2002 and 2001, respectively. The leasehold improvements and certain other equipment, all fully depreciated, were written off at December 31, 2003 at the end of the Company's former facility lease. (See Note 7.)

**NOTE 4 — Collaborative Research and Development Agreement**

On November 6, 2002, Alteon entered into an agreement, effective as of April 15, 2002, with The Picower Institute for Medical Research ("The Picower Institute"), which terminated its License Agreement dated as of September 5, 1991. Pursuant to this termination agreement, The Picower Institute assigned to Alteon all of its patents, patent applications and other technology related to A.G.E.'s and Alteon agreed to prosecute and maintain the patents and patent applications. Alteon will pay The Picower Institute royalties on any sales of products falling within the claims of these patents and patent applications until they expire or are allowed to lapse.

Effective as of August 5, 2002, Alteon entered into a letter agreement with Yamanouchi Pharmaceutical Co. Ltd. ("Yamanouchi"), which terminated its License Agreement dated as of June 16, 1989. Pursuant to the letter agreement, for a period of fifteen years, Alteon will pay Yamanouchi royalties on any sales of pimagedine or pimagedine products in the territory covered by the License Agreement.

**NOTE 5 — Other Development Agreements**

Alteon has entered into a number of licensing and collaboration agreements relating to the development and distribution of its A.G.E.-related technology. Pursuant to an agreement with Rockefeller University, the Company has exclusive, royalty-free, worldwide and perpetual rights to the technology and inventions relating to A.G.E.s and other protein crosslinking, including those relating to the complications of aging and diabetes.

Alteon has also entered into an exclusive licensing arrangement with Roche Diagnostics GmbH for Alteon's technology for diagnostic applications, and also entered into clinical testing and distribution agreements with Gamida for Life ("Gamida"), which grant Gamida the exclusive right to distribute pimagedine, if successfully developed and approved for marketing, in Israel, Bulgaria, Cyprus, Jordan and South Africa. All of these agreements will entitle Alteon to receive royalties on sales if any products covered by the agreements are developed and sold.

Alteon's commercial partners may develop, either alone or with others, products that compete with the development and marketing of the Company's products. Competing products, either developed by the commercial partners or to which the commercial partners have rights, may result in their withdrawal of support with respect to all or a portion of the Company's technology, which could have a material adverse effect on the Company's future results of operations.

The Company has also entered into various arrangements with independent research laboratories to conduct studies in conjunction with the development of the Company's technology. The Company pays for this research and receives certain rights to inventions or discoveries that may arise from this research.

**NOTE 6 — Accrued Expenses**

Accrued expenses consisted of the following:

December 31,	2003	2002
Clinical trial expense .....	\$ 793,485	\$ 2,706,678
Professional fees .....	216,537	204,723
Payroll and related expenses .....	239,997	106,629
Rent expense .....	21,953	45,761
Patent fees .....	64,608	107,187
Other .....	63,132	87,751
	\$ 1,399,712	\$ 3,258,729

**NOTE 7 — Contingencies and Commitments**

*Commitments*

The Company's lease for its office and laboratory space in Ramsey, New Jersey, expired on November 1, 2003, and was extended through January 31, 2004. Alteon signed a three-year lease, commencing December 1, 2003, for 10,800 square feet of office space in Parsippany, New Jersey. Annual rent over the term of the lease ranges from approximately \$260,000 in the first year to \$280,000 in the third year. As a provision of the lease, Alteon provided a letter of credit, which is collateralized with a \$250,000 restricted certificate of deposit. As of December 31, 2003, future minimum rentals under operating leases, including office equipment, that have initial or remaining non-cancelable terms in excess of one year are as follows:

	Operating Leases
2004 .....	\$ 303,377
2005 .....	314,207
2006 .....	325,037
2007 .....	4,249
Thereafter .....	—
	\$ 946,870

Rent expense for the years ended December 31, 2003, 2002 and 2001, was \$674,493, \$604,690 and \$599,655, respectively.

The Company has employment agreements with its executive officers, which provide for salary continuation if Alteon terminates an agreement without cause.

**NOTE 8 — Stockholders' Equity**

*Common/Preferred Stock Issuances*

In October 2003, Alteon completed a public offering of 4,457,146 shares of common stock at \$1.75 per share, which provided net proceeds of \$7,772,331. The Stock Purchase Agreement, as amended, provides that the Company could sell up to a total of 1,559,456 additional shares of common stock at \$1.85 per share for \$2,884,994 in gross proceeds to the investors who elect to purchase shares on April 20, 2004, which is 120 business days after the initial closing. The investors are not obligated and at their discretion may elect not to purchase additional shares.

In July 2003, warrants for 87,462 shares of common stock were exercised in a "net" exercise transaction in which the exercise price was paid by cancellation of 29,989 shares of common stock issuable upon the exercise, for a net issuance of 57,473 shares. The shares canceled in payment of the exercise were valued at the average of the closing prices on the American Stock Exchange for the 20 business days prior to the exercise of the warrants.



## Notes to Financial Statements

In March 2003, Alteon completed a public offering of 2,300,000 shares of common stock at \$3.50 per share, which provided net proceeds of \$7,655,945.

In December 2002, Alteon completed a public offering of 1,714,285 shares of common stock at \$1.75 per share, which provided net proceeds of \$2,964,495. In connection with this offering, certain previously issued warrants were repriced from \$2.25 to \$1.75 per share pursuant to antidilution provisions connected to the warrants.

In January 2002, Alteon completed a public offering of 4,450,000 shares of common stock at \$4.25 per share, which provided net proceeds of \$18,610,521.

In July 2001, Alteon completed a public offering of 4,500,000 shares of common stock at \$2.25 per share, which provided net proceeds of \$9,410,080. In connection with this offering, certain previously issued warrants were repriced from \$3.40 to \$2.25 per share pursuant to antidilution provisions connected to the warrants.

In connection with a 2000 offering of common stock, warrants to purchase 1,133,636 shares of common stock were issued and 1,046,174 are outstanding as of December 31, 2003. In connection with subsequent offerings, the exercise price of 953,890 of the warrants was adjusted to \$1.75 per share, which could be adjusted further if more common stock is sold below \$1.75 per share, and the exercise price of 92,284 of the warrants was adjusted to \$2.25 per share, which is not subject to further adjustment upon the sale of more common stock.

In December 1997, the Company and Genentech, Inc. ("Genentech") entered into a stock purchase agreement pursuant to which Genentech agreed to buy shares of Common Stock, Series G Preferred Stock and Series H Preferred Stock. In December 1997, Genentech purchased Common Stock and Series G Preferred Stock for an aggregate purchase price of \$15,000,000. On July 27, 1998 and October 1, 1998, Genentech purchased \$8,000,000 and \$14,544,000, respectively, of Series H Preferred Stock. As of December 31, 2003, 2002 and 2001, respectively, \$3,790,847, \$3,485,042 and \$3,203,906 of Preferred Stockholder dividends were recorded. Series G Preferred Stock and Series H Preferred Stock dividends are payable quarterly in shares of preferred stock at a rate of 8.5% of the accumulated balance. Each share of Series G Preferred Stock and Series H Preferred Stock is convertible, upon 70 days' prior written notice, into the number of shares of common stock determined by dividing \$10,000 by the average of the closing sales price of the common stock, as reported on the American Stock Exchange, for the 20 business days immediately preceding the date of conversion.

In connection with an April 1997 convertible preferred stock offering, warrants to purchase 60,000 shares of common stock at an exercise price of \$4.025 per share were issued and are outstanding as of December 31, 2003.

### Stock Option Plan

The Company has established two stock option plans for its employees, officers, directors, consultants and independent contractors. Options to purchase up to 4,192,000 shares of the Company's common stock may be granted under the first plan, and options to purchase up to 7,000,000 shares of the Company's common stock may be granted under the second plan.

The plans are administered by a committee of the Board of Directors, which may grant either nonqualified or incentive stock options. The committee determines the exercise price and vesting schedule at the time the option is granted. Options vest over various periods and may expire no later than 10 years from date of grant. Each option entitles the holder to purchase one share of common stock at the indicated exercise price. The plans also provide for certain antidilution and change in control rights, as defined.

The following table summarizes the activity in the Company's stock options:

Options	Weighted Average Grant Date Exercise Price	Weighted Average Grant Date Fair Value
Balance, December 31, 2000	5,254,819	\$ 4.02
Granted at market price	873,942	3.13
Exercised	(415,186)	1.04
Canceled	(1,008,269)	8.53
Balance, December 31, 2001	4,705,306	\$ 3.15
Granted at market price	676,400	2.94
Granted above market price	250,000	1.95
Granted below market price	10,000	0.01
Exercised	(121,710)	1.02
Canceled	(83,717)	4.25
Balance, December 31, 2002	5,436,279	\$ 3.08
Granted at market price	812,465	2.41
Exercised	(51,688)	1.07
Canceled	(217,738)	5.13
Balance, December 31, 2003	5,979,318	\$ 2.93

Stock options exercisable at December 31, 2003, 2002 and 2001 were 4,337,316, 3,836,930 and 3,336,159, respectively, at weighted average grant date exercise prices of \$3.06, \$3.08 and \$2.95, respectively.

# Notes to Financial Statements

The following table summarizes information regarding stock options outstanding at December 31, 2003:

Range of Exercise Prices	Options Outstanding at December 31, 2003			Options Exercisable at December 31, 2003	
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.7810 - \$ 1.1250	1,785,182	4.54	\$ 0.9823	1,785,182	\$ 0.9823
1.3600 - 2.6000	1,801,678	8.68	1.9974	660,545	2.1119
2.8750 - 4.6250	1,548,080	6.77	3.8839	1,051,326	3.7781
5.0300 - 15.0000	844,378	3.53	7.2994	840,263	7.3102
\$0.7810 - \$15.0000	5,979,318	6.22	\$ 2.9315	4,337,316	\$ 3.0579

Included in options at December 31, 2003 are 1,406,667 options granted to certain executives with option exercise prices ranging from \$0.875 per share to \$4.380 per share, the fair value of the Company's common stock on the date of grant. Such options vest upon the earlier of five years after grant or upon achievement of certain Company milestones. Expenses recorded for options granted to consultants totaled \$31,228, \$34,424 and \$66,567 in 2003, 2002 and 2001, respectively.

On February 2, 1999, the Company repriced certain stock options. In accordance with FIN 44, the Company recognized a total non-cash stock compensation expense/(benefit) resulting from the repricing for the years ended December 31, 2003, 2002 and 2001 of \$20,019, \$(1,409,151) and \$822,283, respectively, which included research and development charges of \$20,019, \$(93,516) and \$164,988 and general and administrative charges of \$0, \$(1,315,635) and \$657,295, respectively. As of December 31, 2003, there were 548,409 repriced options outstanding, which expire on various dates through January 2008.

### NOTE 9 — Savings and Retirement Plan

The Company maintains a savings and retirement plan under Section 401(k) of the Internal Revenue Code which allows eligible employees to annually contribute a portion of their annual salary to the plan. In 1998, the Company began making discretionary contributions at a rate of 25% of an employee's contribution up to a maximum of 5% of the employee's base salary, as defined. The Company made contributions of \$59,183, \$54,024 and \$38,669 for the years ended December 31, 2003, 2002 and 2001, respectively.

### NOTE 10 — Income Taxes

At December 31, 2003, the Company had available federal net operating loss carryforwards, which expire in the years 2006 through 2023, of \$144,952,000 for income tax purposes and State net operating loss carryforwards, which expire in the years 2004 through 2010, of \$91,343,000. In addition, the Company has federal research and development tax credit carryforwards of \$6,401,000 and State research and development tax credit carryforwards of \$1,600,000. The amount of federal net operating loss and research and development tax credit carryforwards which can be utilized in any one period may become limited by federal income tax regulations if a cumulative change in ownership of more than 50% occurs within a three-year period.

The components of the deferred tax assets and the valuation allowance are as follows:

December 31,	2003	2002
Net operating loss carryforwards	\$ 54,800,000	\$ 59,800,000
Research and development credit	8,000,000	7,800,000
Capitalized research and development credits	8,900,000	—
Other temporary differences	2,200,000	1,200,000
Gross deferred tax assets	73,900,000	68,800,000
Valuation allowance	(73,900,000)	(68,800,000)
Net deferred tax assets	\$ —	\$ —

During 2003, in connection with filing the Company's 2002 tax return, the Company elected to capitalize research and development expenses for tax purposes. For the year ended December 31, 2002, the Company capitalized \$15,085,934 of research and development expenses that were previously recorded as net operating loss carryforwards. The Company has elected to amortize the expenses ratably for tax purposes over a 10-year period. For the year ended 2003, the Company will capitalize \$9,909,684 of research and development expenses for tax purposes and elect to amortize the expenses ratably for tax purposes over a 10-year period.

Given the Company's history of incurring operating losses, management believes that it is unlikely that any of the deferred tax assets will be recoverable. As a result, a valuation allowance equal to the gross deferred tax assets was established. In 2003, 2002 and 2001, the Company sold \$2,083,000, \$1,839,000 and \$6,243,000, respectively, of its gross State net operating loss carryforwards and \$209,000, \$578,000 and \$802,000, respectively, of its State research and development tax credit carryforwards under the State of New Jersey's Technology Business Tax Certificate Transfer Program (the "Program"). The Program allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of net operating loss carryforwards and defined research and development tax credits for cash. The proceeds from the sale of the Company's carryforwards and credits in 2003, 2002 and 2001 were \$345,000, \$647,000 and \$1,187,000, respectively, and such amounts were recorded as a tax benefit in the statements of operations. The State of New Jersey renews the Program annually and limits the aggregate benefit to \$10,000,000. Due to the uncertainty at any time as to the Company's ability to effectuate the sale of Alteon's available New Jersey net operating losses, and since the Company has no control or influence over the Program, the benefits are recorded once the agreement with the counterpart is signed and the sale is approved by the State.

**Exhibit**

<b>No.</b>	<b>Description of Exhibit</b>
3.1	Restated Certificate of Incorporation, as amended. (Incorporated by reference to Exhibit 3.1 to the Company's Report on Form 10-Q filed on November 10, 1999, SEC File Number 000-19529.)
3.2	Certificate of the Voting Powers, Designations, Preference and Relative Participating, Optional and Other Special Rights and Qualifications, Limitations or Restrictions of Series F Preferred Stock of Alteon Inc. (Incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, SEC File Number 001-16043.)
3.3	Certificate of Retirement dated September 10, 2000, of Alteon Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Report on Form 10-Q filed on November 10, 1999, SEC File Number 000-19529.)
3.4	Certificate of Designations of Series G Preferred Stock of Alteon Inc. (Incorporated by reference to Exhibit 3.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1997, SEC File Number 000-19529.)
3.5	Certificate of Amendment of Certificate of Designations of Series G Preferred Stock of Alteon Inc. (Incorporated by reference to Exhibit 3.4 to the Company's Report on Form 10-Q filed on August 14, 1998, SEC File Number 000-19529.)
3.6	Certificate of Designations of Series H Preferred Stock of Alteon Inc. (Incorporated by reference to Exhibit 3.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 1997, SEC File Number 000-19529.)
3.7	Amended Certificate of Designations of Series H Preferred Stock of Alteon Inc. (Incorporated by reference to Exhibit 3.6 to the Company's Report on Form 10-Q filed on August 14, 1998, SEC File Number 000-19529.)
3.8	Certificate of Retirement dated November 20, 2000, of Alteon Inc. (Incorporated by reference to Exhibit 3.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, SEC File Number 001-16043.)
3.9	Certificate of Amendment to Restated Certificate of Incorporation of Alteon Inc., dated June 7, 2001 (Incorporated by reference to Exhibit 3.8 to the Company's Report on Form 10-Q filed on August 14, 2001, SEC File Number 001-16043.)
3.10	By-laws, as amended. (Incorporated by reference to Exhibit 3.10 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, SEC File Number 001-16043.)
4.1	Stockholders' Rights Agreement dated as of July 27, 1995, between Alteon Inc. and Registrar and Transfer Company, as Rights Agent. (Incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, SEC File Number 001-16043.)
4.2	Amendment to Stockholders' Rights Agreement dated as of April 24, 1997, between Alteon Inc. and Registrar and Transfer Company, as Rights Agent. (Incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed on May 9, 1997, SEC File Number 000-19529.)
4.3	Registration Rights Agreement dated as of April 24, 1997, between Alteon Inc. and the investors named on the signature page thereof. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 9, 1997, SEC File Number 000-19529.)
4.4	Form of Common Stock Purchase Warrant. (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on May 9, 1997, SEC File Number 000-19529.)
4.5	Amendment to Stockholders' Rights Agreement dated as of December 1, 1997, between Alteon Inc. and Registrar and Transfer Company, as Rights Agent. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 10, 1997, SEC File Number 000-19529.)
4.6	Registration Rights Agreement dated September 29, 2000. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on October 5, 2000, SEC File Number 001-16043.)
4.7	Form of Series 1 Common Stock Purchase Warrant. (Incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on October 5, 2000, SEC File Number 001-16043.)
4.8	Form of Series 2 Common Stock Purchase Warrant. (Incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on October 5, 2000, SEC File Number 001-16043.)
4.9	Notice of Appointment, dated August 29, 2002, of The American Stock Transfer & Trust Company as successor Rights Agent, pursuant to Stockholders' Rights Agreement dated as of July 27, 1995. (Incorporated by reference to Exhibit 4.4 of the Company's Report on Form 10-Q filed on November 13, 2002, SEC File Number 001-16043.)
10.1†	Amended and Restated 1987 Stock Option Plan. (Incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1997, SEC File Number 000-19529.)
10.2†	Amended 1995 Stock Option Plan. (Incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001, SEC File Number 001-16043.)
10.3	Form of Employee's or Consultant's Invention Assignment, Confidential Information and Non-Competition Agreement executed by all key employees and consultants as employed or retained from time to time. (Incorporated by Reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1, SEC File Number 33-42574, which became effective on November 1, 1991.)

# E x h i b i t I n d e x

No.	Description of Exhibit
10.4	Lease Agreement dated January 11, 1993, between Ramsey Associates and Alteon Inc. (Incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, SEC File No. 001-16043.)
10.5†	Employment Agreement dated as of October 21, 2000, between Alteon Inc. and Elizabeth O'Dell. (Incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, SEC File Number 001-16043.)
10.6†	Alteon Inc. Change in Control Severance Benefits Plan. (Incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000, SEC File Number 001-16043.)
10.7	Preferred Stock Investment Agreement dated as of April 24, 1997, between Alteon Inc. and the investors named on the signature page thereof. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 9, 1997, SEC File Number 000-19529.)
10.8†	Amended and Restated Employment Agreement dated as of December 15, 1998, between Alteon Inc. and Kenneth I. Moch (Incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, SEC File Number 000-19529.)
10.9†	Employment Agreement dated as of March 14, 2000, between Alteon Inc. and Robert deGroof, Ph.D. (Incorporated by reference to Exhibit 10.1 to the Company's Report on Form 10-Q filed on May 12, 2000, SEC File Number 001-16043.)
10.10	Common Stock and Warrants Purchase Agreement dated as of September 29, 2000, among Alteon Inc. and EGM Medical Technology Fund, L.P., EGM Technology Offshore Fund, Narragansett I, L.P., Narragansett Offshore, Ltd., S.A.C. Capital Associates, LLC, SDS Merchant Fund, LP and Herriot Tabuteau. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 5, 2000, SEC File Number 001-16043.)
10.11†	Letter Agreement dated December 3, 2001, between Alteon Inc. and Kenneth I. Moch amending Amended and Restated Employment Agreement dated as of December 15, 1998. (Incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001, SEC File Number 001-16043.)
10.12	Stock Purchase Agreement dated January 4, 2002, between Alteon Inc. and the Purchasers named therein. (Incorporated by reference to the Company's Current Report on Form 8-K filed on January 7, 2002, SEC File Number 001-16043.)
10.13†	Employment agreement dated as of February 11, 2002, between Alteon Inc. and Judith S. Hedstrom. (Incorporated by reference to Exhibit 10.2 of the Company's Report on Form 10-Q filed on May 14, 2002, SEC File Number 001-16043.)
10.14	Stock Purchase Agreement dated December 20, 2002, between Alteon Inc. and the Purchasers named therein. (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on December 24, 2002, SEC File Number 001-16043.)
10.15†	Letter Agreement, dated May 5, 2003, between Alteon Inc. and Robert C. deGroof, Ph.D., amending Employment Agreement, dated as of March 14, 2000. (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2003, SEC File Number 001-16043.)
10.16†	Letter Agreement, dated June 5, 2003, between Alteon Inc. and Robert C. deGroof, Ph.D., amending Amended and Restated Employment Agreement, dated as of May 5, 2003. (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2003, SEC File Number 001-16043.)
10.17†	Letter Agreement, dated June 5, 2003, between Alteon Inc. and Judith S. Hedstrom, amending Employment Agreement, dated as of February 11, 2002. (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2003, SEC File Number 001-16043.)
10.18†	Letter Agreement, dated June 5, 2003, between Alteon Inc. and Elizabeth O'Dell, amending Employment Agreement, dated as of October 21, 2000. (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2003, SEC File Number 001-16043.)
10.19	Stock Purchase Agreement, dated October 15, 2003. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 20, 2003, SEC File Number 001-16043.)
10.20	Amendment to Stock Purchase Agreement, dated October 24, 2003. (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 13, 2003, SEC File Number 001-16043.)
10.21†	Letter Agreement, dated December 22, 2003, between Alteon Inc. and Elizabeth O'Dell, amending Amended and Restated Employment Agreement, dated as of June 5, 2003.
23.1	Consent of KPMG LLP.
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

† Denotes a management contract or compensatory plan or arrangement required to be filed as an exhibit pursuant to Item 14(c) to this Form 10-K.

# Corporate Information

## Board of Directors

**Kenneth I. Moch**  
 Chairman of the Board  
 President and Chief Executive Officer  
 Alteon Inc.

**Edwin D. Bransome, Jr., M.D.**  
 Professor of Medicine and Physiology Emeritus  
 Medical College of Georgia  
 Past President, United States Pharmacopoeia

**Marilyn G. Breslow**  
 President  
 W.P. Stewart & Co., Inc.

**Alan J. Dalby**  
 Retired Chairman, Reckitt Benckiser plc  
 Former Chairman and Chief Executive Officer  
 Cambridge Neuroscience, Inc.  
 Former Executive Vice President, Smith Kline  
 Beckman Corporation

**David K. McGurdy**  
 President, Electronic Industries Alliance  
 Former Congressman, U.S. House  
 of Representatives  
 Fourth District, Oklahoma

**Thomas A. Moore**  
 Former President and Chief Executive Officer  
 Biopure Corporation

**George M. Naimark, Ph.D.**  
 President, Naimark & Barba, Inc.  
 President, Naimark & Associates, Inc.

**Mark Novitch, M.D.**  
 Retired Vice Chairman and  
 Chief Compliance Officer  
 The Upjohn Company

Former Deputy Commissioner  
 of the Food and Drug  
 Administration (FDA)

## Corporate Officers

**Kenneth I. Moch**  
 President and Chief Executive Officer

**Robert G. deGroot, Ph.D.**  
 Senior Vice President, Scientific Affairs

**Judith S. Hedstrom**  
 Senior Vice President, Corporate Development

**Elizabeth A. O'Dell**  
 Vice President, Finance, Treasurer and Secretary

## Corporate Information

**Corporate Headquarters**  
 Alteon Inc.  
 6 Campus Drive  
 Parsippany, New Jersey 07054  
 201-934-5000

[www.alteon.com](http://www.alteon.com)

**Legal Counsel**  
 Stevens & Lee, P.C.  
 Princeton, New Jersey 08540

**Independent Public Accountants**  
 KPMG LLP  
 Short Hills, New Jersey 07078

**Transfer Agent**  
 American Stock Transfer & Trust Company  
 59 Maiden Lane  
 New York, New York 10038  
 800-937-5449

Inquiries regarding transfers, lost certificates  
 and changes of address should be directed  
 to the transfer agent.

## Annual Meeting

Date: June 2, 2004  
 Time: 9:00 AM  
 Place: Hilton Parsippany  
 1 Hilton Court  
 Parsippany, New Jersey 07054



Equinox Drive

Princeton, New Jersey 07054

☎ (201) 934-5000      Fax: (201) 934-8880

[www.alteon.com](http://www.alteon.com)