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Alteon INC

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# ALTEON

A N N U A L 2 0 0 2 R E P O R T



## A b o u t   A l t e o n

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 and kidney diseases in older or diabetic individuals.

*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.*



**Dear Shareholders:**

The year 2002 was marked by significant growth and achievement for Alteon. With each passing year, the role of advanced glycation in the pathologies of aging and diabetes becomes more widely accepted. As this occurs, Alteon's technology, particularly our pipeline of A.G.E. Crosslink Breaker compounds, is being increasingly recognized for its medical and economic potential.

Alteon is moving aggressively ahead with the development of our lead compound, ALT-711, which continues to show potential as a novel agent in the cardiovascular, diabetes and primary care markets.

We are encouraged by the growing and consistent body of preclinical and clinical safety and efficacy data that supports the development of ALT-711 in systolic hypertension and diastolic heart failure (DHF). These two medical conditions have become a major focus of the cardiovascular community because of the clear evidence that they affect large patient populations that are not being adequately treated by existing therapies. Recent positive data from the Phase 2a DIAMOND trial of ALT-711 in patients with DHF, as well as anticipation of upcoming data from the Phase 2b SAPPHIRE/SILVER program of ALT-711 in patients with systolic hypertension, have generated an enthusiastic response as well as increasing interest from the scientific, pharmaceutical and investment communities.

**ALT-711, Alteon's Lead A.G.E. Crosslink Breaker**

ALT-711 works by "cleaving" the glucose/protein bonds, known as A.G.E. crosslinks, that 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. Systolic hypertension and DHF are two of the conditions that result from this age- and diabetes-related stiffening process. We believe that, through a unique mechanism of action that increases the elasticity of the vascular wall itself, ALT-711 represents a new therapeutic frontier in cardiovascular medicine, and that its benefits will be over and above current standard treatment. No other compound like ALT-711 is currently prescribed or in development.

*The ALT-711 SAPPHIRE/SILVER Phase 2b Clinical Trials*

As a development-stage company, Alteon places the highest priority on achieving clinical milestones. During the year, we focused our efforts on the expansion of our ALT-711 clinical development program. We completed the enrollment of over 760 patients in Phase 2b SAPPHIRE/SILVER clinical trials in systolic hypertension. In the SAPPHIRE trial, 486 patients are randomized into one of five treatment arms (four different oral tablet doses of ALT-711 or placebo). In the SILVER trial, we are also assessing the effect of ALT-711 in 282 patients that have left ventricular hypertrophy (LVH), or enlarged hearts, in addition to their systolic hypertension; SILVER patients are randomized into one of two treatment arms (ALT-711 or placebo). Patients in the SAPPHIRE/SILVER program must be older than 50 years of age and have a systolic blood pressure of over 150 mmHg. The primary endpoint in both trials is the change in systolic blood pressure; secondary endpoints include additional blood pressure measurements and changes in certain urological characteristics. Patients are being treated for six months, and data is expected to be released concurrently mid-year 2003.

Because of the positive safety profile of ALT-711 in testing to date, SAPPHIRE and SILVER patients who have completed the initial six-month treatment period at selected sites are eligible for a six-month, open-label extension during which they will receive the high dose of ALT-711. Our objective is to further strengthen the overall safety database for the drug. We plan to enroll up to 300 patients in this open-label extension, and we are pleased to report that over 230 patients are enrolled at the time this letter was written. Over 40 of these patients are entering their second year on ALT-711.

*The ALT-711 Phase 2a DIAMOND Trial*

In July 2002, we initiated the Phase 2a DIAMOND (Distensibility Improvement and Remodeling in Dia<sup>s</sup>to<sup>l</sup>ic Heart Failure) trial in patients with DHF. DHF is characterized by the inability of the heart to fill properly due to the stiffening of the heart 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, 23 patients received 210 mg of ALT-711 twice daily on an open-label, outpatient basis for 16 weeks in addition to their current medications, which included ACE inhibitors or angiotensin II antagonists, beta-blockers and diuretics. Primary endpoints included changes in exercise tolerance and aortic stiffness; effects on LVH, diastolic filling and quality of life were also assessed.

I am delighted to report that positive findings from this pilot, open-label study were reported at the 9th Annual Scientific Sessions of the Society of Geriatric Cardiology in March 2003. In the DIAMOND trial, the 21 patients who completed the 16 weeks of ALT-711 therapy experienced a statistically significant reduction in left ventricular (LV) mass. 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.



## Letter to Shareholders

Though a small study, the DIAMOND results suggest that ALT-711 can have a direct remodeling effect on the enlarged heart, and that the drug warrants further investigation as a potential treatment for DHF, a disorder for which no optimal therapy currently exists. We are preparing a Phase 2b trial protocol in DHF, and are evaluating the steps necessary to initiate this program in early 2004.

### Building a Product Pipeline

In addition to determining ALT-711's effects in systolic hypertension and the vasculature, we are evaluating other areas where glucose/protein crosslinking may be pathological and A.G.E. Crosslink Breaker compounds may have a therapeutic benefit. Built into the SAPPHIRE/SILVER cardiovascular clinical program are secondary endpoints that include an American Urological Questionnaire used to approve drugs for urinary elastic dysfunction. Early clinical experience in human studies of ALT-711 suggests that ALT-711 may have an impact on the elasticity of the bladder. The information generated from the SAPPHIRE/SILVER trial may further define that effect, and help us to determine whether or not to pursue clinical development in that area. Other secondary endpoints will help us understand the drug's effect on the kidney.

Our research and preclinical work also point to the possible utility of A.G.E. Crosslink Breaker compounds in diabetic retinopathy and dermatological conditions, as well as in the treatment of complications in patients undergoing dialysis.

### Building a Company and a Culture

One of the most difficult challenges for an emerging pharmaceutical company is to attract and motivate the highest caliber personnel in the face of the vagaries and complexities of the pharmaceutical development process. I am truly pleased by the progress that Alteon has made during 2002 in bringing stellar people to the firm. During the year, we made numerous key hires in the clinical, scientific and human resources areas. 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.

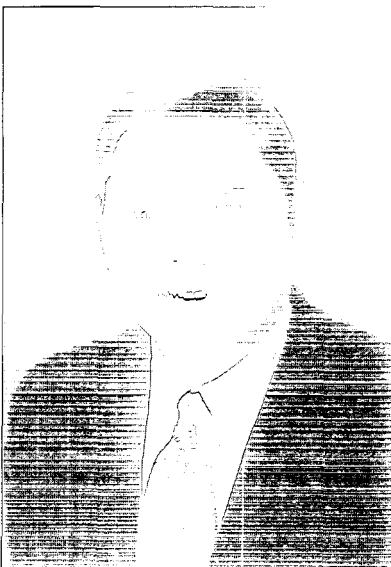
### Finance

During 2002, we raised approximately \$23 million, including two separate financings with institutional investors and proceeds through the sale of our New Jersey State Net Operating Losses. We ended 2002 with \$17.4 million, which we supplemented in March 2003 with a financing that netted Alteon an additional \$7.7 million. We are managing our resources efficiently with a focus on seeing our clinical programs through to completion. Our plans for the development of ALT-711 are aggressive, and we continue to evaluate strategic opportunities and potential corporate partnerships.

In addition, interest in Alteon from the financial community has been growing, as evidenced by the initiation of coverage by several financial analysts, as well as our participation at several high-profile financial conferences.

### Looking Forward

The year 2003 will be pivotal for Alteon. We are pleased by the positive response to our DIAMOND data and eagerly look forward to the data from the SAPPHIRE/SILVER program in systolic hypertension in the upcoming months. I would like to thank the entire Alteon team – their commitment to achieving our clinical milestones was reflected in their teamwork and the high standards they set throughout 2002. I also thank you, our shareholders, for your continued support.



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

April 10, 2003



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, 2002, 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.)

**170 Williams Drive, Ramsey, New Jersey 07446**

(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 (\$2.06 per share), as of June 28, 2002, was \$65,516,106.

At February 28, 2003, 33,600,841 shares of the registrant's common stock, par value \$.01 per share, were outstanding.

Documents Incorporated By Reference

Document  
Proxy Statement for 2003  
Annual Meeting of Stockholders

Where Incorporated  
Part III



## PART I

### Item 1. Business.

#### Overview

We are a product-based biopharmaceutical company primarily engaged in the discovery and development of oral 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 Phase 2b 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-Products ("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 current research and drug development activities targeting the A.G.E. pathway take 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. We have 99 issued United States patents and over 80 issued foreign patents focused primarily on A.G.E. technology.

ALT-711 is an A.G.E. Crosslink Breaker and our lead product candidate. ALT-711 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 blood vessels and organs of the body. We are initially developing ALT-711 for the treatment of cardiovascular diseases, and have completed two Phase 2a safety, efficacy and pharmacology studies. Preliminary results from the first 17 patients in the recently conducted Phase 2a DIAMOND (Distensibility Improvement and Remodeling in Diastolic Heart Failure) clinical trial evaluating the activity of ALT-711 in diastolic heart failure ("DHF") patients demonstrated that patients who received ALT-711 for 16 weeks experienced a statistically significant reduction in left ventricular mass, a marked improvement in left ventricular diastolic filling and a positive effect on patients' quality of life. In 2001, we conducted a Phase 2a clinical trial, in which 93 patients received ALT-711 or placebo tablets once daily for eight weeks. Study results showed that ALT-711 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*.

The positive results from the Phase 2a trials suggest that ALT-711 may be a novel therapy for a number of cardiovascular conditions, including systolic hypertension and diastolic heart failure, two diseases that occur as a result of vascular stiffening due to age or diabetes.

We have initiated two companion Phase 2b clinical trials, the SAPHIRE (Systolic And Pulse Pressure Hemodynamic Improvement by Restoring Elasticity) trial focused on patients with systolic hypertension and the SILVER (Systolic Hypertension Interaction with Left Ventricular Remodeling) trial in patients with systolic hypertension and left ventricular hypertrophy ("LVH"). Data from these trials is expected to be reported concurrently about mid-year 2003. We are also considering further clinical development of ALT-711 for DHF and other related conditions.

A topical formulation of an A.G.E. Crosslink Breaker, ALT-744, is being clinically evaluated in skin aging for cosmetic applications. We continue to evaluate potential clinical trials in other cardiovascular and therapeutic indications where A.G.E. Crosslink Breaker compounds may address significant unmet needs.

We are also actively evaluating product development opportunities from other classes of compounds in our patent estate, including A.G.E.-Formation Inhibitors, which target the A.G.E. pathway by inhibiting the formation and crosslinking of A.G.E.s. In addition, we are utilizing our technical expertise in the field of diabetes to develop compounds focused on glucose regulation and control, our GLA compounds. We are evaluating our lead compounds in these classes to determine the optimal strategy for pre-clinical development.

We were incorporated in Delaware in October 1986 under the name Geritech Inc. Our name was changed to Alteon Inc. in August 1991. We are headquartered at 170 Williams Drive, Ramsey, New Jersey 07446. Our web address is [www.alteon.com](http://www.alteon.com), and our telephone number is (201) 934-5000.

#### 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 our drug candidates to corporate partners. As we continue clinical development of ALT-711, 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 addition to ALT-711, we have identified compounds in multiple chemical classes that 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 systolic hypertension and diastolic 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, thus potentially broadening our markets of opportunity.

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, nearly 62 million Americans have one or more types of cardiovascular disease. Cardiovascular disease has been the number one killer of Americans since the early 1900's. 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 general cardiovascular risk. Currently available anti-hypertensive agents reduce pressure on the vessel wall in such a manner as to lower both systolic and diastolic blood pressures without significantly affecting pulse pressure. Our approach rapidly increases large artery elasticity, thereby reducing pulse pressure beyond what would be expected from restoring the dynamic range of the vessel wall with a reduction in blood pressure alone. Pharmacologic intervention targeting the stiffness of the cardiovascular system may decrease the incidence and severity of complications such as LVH, a thickening and stiffening of the heart tissue, and congestive heart failure. Published studies have shown that a 10mm 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 140mm 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 ability of ALT-711 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 – ALT-711." Although currently marketed anti-hypertensive agents are being used to treat the disease, it is not adequately treated by these therapies. ALT-711 is the first drug to show direct activity by targeting the stiff vessels that cause systolic hypertension. We believe that ALT-711 will provide additional benefit because it exerts its activity by a mechanism unique from currently marketed anti-hypertension drugs.

### ***Diastolic Heart Failure***

Diastolic heart failure is caused by an impaired ability of the heart to relax after a contraction and fill properly, in part due to the stiffening of the heart tissue. When the ventricles (the heart's lower pumping chambers) do not relax normally, increased pressure and fluid in the blood vessels of the lungs may be a result (pulmonary congestion). DHF can also cause increased pressure and fluid in the blood vessels coming back to the heart (systemic congestion). DHF is a poorly treated medical condition that is estimated to account for 30-50% of all heart failure cases, which total nearly five million cases in the United States alone. ALT-711 offers promise as a novel therapy for DHF because currently available therapies do not specifically target the stiffening heart and vessel walls.

### ***Left Ventricular Hypertrophy***

Left ventricular hypertrophy refers to the thickening of the left ventricle that can occur with hypertension. LVH can lead to decreased cardiac output, the inability to meet the circulatory needs of the body and to heart failure itself. LVH is a component of 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 ALT-711. Additionally, in several pre-clinical studies, ALT-711 has been shown to reduce the thickening of the left ventricle and remodel the heart.

## **Complications of Diabetes**

The Diabetes Control and Complications Trial ("DCCT"), 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***

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. 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"). Approximately 34% of patients with Type 1 diabetes and approximately 10-15% of patients with Type 2 diabetes develop nephropathy.

In the Phase 2/3 ACTION (A Clinical Trial In Overt Nephropathy) trial in diabetic patients with overt nephropathy, therapy with our first A.G.E.-Formation Inhibitor, pimagedine, showed a statistically significant reduction in urinary protein excretion, although it did not reach statistical significance in its primary endpoint, the time to doubling of serum creatinine. Though pimagedine is no longer in active clinical development, the ACTION trial serves 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 other complications of diabetes. See "—Retinopathy." 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 that of adults without diabetes. The risk of stroke is also two to four times higher in those with diabetes.



### **ESRD**

As a component of our clinical strategy in developing ALT-711 for cardiovascular diseases and diabetic complications, we are currently conducting Phase 1 safety studies of ALT-711 in the critically ill ESRD patient population undergoing peritoneal dialysis. ESRD is a condition in which the kidneys no longer function. Peritoneal dialysis is a method of dialysis that uses the patient's peritoneum (a membrane in the abdomen) to filter out waste products. Latest statistics show that almost 25,000 of the 400,000 Americans living with ESRD are undergoing peritoneal dialysis. The ESRD patient population has a limited five-year survival (less than 30%) and significant cardiovascular complications, including LVH.

### **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. Though not a primary endpoint in the Phase 2/3 ACTION trial, pimagedine therapy did result in a statistically significant reduction in the progression of retinopathy. Pre-clinical evidence suggests that ALT-711 and other compounds from the A.G.E. Crosslink Breaker class also may have a positive impact on retinopathy.

### **Skin Aging**

Pre-clinical data has demonstrated the potential of A.G.E. Crosslink Breaker compounds to increase skin hydration and elasticity. A topical formulation of ALT-744, an A.G.E. Crosslink Breaker, is being clinically evaluated in skin aging for cosmetic applications.

### **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 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 1986 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 pioneer 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. Loss of flexibility of the vasculature may lead to a number of cardiovascular disorders, including systolic hypertension, diastolic dysfunction and LVH, and ultimately may lead to heart failure.

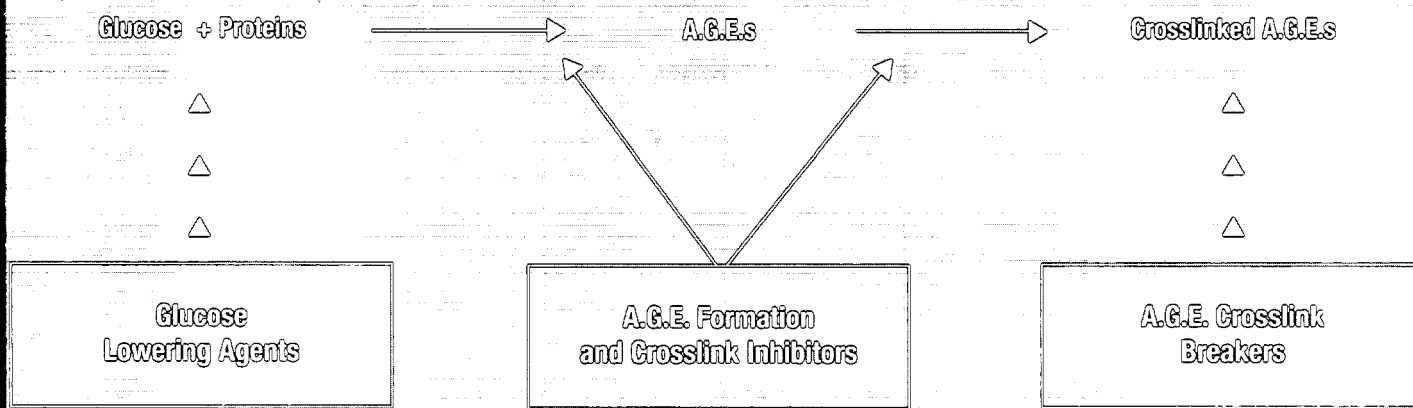
Studies conducted in animal models of diabetes and aging at numerous independent institutions worldwide demonstrate that A.G.E.s are a major factor contributing to many of the disorders of aging and diabetes, including cardiovascular, kidney and eye diseases, as well as atherosclerosis. Recent human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





Our Technology Platform and Product Pipeline



**New Chemical Class**  
(51 Compounds)

**New Mechanism**

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

**9 New Chemical Classes**  
(852 Compounds)

**New Mechanism**

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

Effects additive to  
conventional therapies

**17 New Chemical Classes**  
(658 Compounds)

**New Mechanism**

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

Activity unlike any known drug

Effects additive to  
conventional therapies

**Key Products in Development:**

**Lead Identification**

- Ongoing
- Type 2 Diabetes

**Pimagidine**

Phase 2/3

- Diabetic Kidney Disease  
(inactive)

**Veterinary Health**

- Diabetic Neuropathy

**ALT-711**

Phase 2

- Systolic Hypertension
- DHF

Phase 1

- ESRD

**ALT-744**

Clinical Evaluation

- Skin Aging



We incurred research and development expenditures of approximately \$14,992,000, \$8,461,000 and \$6,375,000 for the years ended December 31, 2002, 2001 and 2000, 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, ALT-711, has demonstrated the ability to reverse tissue damage and restore function to the cardiovascular system in two Phase 2a 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. Early clinical experience in human studies of ALT-711 suggests that urinary elastic dysfunction (leading to urinary incontinence) is a potential therapeutic target. 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 distinct chemical classes of A.G.E. Crosslink Breakers, and have a library of more than 650 compounds.

#### **ALT-711**

Through its unique mechanism of action, ALT-711 is the first compound that breaks A.G.E. crosslinks between proteins, both in vitro and in vivo. ALT-711 is an orally bioavailable compound dosed in tablet form. The compound is under Phase 2 clinical evaluation in cardiovascular diseases, as well as in Phase 1 evaluation in ESRD patients undergoing peritoneal dialysis. ALT-711 is being evaluated in various pre-clinical models to assess its potential in a number of other disease states.

In January 2003, we announced positive results from a preliminary analysis of the first 17 patients in the Phase 2a DIAMOND clinical trial evaluating ALT-711 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 ALT-711 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 ALT-711 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 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 ALT-711 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 ALT-711. The trial enrolled 93 patients over the age of 50 with measurably stiffened large vessels, including systolic blood pressure of at least 140mm Hg and pulse pressure of at least 60mm Hg. Patients were randomized to receive oral doses of either 210mg of ALT-711 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 and cardiac output. Under this protocol, ALT-711 treatment was in addition to the best available therapeutic regimen chosen by the treating physicians. Study results showed that patients who received ALT-711 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*.

Based on the positive results of this trial, we initiated two Phase 2b efficacy trials of ALT-711 in systolic hypertension, the SAPPHIRE and SILVER trials. These trials further evaluate ALT-711's ability to lower systolic blood pressure and pulse pressure in aging and diabetic patients and extend the range of doses and the dosing period of ALT-711 used in the Phase 2a trial.

In the SAPPHIRE trial, ALT-711 is being tested in 479 patients at more than 60 sites throughout the United States. Recruited patients receive ALT-711 tablets once a day for six months, in addition to their existing medications. The study consists of five treatment arms, comprised of four different dose levels of ALT-711 plus placebo. Patients enrolled in the trial are older than 50 years of age and have systolic blood pressure of greater than 150mm Hg and diastolic blood pressure of less than 90mm Hg. The trial includes male and female, non-diabetic and diabetic patients.

The SILVER trial is designed as a companion trial to the SAPPHIRE trial, and is being conducted at the same clinical sites. Entry criteria are identical to that in the SAPPHIRE trial, except that patients have LVH in addition to systolic hypertension. The trial will evaluate the blood pressure lowering effects of ALT-711 in approximately 282 patients who are randomized to one of two treatment arms, ALT-711 or placebo.

The primary endpoint of both studies will be the change in systolic blood pressure. In addition, secondary endpoints will include additional blood pressure measurements and change in certain urological characteristics.

During 2001, we also initiated a Phase 1 trial assessing the safety of ALT-711 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. The ongoing Phase 1 program is an important component of our clinical strategy in developing ALT-711 for cardiovascular disease.



ALT-711 data is consistent across species. Studies in animal models in several laboratories around the world have demonstrated rapid reversal of impaired cardiovascular functions with ALT-711. In these pre-clinical models, ALT-711 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 ALT-711 conducted by researchers from the National Institute on Aging and Johns Hopkins Geriatric Center demonstrated the ability of the compound to significantly reduce arterial stiffness in elderly Rhesus monkeys. In a pre-clinical study of ALT-711 in aged dogs, administration of ALT-711 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 ALT-711 may prove beneficial in the treatment of systolic hypertension in the elderly or in the diabetic. Additionally, in several pre-clinical studies, ALT-711 has been shown to normalize the thickening of the left ventricle and remodel the heart.

ALT-711 is a small, easily synthesized compound with a rapid mode of action. It is well absorbed from an oral tablet formulation. In addition to the Phase 2a human trials, a series of Phase 1 safety and dose escalation studies were conducted. These trials have shown the drug to be well tolerated.

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

ALT-744 is another A.G.E. Crosslink Breaker in a topical formulation. It is being clinically evaluated in skin aging for cosmetic applications. We continue to evaluate other A.G.E. Crosslink Breakers from our library of compounds.

#### ***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 has been the lead compound in the A.G.E.-Formation inhibitor class.

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, the ACTION trial serves 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 other complications of diabetes. ALT-946, another A.G.E.-Formation Inhibitor, has demonstrated the ability to slow the progression of overt nephropathy in a pre-clinical study.

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.

#### ***Collaborative Arrangements and License Agreements***

We have entered into a number of licensing and collaboration agreements relating to the development and distribution of our A.G.E.-related technology. Pursuant to an agreement with Rockefeller University, we have 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. See "—Patents, Trade Secrets and Licenses." We have also entered into an exclusive licensing arrangement with Roche Diagnostics GmbH ("Roche") 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 have a license and supply agreement with IDEXX Laboratories, Inc., pursuant to which we licensed pimagedine to IDEXX as a potential therapeutic in companion animals (dogs, cats and horses) and our A.G.E. diagnostics technology for companion animal use. All of these agreements will entitle us to receive royalties on sales if any products covered by the agreements are developed and sold.

On November 6, 2002, we entered into a new agreement, effective as of April 15, 2002, with The Picower Institute for Medical Research ("The Picower Institute"), which terminated their license agreement dated as of September 5, 1991. Pursuant to this termination agreement, The Picower Institute assigned to us all of its patents, patent applications and other technology related to A.G.E.'s, and we agreed to prosecute and maintain the patents and patent applications. We 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. See "—Patents, Trade Secrets and Licenses."



Effective as of August 5, 2002, we entered into a letter agreement with Yamanouchi Pharmaceutical Co. Ltd. ("Yamanouchi"), which terminated their License Agreement dated as of June 16, 1989. Pursuant to the letter agreement, for a period of fifteen years, (i) we will pay Yamanouchi royalties on any sales of pimagedine or pimagedine products in the territory covered by the License Agreement and (ii) we will have the option to purchase from Yamanouchi all or any part of our common stock owned by Yamanouchi.

In October 2000, we entered into an agreement with HemoMax, LLC ("HemoMax") for the development of a novel technology designed to increase the delivery of oxygen to tissues in the body through enhanced blood circulation. On February 9, 2002, HemoMax advised us that because of uncertainties regarding its ability to receive patents adequate to support commercialization of the technology, it has decided to cease operations and liquidate.

#### **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. See "—Collaborative Arrangements and License Agreements."

#### **Marketing and Sales**

We retain worldwide marketing rights to our A.G.E. Crosslink Breaker compounds. 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. We believe that ALT-711 may address the cardiovascular, diabetes and primary care physician markets. Such arrangements may be exclusive or nonexclusive and may provide for marketing rights worldwide or in a specific market.

For certain of our products, we have licensed exclusive marketing rights, formed joint marketing arrangements or granted distribution rights within specified territories with our corporate partner, Roche. See "—Collaborative Arrangements and License Agreements."

#### **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.

As of December 31, 2002, our patent estate of owned and/or licensed patent rights consisted of 99 issued United States patents, none of which expire prior to 2005, and 23 pending patent applications in the United States, the majority of which are A.G.E.-related. We also own or have exclusive rights to over 80 issued patents in Europe, Japan, Australia and Canada.

We have seven issued United States patents and five issued foreign patents, including one from the European Patent Office, as well as 19 pending patent applications in the United States, covering certain novel compounds in the A.G.E. Crosslink Breaker category. These patents and additional patent applications contain compound, composition and method of treatment claims for several chemical classes of crosslink breaker compounds, including ALT-711.

Pimagedine is not protected by a composition-of-matter patent but is protected by a series of use patents. In 1992, a United States patent on the use of pimagedine was issued to Rockefeller University and subsequently exclusively licensed to us with claims relating to the inhibition of A.G.E. formation. The patent claims the new use of a known agent for the treatment of the complications of aging and diabetes. In 1994, corresponding patents were granted in France, Germany, Italy, the United Kingdom and other European countries. A corresponding patent was issued in Japan in 1995. We continue to pursue and patent chemical analogs of known A.G.E.-Formation Inhibitors, as well as novel compounds having potential inhibitory properties.

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. 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.

In 1987, we acquired an exclusive, royalty-free, worldwide license (including the right to sub-license to others) to issued patents, patent applications and trade secrets from Rockefeller University relating to the A.G.E.-formation and crosslinking technology currently under development by us. Additional patent applications have since been filed on discoveries made in support of the technology from research conducted at Rockefeller University, The Picower Institute and our laboratories. Pursuant to our agreement with The Picower Institute, certain patentable inventions and discoveries relating to A.G.E. technology have been licensed exclusively to us. On December 31, 2001, The Picower Institute ceased operations. On November 6, 2002, we entered into an agreement, effective as of April 15, 2002, with The Picower Institute, which terminated their license agreement dated as of September 5, 1991. Pursuant to this termination agreement, The Picower Institute assigned to us all of its patents, patent applications and other technology related to A.G.E.'s and we agreed to prosecute and maintain the patents and patent applications. We 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.



We intend to continue to focus our research and development efforts on the synthesis of novel compounds and on the search for additional therapeutic applications to 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.

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.

In addition to regulations enforced by the FDA, we are also subject to regulations under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local regulations. Our research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

#### **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, 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 and may have commitments to, or consulting or advisory agreements with, other entities that may limit their availability to us. These companies may also be competitors of ours. 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-Presbyterian/St. Luke's 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.; former 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 *Hypertension* journal.

**Richard J. Glassock, M.D.**, M.A.C.P., Professor Emeritus, The David Geffen School of Medicine at the University of California Los Angeles, Past-President, National Kidney Foundation; Past-President, American Society of Nephrology.

**Norman K. Mollenberg, M.D.**, Ph.D., Assistant, Associate and Full Professor, Peter Bent Brigham Hospital, Boston, Massachusetts; served as an Editor of the *New England Journal of Medicine*.

### Employees

As of February 28, 2003, we employed 43 persons; 31 were engaged in research and development and 12 were engaged in administration and management. Seven 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, 2002, we had working capital of approximately \$13,786,000, including approximately \$17,439,000 of cash, cash equivalents and short-term investments. During 2002, we sold 6,164,285 shares of common stock, raising net proceeds of approximately \$21,575,000. Our cash used in operations for the year ended December 31, 2002, 2001 and 2000 was approximately \$14,931,000, \$9,032,000 and \$8,986,000, respectively. We expect to utilize cash to fund our operations at levels similar to those used in 2002 through the expected completion date of the SAPHIRE and SILVER trials in mid-2003, and believe we have adequate cash and cash equivalents and short-term investments to fund such trials. However, we do not believe we will have adequate cash at these spending levels to complete the fiscal year. As a result, throughout 2003, we will monitor our liquidity position and the status of our clinical trials. Depending upon the results of any attempts made by us to raise additional funds through the sale of additional equity securities, we may be required to significantly reduce or curtail our research and product development activities 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 actions will enable us to fund our operations through the first quarter of 2004.

We will require, over the long-term, substantial new funding to pursue development and commercialization of ALT-711 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 or not 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 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 are still in research or clinical development. We may not succeed in the development and marketing of any therapeutic or diagnostic product. 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 ALT-711, 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, 2002, we had an accumulated deficit of approximately \$169,376,000. 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 increase. 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, we repriced certain employee stock options on February 2, 1999, in order to bolster employee retention. 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, results of operations and liquidity.

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, results of operations and liquidity.

***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 for commercial purposes 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, results of operations and liquidity.

***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 conditions 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 ALT-711 or other compounds, exposes us to liability claims resulting from the use of products or product candidates. A claim, which was subsequently settled, was made by a participant in one of our clinical trials, and additional claims might be made directly by other such participants, 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 conditions 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, results of operations and liquidity.



**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.

**Our operations involve a risk of injury or damage from hazardous materials, and if an accident were to occur, we could be subject to costly and damaging liability claims, which could have a material adverse effect on our business, financial condition and results of operations.**

Our research and development activities involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for handling and disposing of hazardous materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages or fines that result. Such liability could have a material adverse effect on our business, financial condition, results of operations and liquidity.

**Item 2. Properties.**

We lease a 37,000 square foot building in Ramsey, New Jersey, which contains our executive and administrative offices and research laboratory space. The lease, which commenced on November 1, 1993, has a 10-year term. In addition, the lease has two five-year renewal options.

**Item 3. Legal Proceedings.**

On August 5, 2002, Lisa Weller, a former employee of ours, filed suit against us in the Superior Court of New Jersey asserting claims for alleged pregnancy, sex and handicap discrimination, wrongful termination and intentional infliction of emotional distress, all arising from our termination of her employment as an executive assistant. We removed the case to the United States District Court for the District of New Jersey. In December 2002, we agreed to a settlement with Ms. Weller under which we deny all liability in exchange for a dismissal and release by Ms. Weller of any and all claims against us. The settlement is currently being executed by both parties.

**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 ("Amex") since August 7, 2000, under the symbol "ALT."

<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
<b>2001</b>	<b>High</b>	<b>Low</b>
First Quarter . . . . .	\$ 6.50	\$ 3.15
Second Quarter . . . . .	4.71	2.70
Third Quarter . . . . .	3.49	2.25
Fourth Quarter . . . . .	4.93	2.33

As of February 28, 2003, there were 325 holders of the common stock. On February 28, 2003, the last sale price reported on the Amex for the common stock was \$3.74 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, 2002, has been derived from our audited financial statements.

Year Ended December 31,	2002	2001	2000	1999	1998
	(in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Revenues:					
Investment income	\$ 410	\$ 452	\$ 570	\$ 835	\$ 1,321
Other income	—	—	—	600	—
Total revenues	410	452	570	1,435	1,321
Expenses:					
Research and development (which includes non-cash variable stock compensation (benefit)/expense in 2002, 2001 and 2000 of \$(94), \$165 and \$353, respectively)	14,992	8,461	6,375	10,598	24,592
Elimination of previously accrued loss contingency	—	—	—	—	(1,771)
General and administrative (which includes non-cash variable stock compensation (benefit)/expense in 2002, 2001 and 2000 of \$(1,316), \$657 and \$891, respectively)	2,946	4,761	5,313	4,357	4,842
Interest	—	—	—	—	4
Total expenses	17,938	13,222	11,688	14,955	27,667
Loss before income tax benefit	(17,528)	(12,770)	(11,118)	(13,520)	(26,346)
Income tax benefit	647	1,187	1,548	2,588	—
Net loss	(16,881)	(11,583)	(9,570)	(10,932)	(26,346)
Preferred stock dividends	3,485	3,204	2,945	2,707	2,207
Common stock warrant deemed dividends	—	210	—	—	—
Net loss applicable to common stockholders	\$ (20,366)	\$ (14,997)	\$ (12,515)	\$ (13,639)	\$ (28,553)
Basic/diluted net loss per share applicable to common stockholders					
	\$ (0.64)	\$ (0.61)	\$ (0.63)	\$ (0.72)	\$ (1.57)
Weighted average common shares used in computing basic/diluted net loss per share					
	31,793	24,556	19,861	19,055	18,211

**Balance Sheet Data:**

Cash, cash equivalents and short-term investments	\$ 17,439	\$ 10,726	\$ 9,955	\$ 12,370	\$ 24,132
Working capital	13,786	9,758	9,754	10,425	20,093
Total assets	18,099	13,233	13,389	15,021	27,652
Accumulated deficit	(169,376)	(149,009)	(134,011)	(121,496)	(107,857)
Total stockholders' equity	14,303	10,871	11,453	12,827	23,338

**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 oral 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 Phase 2b 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.

Our lead compound, ALT-711, is being developed initially for cardiovascular indications, and two Phase 2a clinical trials in cardiovascular compliance and in DHF have been successfully completed. Based on the positive results of the trial in cardiovascular compliance, we have initiated two Phase 2b efficacy trials of ALT-711, the SAPPHIRE and SILVER trials in systolic hypertension, for which data is expected to be reported concurrently about mid-year 2003. We are also considering further clinical development in DHF and related conditions.

As we continue clinical development of ALT-711, 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 ALT-711 may address the cardiovascular, diabetes and primary care physician markets.



A topical formulation of an A.G.E. Crosslink Breaker, ALT-744, is being clinically evaluated in skin aging for cosmetic applications. We continue to evaluate product development opportunities from among our A.G.E. Crosslink Breaker compounds and other classes of compounds in our patent estate.

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 approximately \$169,376,000 as of December 31, 2002, 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.

In December 2002, we completed a public offering of 1,714,285 shares of common stock at \$1.75 per share, which provided net proceeds of approximately \$2,965,000. In connection with this offering, certain previously issued warrants were repriced pursuant to antidilution provisions connected to the warrants.

In January 2002, we completed a public offering of 4,450,000 shares of common stock, which provided net proceeds of approximately \$18,611,000.

In July 2001, we completed a public offering of 4,500,000 shares of common stock, which provided net proceeds of approximately \$9,410,000. In connection with this offering, certain previously issued warrants were repriced pursuant to antidilution provisions connected to the warrants.

In March 2000, the FASB released Interpretation No. 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 occur 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. On February 2, 1999, we repriced certain stock options. The total compensation (benefit)/expense resulting from the repricing and included in net loss for the years ended December 31, 2002, 2001 and 2000, was approximately \$(1,409,000), \$822,000 and \$1,244,000, respectively. As of December 31, 2002, there were approximately 590,000 repriced options outstanding, which expire at various dates through 2008.

In 2002, 2001 and 2000, we sold \$1,839,000, \$6,243,000 and \$14,129,000, respectively, of our gross State net operating loss carryforwards and \$578,000, \$802,000 and \$590,000, respectively, of our 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 in 2002, 2001 and 2000 were approximately \$647,000, \$1,187,000 and \$1,548,000, respectively, and such amounts were recorded as a tax benefit in the statements of operations.

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 2002, 2001, 2000

#### Revenues

Total revenues for 2002, 2001 and 2000 were \$410,000, \$452,000 and \$570,000, respectively. Revenues were derived from interest earned on cash and cash equivalents and short-term investments. The decrease in revenues in 2002 over 2001 and 2000 was attributed to decreased interest rates, partially offset by larger investment balances.

#### Operating Expenses

Total expenses increased to \$17,938,000 in 2002 from \$13,222,000 in 2001, and from \$11,688,000 in 2000, and in each year consisted primarily of research and development expenses. Research and development expenses were \$14,992,000 in 2002, \$8,461,000 in 2001 and \$6,375,000 in 2000, and included non-cash variable stock compensation (benefit)/expense of \$(94,000), \$165,000 and \$353,000, respectively. Research and development expenses consisted primarily of third-party expenses associated with pre-clinical and 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 increased in 2002 from 2001 by \$6,531,000, or 77.2%. This increase 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 were related to the Phase 2b SAPPHIRE and SILVER trials and the Phase 2a DIAMOND trial. 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 Phase 3 clinical trial supplies and potential commercialization of ALT-711, drug stability studies and drug packaging. The Phase 2b SAPPHIRE and SILVER trials completed enrollment in November 2002. The release of the data from these trials is expected to be reported concurrently about mid-year 2003.



The development and successful commercialization of ALT-711 are subject to substantial risks, which are described in this Report. For example, See "—Forward-Look Statements and Cautionary Statements — If we do not successfully develop any products, we may not derive any revenues."

Research and development expenses increased in 2001 from 2000 by \$2,086,000, or 32.7%. This increase was primarily related to additional manufacturing costs and expenditures for the crosslink breaker program. Manufacturing costs were approximately \$1,916,000 in 2001, which included the production of supplies for the ongoing clinical programs (tableting and packaging), drug stability studies and the development of manufacturing processes for the production of Phase 3 clinical trial supplies. In 2001, approximately \$1,730,000 was spent on various pre-clinical and clinical programs and the initiation of the Phase 2b SAPPHIRE and SILVER trials. The 2001 results also included personnel and personnel-related costs of \$2,554,000. In 2000, approximately \$1,769,000 was related to pre-clinical and clinical programs including the Phase 2a trial, \$1,859,000 was related to personnel costs and \$345,000 to manufacturing expense. The Phase 2a trial was completed in 2000, and the data was released in 2001.

General and administrative expenses were \$2,946,000 in 2002, decreased from \$4,761,000 in 2001 and from \$5,313,000 in 2000. The changes in general and administrative expenses consisted primarily of non-cash variable stock compensation (benefit)/expense of \$(1,316,000), \$657,000 and \$891,000 in 2002, 2001 and 2000, respectively. Excluding the non-cash variable stock compensation, general and administrative expenses were \$4,262,000, \$4,104,000 and \$4,422,000 in 2002, 2001 and 2000, respectively. The increase in 2002 over 2001 is primarily related to increased personnel costs.

At December 31, 2002, we had available federal net operating loss carryforwards, which expire in various amounts from the years 2006 through 2022, of approximately \$152,365,000 and State net operating loss carryforwards, which expire in the years 2004 through 2009, of approximately \$106,771,000. In addition, we had federal research and development credit carryforwards of approximately \$7,048,000 and State research and development tax credit carryforwards of approximately \$811,000. We had net losses of \$16,882,000 in 2002, \$11,584,000 in 2001 and \$9,570,000 in 2000.

#### **Net Loss**

Included in our net loss in 2002, 2001 and 2000 was the sale of approximately \$1,839,000, \$6,243,000 and \$14,129,000, respectively, of our gross State net operating loss carryforwards and approximately \$578,000, \$802,000 and \$590,000, respectively, of our State research and development tax credit carryforwards. The proceeds from the sale in 2002, 2001 and 2000 were approximately \$647,000, \$1,187,000 and \$1,548,000, respectively.

Included in the net loss applicable to common stockholders for 2002, 2001 and 2000 were preferred stock dividends of approximately \$3,485,000, \$3,204,000 and \$2,945,000, respectively, and common stock deemed dividends of \$210,000 in 2001.

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

We had cash, cash equivalents and short-term investments at December 31, 2002, of \$17,439,000 compared to \$10,726,000 at December 31, 2001. This is an increase in cash, cash equivalents and short-term investments of \$6,713,000 for the year ended December 31, 2002. This consisted of \$21,697,000 of financing activities related to public offerings of common stock and proceeds from stock option exercises. In December 2002, we completed a public offering of 1,714,285 shares of common stock at \$1.75 per share, which provided net proceeds of approximately \$2,964,500. In connection with this offering, certain previously issued warrants were repriced pursuant to antidilution provisions connected to the warrants. In January 2002, we completed a public offering of 4,450,000 shares of common stock, which provided net proceeds of approximately \$18,611,000. This was offset by \$14,931,000 of cash used in operations, net of \$1,833,000 of cash received for the sales of our New Jersey State net operating loss carryforwards, and consisted primarily of research and development expenses, personnel and related costs, facility expenses and approximately \$45,000 of capital expenditures.

In 2002, 2001 and 2000, we sold \$1,839,000, \$6,243,000 and \$14,129,000, respectively, of our gross State net operating loss carryforwards and \$578,000, \$802,000 and \$590,000, respectively, of our State research and development tax credit carryforwards under the State Program. The proceeds from the sale in 2002, 2001 and 2000 were \$647,000, \$1,187,000 and \$1,548,000, respectively, and such amounts were recorded as a tax benefit in the statements of operations. The proceeds from the sale of the net operating loss carryforwards and the research and development tax credit carryforwards sold in 2001 were received in January 2002, and the proceeds from the carryforwards sold in 2002 were received in December 2002. As of December 31, 2002 and 2001, we had State net loss carryforwards and State research and development tax credit carryforwards available for sale of approximately \$107,582,000 and \$85,100,000, respectively. The State renews the Program annually and limits the aggregate proceeds 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 expect to utilize our cash, cash equivalents and short-term investments to fund our operations at levels similar to those used in 2002 through the expected completion date of the SAPPHIRE and SILVER trials in mid-2003, and believe we have adequate cash and cash equivalents and short-term investments to fund such trials. However, we do not believe we will have adequate cash at these spending levels to complete the fiscal year. As a result, throughout 2003, we will monitor our liquidity position and the status of our clinical trials. Depending upon the results of any attempts made by us to raise additional funds through the sale of additional equity securities, we may be required to significantly reduce or curtail our research and product development activities 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 actions will enable us to fund our operations through the first quarter of 2004.

We will require, over the long-term, substantial new funding to pursue development and commercialization of ALT-711 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.

Our current priorities and the focus of our resources are the evaluation and continued development of ALT-711 and determining the optimal course for the development of other compounds in our patent estate. As we continue clinical development of ALT-711, 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 find additional sources of funding.

**Recently Issued Accounting Standards**

In June 2002, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." The standard requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of commitment to an exit or disposal plan. SFAS No. 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002.

**Related Party Transactions**

Since our inception, we have entered into certain collaborative agreements with organizations with which Dr. Anthony Cerami, a former member of our Board of Directors, was affiliated. These organizations included The Picower Institute and Rockefeller University. We paid patent maintenance fees for technology licensed from these organizations of \$1,450, \$17,000 and \$120,000 in 2002, 2001 and 2000, respectively. Although we have terminated our collaborative relationship with The Picower Institute, we have a royalty obligation on all net sales and other revenues associated with certain technologies developed, payable to The Picower Institute's successor.

**Critical Accounting Policies**

In December 2001, the United States Securities and Exchange Commission 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, 2002, 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. FIN 44 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 income applicable to common stockholders and net loss per share 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, 2002 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>2002</u>
Cash equivalents:	
Fixed Rate .....	\$14,452,413
Average interest rate .....	1.32%
Short-term investments:	
Fixed Rate .....	\$2,986,200
Average interest rate .....	1.30%
Total investment securities:	\$17,438,613
Average interest rate .....	1.31%



**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 27.

(b) The unaudited quarterly financial data for the two-year period ended December 31, 2002 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>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)
<b>2001</b>					
First Quarter	\$ 153	\$ 4,181	\$ (4,028)	\$ (4,793)	\$ (0.21)
Second Quarter	101	2,407	(2,306)	(3,096)	(0.14)
Third Quarter	107	2,321	(2,214)	(3,239)	(0.13)
Fourth Quarter	91	4,313	(4,222)	(3,869)	(0.13)
Total Year	\$ 452	\$ 13,222	\$ (12,770)	\$ (14,997)	\$ (0.61)

**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.

**PART III**

**Item 10. Directors and Executive Officers of the Company.**

The information called for by Item 10 is incorporated by reference from the information under the caption "Election of Directors," "Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our Proxy Statement for our 2003 Annual Meeting of Stockholders to be held on June 4, 2003.

**Item 11. Executive Compensation.**

The information called for by Item 11 is incorporated by reference from the information under the caption "Executive Compensation" in our Proxy Statement for our 2003 Annual Meeting of Stockholders to be held on June 4, 2003.

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

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, 2002:





<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 .....	5,436,279	\$3.08	2,773,097
Equity compensation plans not approved by security holders .....	N/A	N/A	N/A
<b>Total .....</b>	<b>5,436,279</b>	<b>\$3.08</b>	<b>2,773,097</b>

The additional information called for by Item 12 is incorporated by reference from the information under the caption "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement for our 2003 Annual Meeting of Stockholders to be held on June 4, 2003.

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

The information called for by Item 13 is incorporated by reference from the information under the caption "Certain Relationships and Related Transactions" in our Proxy Statement for our 2003 Annual Meeting of Stockholders to be held on June 4, 2003.

**Item 14. Controls and Procedures.**

*(a) Evaluation of Disclosure Controls and Procedures.*

Within the 90 days prior to the filing date of this Annual Report on Form 10-K, our Chief Executive Officer and our Vice President, Finance, evaluated the effectiveness of our disclosure controls and procedures as defined in Rule 13a-14(c) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based upon that evaluation, the Chief Executive Officer and the Vice President, Finance, have concluded that 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 have been no significant changes in our internal controls or in other factors that could significantly affect internal controls subsequent to the date of their evaluation by the Chief Executive Officer and the Vice President, Finance.

**PART IV**

**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 27.

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

On December 24, 2002, we filed a current report on Form 8-K, dated December 20, 2002, announcing that we entered into a Stock Purchase Agreement to sell 1,714,285 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 10th day of March 2003.

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.

Signature	Title	Date
<u>/s/ Kenneth I. Moch</u> Kenneth I. Moch	Chairman of the Board, President and Chief Executive Officer (principal executive officer)	March 10, 2003
<u>/s/ Elizabeth O'Dell</u> Elizabeth O'Dell	Vice President, Finance, Secretary and Treasurer (principal accounting officer)	March 10, 2003
<u>/s/ Edwin Bransome, Jr., M.D.</u> Edwin Bransome, Jr., M.D.	Director	March 10, 2003
<u>/s/ Marilyn G. Breslow</u> Marilyn G. Breslow	Director	March 10, 2003
<u>/s/ Alan J. Dalby</u> Alan J. Dalby	Director	March 10, 2003
<u>/s/ David K. McCurdy</u> David K. McCurdy	Director	March 10, 2003
<u>/s/ Thomas A. Moore</u> Thomas A. Moore	Director	March 10, 2003
<u>/s/ George M. Naimark, Ph.D.</u> George M. Naimark, Ph.D.	Director	March 10, 2003
<u>/s/ Mark Novitch, M.D.</u> Mark Novitch, M.D.	Director	March 10, 2003



**I, Kenneth I. Moch, certify that:**

1. I have reviewed this annual report on Form 10-K of Alteon Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements and other financial information included in this annual report fairly present, in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant, and have:
  - (a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - (b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - (c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: March 10, 2003

/s/ Kenneth I. Moch  
Kenneth I. Moch  
President and Chief Executive Officer



## Certifications

*I, Elizabeth O'Dell, certify that:*

1. I have reviewed this annual report on Form 10-K of Alteon inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements and other financial information included in this annual report fairly present, in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant, and have:
  - (a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - (b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - (c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: March 10, 2003

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



# I n d e p e n d e n t   A u d i t o r s '   R e p o r t

Form 10-K – Item 14(a)(1)

Alteon Inc.

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## INDEPENDENT AUDITOR'S REPORT

To the Board of Directors and Stockholders  
Alteon Inc.:

We have audited the accompanying balance sheet of Alteon Inc. as of December 31, 2002, and the related statements of operations, stockholders' equity and cash flows for the year 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 audit. The balance sheets of Alteon Inc., as of December 31, 2001 and 2000 and related statements of operations, stockholders' equity and cash flows for the years then ended 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 audit 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 audit provides 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, 2002, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ KPMG LLP

Short Hills, New Jersey  
January 27, 2003



Report of Independent Public Accountants

**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 SHEET AS OF DECEMBER 31, 2000 AND THE CONSOLIDATED STATEMENTS OF OPERATIONS, STOCKHOLDERS' EQUITY AND CASH FLOWS FOR THE YEAR ENDED DECEMBER 31, 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



## Balance Sheets

December 31,	2002	2001
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents .....	\$ 14,452,413	\$ 4,249,439
Short-term investments .....	2,986,200	6,476,384
Other current assets .....	143,124	1,394,765
Total current assets .....	17,581,737	12,120,588
Property and equipment, net .....	517,623	1,109,676
Deposits and other assets .....	—	2,815
Total assets .....	<u>\$ 18,099,360</u>	<u>\$ 13,233,079</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities:</b>		
Accounts payable .....	\$ 537,394	\$ 307,153
Accrued expenses .....	3,258,729	2,054,980
Total current liabilities .....	3,796,123	2,362,133
<b>Stockholders' Equity:</b>		
Preferred stock, \$.01 par value; 1,993,329 shares authorized, and 1,079 and 992 shares of Series G and 3,241 and 2,980 shares of Series H issued and outstanding, as of December 31, 2002 and December 31, 2001, respectively .....	43	40
Common stock, \$.01 par value; 80,000,000 shares authorized, and 33,600,841 and 27,314,846 shares issued and outstanding as of December 31, 2002 and December 31, 2001, respectively .....	336,008	273,148
Additional paid-in capital .....	183,341,416	159,596,934
Accumulated deficit .....	(169,375,594)	(149,008,641)
Accumulated other comprehensive income .....	1,364	9,465
Total stockholders' equity .....	14,303,237	10,870,946
Total liabilities and stockholders' equity .....	<u>\$ 18,099,360</u>	<u>\$ 13,233,079</u>

The accompanying notes are an integral part of these balance sheets.



## Statements of Operations

Year Ended December 31,	2002	2001	2000
Revenues:			
Investment income	\$ 409,853	\$ 451,518	\$ 570,444
Expenses:			
Research and development (which includes non-cash variable stock compensation (benefit)/expense in 2002, 2001 and 2000 of \$(93,516), \$164,988 and \$353,065, respectively)	14,992,418	8,461,476	6,375,380
General and administrative (which includes non-cash variable stock compensation (benefit)/expense in 2002, 2001 and 2000 of \$(1,315,635), \$657,295 and \$890,604, respectively)	2,945,846	4,760,747	5,312,750
Total expenses	17,938,264	13,222,223	11,688,130
Loss before income tax benefit	(17,528,411)	(12,770,705)	(11,117,686)
Income tax benefit	646,500	1,186,921	1,547,763
Net loss	(16,881,911)	(11,583,784)	(9,569,923)
Preferred stock dividends	3,485,042	3,203,906	2,945,451
Common stock warrant deemed dividends	—	209,528	—
Net loss applicable to common stockholders	\$ (20,366,953)	\$ (14,997,218)	\$ (12,515,374)
Basic/diluted net loss per share applicable to common stockholders	\$ (0.64)	\$ (0.61)	\$ (0.63)
Weighted average common shares used in computing basic/diluted loss per share	31,793,466	24,555,885	19,860,847

The accompanying notes are an integral part of these 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

	Preferred Stock		Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in	Deficit	Other	Stockholders'
					Capital		Comprehensive	Equity
							Income/(Loss)	
Balances at								
DECEMBER 31, 1999	3,357	\$34	19,189,701	\$191,897	\$134,129,513	\$(121,496,049)	\$ 1,293	\$12,826,688
Net loss	—	—	—	—	—	(9,569,923)	—	(9,569,923)
Change in unrealized gains/(losses)	—	—	—	—	—	—	(2,163)	(2,163)
Comprehensive loss								(9,572,086)
Issuance of Series G and H preferred stock dividends	294	3	—	—	2,945,448	(2,945,451)	—	—
Exercise of employee stock options	—	—	375,871	3,759	500,786	—	—	504,545
Private placement of common stock and warrants	—	—	2,834,088	28,341	6,103,151	—	—	6,131,492
Compensation expense related to variable plan employee stock options	—	—	—	—	1,243,669	—	—	1,243,669
Compensation expense in connection with the issuance of non-qualified stock options, stock option modifications and options granted to non-employees	—	—	—	—	318,698	—	—	318,698
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 offering 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, stock option modifications and 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

The accompanying notes are an integral part of these statements.



## Statements of Cash Flows

Year Ended December 31,	2002	2001	2000
Cash flows from operating activities:			
Net loss	\$ (16,881,911)	\$ (11,583,784)	\$ (9,569,923)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	637,162	636,565	765,601
Stock compensation expense	34,424	326,177	318,698
Non-cash compensation expense related to variable plan employee stock options	(1,409,151)	822,283	1,243,669
Changes in operating assets and liabilities:			
Other assets	1,254,456	340,895	(1,486,677)
Accounts payable and accrued expenses	1,433,990	425,775	(257,844)
Net cash used in operating activities	(14,931,030)	(9,032,089)	(8,986,476)
Cash flows from investing activities:			
Capital expenditures	(45,109)	(50,159)	(62,377)
Purchases of marketable securities	(18,020,917)	(16,743,570)	(11,550,202)
Maturities of marketable securities	21,503,000	16,632,000	12,227,817
Net cash provided by (used in) investing activities	3,436,974	(161,729)	615,238
Cash flows from financing activities:			
Net proceeds from issuance of common stock	21,575,016	9,410,080	6,131,492
Net proceeds from exercise of employee stock options	122,014	432,849	504,545
Net cash provided by financing activities	21,697,030	9,842,929	6,636,037
Net increase/(decrease) in cash and cash equivalents	10,202,974	649,111	(1,735,201)
Cash and cash equivalents, beginning of period	4,249,439	3,600,328	5,335,529
Cash and cash equivalents, end of period	\$ 14,452,413	\$ 4,249,439	\$ 3,600,328

The accompanying notes are an integral part of these 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 oral drugs to reverse or inhibit cardiovascular aging and diabetic complications. The Company's product candidates represent novel approaches to some of the largest pharmaceutical markets, such as cardiovascular and kidney diseases. 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.

The Company's lead compound, ALT-711, is being developed initially for cardiovascular indications, and two Phase 2a clinical trials in cardiovascular compliance and in diastolic heart failure ("DHF") have been successfully completed. Based on the positive results of the trial in cardiovascular compliance, Alteon has initiated two Phase 2b efficacy trials of ALT-711 in systolic hypertension, the SAPPHIRE (Systolic And Pulse Pressure Hemodynamic Improvement by Restoring Elasticity) trial and the SILVER (Systolic Hypertension Interaction with Left VEentricular Remodeling) trial, for which data is expected to be reported concurrently in mid-2003. The Company is also considering further clinical development in DHF and related conditions.

A topical formulation of an A.G.E. Crosslink Breaker, ALT-744, is being clinically evaluated in skin aging for cosmetic applications. The Company continues to evaluate product development opportunities from its A.G.E. Crosslink Breaker compounds and other classes of compounds in its patent estate.

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 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 and 2001, short-term investments were invested in debt instruments of the United States government, government agencies, financial institutions and corporations with strong credit ratings. They consisted of the following:

<b>December 31,</b>	<b>2002</b>	<b>2001</b>
United States government agency funds . . . . .	\$ 2,986,200	\$ 5,479,434
Corporate obligations . . . . .	—	996,950
	<u>\$ 2,986,200</u>	<u>\$ 6,476,384</u>

The cost of short-term investments was \$2,984,836 and \$6,466,919 at December 31, 2002 and December 31, 2001, respectively.

*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. Leasehold improvements and equipment under capital leases are amortized using the straight-line method over the shorter of the lease term or the useful life of the assets.

*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. Alteon adopted Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" on January 1, 2002. The adoption of SFAS No. 144 had no impact on the Company's policy regarding impairment of long-lived assets or its results of operations, cash flows or financial position.



## Notes to Financial Statements

### 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." 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 all of its option grants, the Company's pro forma net loss and net loss per share applicable to common stockholders for 2002, 2001 and 2000 would be as follows:

Year Ended December 31,	2002	2001	2000
Net loss applicable to common stockholders,			
as reported	\$ (20,366,953)	\$ (14,997,218)	\$ (12,515,374)
Add: Variable non-cash stock compensation			
(benefit)/expense	(1,409,151)	822,283	1,243,669
Less: Total stock-based employee compensation			
expense determined under fair value method	(1,892,584)	(2,029,445)	(1,517,400)
Pro forma net loss applicable to common stockholders	\$ (23,668,688)	\$ (16,204,380)	\$ (12,789,105)
Net loss per share applicable to common stockholders:			
Basic/diluted as reported	\$ (0.64)	\$ (0.61)	\$ (0.63)
Basic/diluted pro forma	\$ (0.73)	\$ (0.64)	\$ (0.63)

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 2002, 2001 and 2000, respectively: risk free interest rates ranging from 1.29% to 5.15%, 2.79% to 5.02% and 5.24% to 6.64%, respectively; expected life of 5.75 years for employee grants and the contractual life for grants to consultants and contractors; expected dividend yield of 0%; and expected volatility of 108.98%, 110.39% and 109.53%, 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 earnings in the period that includes the enactment date. Deferred tax assets are recorded when they are more likely than not to be realized.

### 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, 2002, 2001 and 2000, was 28,872,120, 15,135,350 and 15,148,365 shares, respectively.

### Recently Issued Accounting Standards

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." The standard requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of commitment to an exit or disposal plan. SFAS No. 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. SFAS No. 146 will affect the types and timing of costs included in restructuring programs, if any, but is not expected to have a material impact on the Company's results of operations, cash flows or financial position.

### 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 \$169,375,594 at December 31, 2002, 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 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.



Notes to Financial Statements

As of December 31, 2002, the Company had working capital of \$13,785,614, including \$17,438,613 of cash, cash equivalents and short-term investments. During 2002, the Company sold 6,164,285 shares of common stock, raising net proceeds of \$21,575,016. (See Note 8.) The Company's cash used in operations for the year ended December 31, 2002, 2001 and 2000 was \$14,931,030, \$9,032,089 and \$8,986,476, respectively. The Company expects to utilize cash to fund its operations at levels similar to those used in 2002 through the expected completion date of the SAPPHIRE and SILVER trials in mid-2003, and believes it has adequate cash and cash equivalents and short-term investments to fund such trials. However, it does not believe it will have adequate cash at these spending levels to complete the fiscal year. As a result, throughout 2003, the Company will monitor its liquidity position and the status of its clinical trials. Depending upon the results of any attempts made by the Company to raise additional funds through the sale of additional equity securities, Alteon may be required to significantly reduce or curtail its research and product development activities 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 actions will enable Alteon to fund its operations through the first quarter of 2004.

The Company will require, over the long-term, substantial new funding to pursue development and commercialization of ALT-711 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.

NOTE 3 — Property and Equipment

Table with 3 columns: December 31, 2002, 2001. Rows include Laboratory equipment, Furniture and equipment, Computer equipment, Leasehold improvements, and Less: Accumulated depreciation & amortization.

Depreciation and amortization expense was \$637,162, \$636,565 and \$765,601 for the years ended December 31, 2002, 2001 and 2000, respectively.

NOTE 4 — Collaborative Research and Development Agreement

On November 6, 2002, Alteon entered into a new agreement, effective as of April 15, 2002, with The Picower Institute for Medical Research ("The Picower Institute"), which terminated their 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 their License Agreement dated as of June 16, 1989. Pursuant to the letter agreement, for a period of fifteen years, (i) Alteon will pay Yamanouchi royalties on any sales of pimagedine or pimagedine products in the territory covered by the License Agreement and (ii) Alteon will have the option to purchase from Yamanouchi all or any part of its common stock owned by Yamanouchi.

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 the Company has 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. Alteon has a license and supply agreement with IDEXX Laboratories, Inc. ("IDEXX") pursuant to which the Company licensed pimagedine to IDEXX as a potential therapeutic in companion animals (dogs, cats and horses) and Alteon's A.G.E. diagnostics technology for companion animal use. All of these agreements will entitle Alteon to receive royalties on sales if any products covered by the agreements are developed and sold.

In October 2000, Alteon entered into an agreement with HemoMax, LLC ("HemoMax") for the development of a novel technology designed to increase the delivery of oxygen to tissues in the body through enhanced blood circulation. On February 9, 2002, HemoMax advised Alteon that because of uncertainties regarding its ability to receive patents adequate to support commercialization of the technology, it had decided to cease operations and liquidate.



Notes to Financial Statements

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 would have a material adverse effect on the Company's business, financial condition and 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 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,	2002	2001
Clinical trial expense	\$ 2,706,678	\$ 1,379,693
Professional fees	204,723	191,000
Payroll and related expenses	106,629	224,287
Rent expense	45,761	100,673
Patent fees	107,187	85,571
Other	87,751	73,756
	<u>\$ 3,258,729</u>	<u>\$ 2,054,980</u>

**NOTE 7 — Contingencies and Commitments**

*Commitments*

The Company leases its headquarters and research facility under non-cancelable operating leases. As of December 31, 2002, Alteon has no future minimum rentals under operating leases in excess of one year as the current facility lease term ends October 2003. This facility lease includes two, five-year renewal options which are presently under negotiation.

Rent expense for each of the years in the three-year period ended December 31, 2002, was \$604,690, \$599,655 and \$586,294, respectively.

**NOTE 8 — Stockholders' Equity**

*Common/Preferred Stock Issuances*

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 approximately \$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, 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 September 2000, Alteon entered into an agreement with several investors pursuant to which Alteon sold, in a private placement, an aggregate of 2,834,088 shares of common stock and warrants to purchase 1,133,636 shares of common stock (the "Warrants") for net proceeds of \$6,131,492. The adjusted exercise price of the Warrants, as of December 31, 2002, is \$1.75 per share, while the term is seven years.

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, 2002, 2001 and 2000, respectively, \$3,488,042, \$3,203,906 and \$2,945,451 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%. 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 all are still outstanding.

*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.



Notes to Financial Statements

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, 1999	5,075,196	\$ 3.40	
Granted at market price	1,105,820	4.57	\$ 2.54
Exercised	(375,871)	1.34	
Canceled	(550,326)	1.12	
Balance, December 31, 2000	5,254,819	\$ 4.02	
Granted at market price	873,942	3.13	\$ 1.78
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	\$ 1.62
Granted above market price	250,000	1.95	1.06
Granted below market price	10,000	0.01	4.37
Exercised	(121,710)	1.02	
Canceled	(83,717)	4.25	
Balance, December 31, 2002	<u>5,436,279</u>	\$ 3.08	

Stock options exercisable at December 31, 2002, 2001 and 2000 were 3,836,930, 3,336,159 and 3,637,496, respectively, at weighted average grant date exercise prices of \$3.08, \$2.95 and \$4.35, respectively.

The following table summarizes information regarding stock options outstanding at December 31, 2002:

Range of Exercise Prices	Options Outstanding at December 31, 2002			Options Exercisable at December 31, 2002	
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.7810 - \$ 1.0630	1,464,138	5.15	\$ 0.9491	1,464,138	\$ 0.9491
1.1250 - 2.6000	1,645,457	8.60	1.9369	695,943	1.5661
2.8750 - 4.6250	1,423,080	7.50	3.8314	867,078	3.7897
5.0000 - 15.0000	903,604	4.31	7.4294	807,771	7.4927
\$0.7810 - \$15.0000	5,436,279	6.67	\$ 3.0797	3,834,930	\$ 3.0817

Included in options at December 31, 2002 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 \$34,424, \$66,567 and \$62,255 in 2002, 2001 and 2000, 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 (benefit)/expense resulting from the repricing for the years ended December 31, 2002, 2001 and 2000 of \$(1,409,151), \$822,283 and \$1,243,669, respectively, which included research and development charges of \$(93,516), \$164,988 and \$353,065 and general and administrative charges of \$(1,315,635), \$657,295 and \$890,604, respectively. As of December 31, 2002, there were approximately 589,899 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 \$54,024, \$38,669 and \$30,530 for the years ended December 31, 2002, 2001 and 2000, respectively.



Notes to Financial Statements

**NOTE 10 — Related Party Transactions**

Since the Company's inception, the Company has entered into certain collaborative agreements with organizations with which Dr. Anthony Cerami, a former member of the Company's Board of Directors, was affiliated. These organizations included The Picower Institute and The Rockefeller University. The Company paid patent maintenance fees for technology licensed from these organizations of \$1,449, \$16,799 and \$120,001 in 2002, 2001 and 2000, respectively. Although the Company has terminated its collaborative relationship with The Picower Institute, the Company has a royalty obligation on all net sales and other revenues associated with certain technologies developed, payable to The Picower Institute's successor.

**NOTE 11 — Income Taxes**

At December 31, 2002, the Company had available federal net operating loss carryforwards, which expire in the years 2006 through 2022, of approximately \$152,365,000 for income tax purposes and State net operating loss carryforwards, which expire in the years 2004 through 2009, of approximately \$106,771,000. In addition, the Company has federal research and development tax credit carryforwards of approximately \$7,048,000 and State research and development tax credit carryforwards of approximately \$811,000. 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,	2002	2001
Net operating loss carryforwards . . . . .	\$ 59,800,000	\$ 51,300,000
Research and development credit . . . . .	7,800,000	6,700,000
Other temporary differences . . . . .	1,200,000	4,100,000
Gross deferred tax assets . . . . .	68,800,000	62,100,000
Valuation allowance . . . . .	(68,800,000)	(62,100,000)
Net deferred tax assets . . . . .	\$ —	\$ —

Given the Company's past 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 2002, 2001 and 2000, the Company sold \$1,839,000, \$6,243,000 and \$14,129,000, respectively, of its gross State net operating loss carryforwards and \$578,000, \$802,000 and \$590,000, 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 business 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 2002, 2001 and 2000 were approximately \$647,000, \$1,187,000 and \$1,548,000, 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 proceeds 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.





<b>Exhibit 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, S.E.C. 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 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, S.E.C. 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, S.E.C. 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, S.E.C. 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, S.E.C. 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, S.E.C. 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, S.E.C. 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, S.E.C. 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, S.E.C. File Number 001-16043.)
3.10	By-laws, as amended.
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, S.E.C. 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, S.E.C. 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, S.E.C. 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, S.E.C. 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, S.E.C. 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, S.E.C. 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, S.E.C. 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, S.E.C. 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, S.E.C. File Number 001-16043.)



## Exhibit Index

- 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, S.E.C. 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, S.E.C. 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, S.E.C. File Number 33-42574, which became effective on November 1, 1991.)
- 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, S.E.C. 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, S.E.C. 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, S.E.C. 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, S.E.C. File Number 000-19529.)
- 10.8\* License and Supply Agreement dated June 17, 1997, between IDEXX Laboratories, Inc. and Alteon Inc. (Incorporated by reference to Exhibit 10.1 to the Company's Report on Form 10-Q filed on August 13, 1997, S.E.C. File Number 000-19529.)
- 10.9† 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, S.E.C. File Number 000-19529.)
- 10.10† 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, S.E.C. File Number 001-16043.)
- 10.11 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 Tabureau. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 5, 2000, S.E.C. File Number 001-16043.)
- 10.12† 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, S.E.C. File Number 001-16043.)
- 10.13 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, S.E.C. File Number 001-16043.)
- 10.14† 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, S.E.C. File Number 001-16043.)
- 10.15 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, S.E.C. File Number 001-16043.)
- 23.1 Consent of KPMG LLP.
- 99.1 Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Confidentiality has been granted for a portion of this exhibit.

† 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.



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

**Thomas A. Moore**  
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 C. deGroof, 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.  
170 Williams Drive  
Ramsey, New Jersey 07446  
201-934-5000  
www.alteon.com

**Legal Counsel**  
Smith, Stratton, Wise, Heiler & Brennan LLP  
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  
212-936-5100

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

**Annual Meeting**  
Date: June 4, 2003  
Time: 9:00 AM  
Place: Sheraton Crossroads  
One International Boulevard  
Mahwah, New Jersey 07430



**Alteon**

170 Williams Drive

Ramsey, New Jersey 07446

Tel: (201) 934-5000

Fax: (201) 934-8880

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