

Edgar Filing: ALTEON INC /DE - Form 10-K

ALTEON INC /DE  
Form 10-K  
March 02, 2001

1

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, 2000, OR

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

Commission file number 0-19529

ALTEON INC.

-----  
(Exact name of registrant as specified in its charter)

DELAWARE

13-3304550

-----  
(State or other jurisdiction of  
incorporation or organization)

-----  
(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	Name of Exchange On Which Registered
----- Common Stock, Par Value \$.01 per share	----- 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    X        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

## Edgar Filing: ALTEON INC /DE - Form 10-K

incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

The aggregate market value of the equity stock held by non-affiliates of the Registrant, based on the American Stock Exchange closing price of the Common Stock (\$4.35 per share), as of February 28, 2001, was \$97,862,680.

At February 28, 2001, 22,537,635 shares of the Registrant's Common Stock, par value \$.01 per share, were outstanding.

### Documents Incorporated By Reference

Document	Where Incorporated
----- Proxy Statement for 2001 Annual Meeting of Stockholders	----- Part III

2

### PART 1

#### ITEM 1. BUSINESS.

##### OVERVIEW

We are a product-based biopharmaceutical company engaged in the discovery and development of oral drugs for the treatment of diseases of aging and diabetes. Our product candidates represent novel approaches to some of the largest pharmaceutical markets, such as cardiovascular and kidney diseases. Two of our compounds are in clinical development; several others are undergoing pre-clinical testing. These pharmaceutical candidates were developed as a result of our understanding of the Advanced Glycosylation End-product ("A.G.E.") pathway, a fundamental pathological process and inevitable consequence of aging that may result in many medical disorders.

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 with other proteins (crosslink), 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. We believe 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.

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 98 issued United States patents and over 80 issued foreign patents focused primarily on A.G.E. technology.

ALT-711 is our lead product candidate in a class of proprietary compounds known as A.G.E. Crosslink Breakers. 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

## Edgar Filing: ALTEON INC /DE - Form 10-K

restoring flexibility and function. We are initially developing ALT-711 for the treatment of cardiovascular disease, and have completed a 93-patient, placebo-controlled safety, efficacy and pharmacology trial of ALT-711, known as a Phase IIa clinical trial. In January 2001, we announced that these study results showed that patients who received ALT-711 experienced a statistically significant (p less than or equal to 0.05) and clinically meaningful reduction in pulse pressure, defined as the difference between systolic and diastolic blood pressures. Results also showed a clinically meaningful increase in large artery compliance, an indicator of greater vascular flexibility and volume capacity. Additionally, the drug was well tolerated. The results of the Phase IIa trial were accepted to be presented at the Special Sessions Presentation of "Late Breaking Clinical Trials" at the American College of Cardiology Annual Scientific Session in March 2001.

These positive results suggest that ALT-711 is a novel potential therapy for isolated systolic hypertension, a disease that occurs as a result of vascular stiffening due to age or diabetes. We plan to initiate a Phase IIb efficacy trial to further assess ALT-711's activity in isolated systolic hypertension ("ISH"). Additionally, we are evaluating potential clinical trials in other therapeutic indications where the compound may address significant unmet needs.

We are actively evaluating product development opportunities from our library of compounds. Pimagedine, our clinical lead A.G.E.-Formation Inhibitor, and ALT-946, a pre-clinical lead second-generation A.G.E.-Formation Inhibitor, are being considered for further development. In addition, we are utilizing our technical expertise in the field of diabetes to develop compounds focused on glucose regulation and control. We are evaluating our lead GLA compounds to determine the most appropriate pre-clinical development course.

We were incorporated in Delaware in October 1986 under the name Geritech Inc. Our name was changed to Alteon Inc. in August 1991.

2

3

### OUR BUSINESS STRATEGY

Our strategy is to develop drug candidates from our existing portfolio of new chemical entities. Because of the novel mechanism of action of our compounds, we are seeking to position these compounds to address large medical needs that are unmet by existing therapies. We will seek, as appropriate, to selectively out-license our drug candidates. 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 we believe warrant further evaluation and potential development.

### MARKETS OF OPPORTUNITY

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

These development and research efforts have led us to an initial focus on cardiovascular disease, including ISH, as well as complications of diabetes. Targeting the A.G.E. pathway may impact a number of medical disorders related to aging and diabetes, thus potentially broadening our markets of opportunity.

Cardiovascular Disease

According to the American Heart Association, nearly 60 million Americans have one or more types of cardiovascular disease. Cardiovascular disease has been the number one killer of Americans since the early 1900's. The latest World Health Organization - International Society of Hypertension guidelines for the management of hypertension emphasize the importance of pulse pressure and arterial stiffness (hardening) as predictors of general cardiovascular risk. Currently available hypertensive agents reduce pressure on the vessel wall in such a manner as to lower both systolic and diastolic blood pressures without affecting pulse pressure. Our approach increases large arterial elasticity in such a manner as to increase the volume of the large artery and thereby reduce 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 left ventricular hypertrophy and congestive heart failure. Published studies have shown that a 10mm Hg reduction in pulse pressure correlates with a 35% reduction in cardiovascular mortality.

Isolated Systolic Hypertension

ISH is defined as elevated systolic blood pressure (greater than 160mm Hg) accompanied by normal diastolic blood pressure (less than 90mm Hg). ISH, which affects over eight million Americans, is primarily a consequence of age-related stiffening of the large arteries. It is associated with a significantly increased risk of overall mortality, cardiovascular mortality and congestive heart failure and is not adequately treated by existing therapies. The ability of ALT-711 to decrease pulse pressure and increase large artery compliance (see "A.G.E. Crosslink Breakers - ALT-711") offers an opportunity to provide a treatment option specifically for ISH. Though other hypertensive agents are being used to treat ISH, ALT-711 is the first drug to show direct activity against this condition by targeting stiff vessel disease that causes this form of hypertension. We believe that because ALT-711 exerts its activity by a mechanism uniquely different from currently available therapies, its benefits will be over and above current standard treatment.

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.

3

4

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"), advanced kidney disease requiring dialysis. Approximately 34% of patients with Type 1 diabetes and approximately 10-15% of patients with Type 2 diabetes develop nephropathy. As of 1995, there were approximately 1,000,000 diabetics diagnosed with kidney disease in the United States.

## Edgar Filing: ALTEON INC /DE - Form 10-K

In a Phase II/III trial in diabetic patients with overt nephropathy, the ACTION trial, Pimagedine therapy showed a statistically significant reduction in urinary protein excretion, though it did not reach statistical significance in its primary endpoint, the time to doubling of serum creatinine. In addition, our pre-clinical candidate, ALT-946, has shown a protective effect on the kidneys in a pre-clinical study.

### Retinopathy

Approximately nine out of 10 people with diabetes eventually develop a complication that affects the eyes known as diabetic retinopathy. Retinopathy 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 II/III ACTION trial, Pimagedine therapy did result in a statistically significant reduction in the progression of retinopathy. In addition, we believe that ALT-711 may have an impact on retinopathy.

### Cardiovascular Disease

A significant portion of diabetic individuals develops cardiovascular disease due to the high levels of blood glucose and A.G.E.s within the body.

### Other Diseases

We are actively evaluating other potential indications for our compounds, including the treatment of patients on peritoneal dialysis, with urological conditions, scleroderma and other dermatologic conditions.

### OUR TECHNOLOGY: THE A.G.E. PATHWAY IN AGING AND DIABETES

A.G.E.s are permanent glucose structures that form when glucose binds to the surface of proteins. As the body ages, A.G.E. complexes form on proteins continuously and naturally, though slowly, 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 toughening and discoloration of food during the cooking process and after prolonged storage occurs, in part, as a result of the formation of complexes between sugars and the amino acids of proteins.

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 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 crosslinking of A.G.E.s is an inevitable part of the aging process that leads to a loss of flexibility and function in body tissues, organs and vessels.

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.

Edgar Filing: ALTEON INC /DE - Form 10-K

5

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 mechanical process can impair the normal function of contractile organs, such as blood vessels and cardiac muscle, which depend on flexibility for normal function. Loss of flexibility of the vasculature may lead to a number of cardiovascular disorders including ISH, which creates increased workload for the heart and may lead to heart failure.

The foundation for our technology is the experimental evidence that intervention and treatment along the pathway towards A.G.E. crosslink formation would be likely to provide significant benefit in slowing or reversing the development of the serious pathologies that develop in the diabetic and aging populations. ALT-711 and Pimagedine are the lead compounds resulting from our research in this field.

Studies conducted in animal models of diabetes or 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 a significant beneficial effect on such disease states.

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. cascade where we are attempting to offer pharmaceutical agents to intervene therapeutically.

[ NOTE: THE PRINTED COPY OF THIS FORM 10-K CONTAINS A GRAPHICAL ]  
 [ REPRESENTATION OF THE FOLLOWING. THE "I" REPRESENTS ARROWS ]  
 [ POINTING FROM "GLUCOSE LOWERING AGENTS" TO "GLUCOSE + PROTEINS," ]  
 [ FROM "A.G.E.-FORMATION AND CROSSLINK INHIBITORS" TO "A.G.E.S," AND ]  
 [ FROM "A.G.E. CROSSLINK BREAKERS" TO "CROSSLINKED A.G.E.S" ]

OUR TECHNOLOGY PLATFORM AND PRODUCT PIPELINE

Glucose / Proteins I Glucose Lowering Agents	====>	A.G.E.s I A.G.E. Formation and Crosslink Inhibitors	====>	Crossl A.G.E Br
- New Chemical Class (51 Compounds)	-	9 New Chemical Classes (852 Compounds)	-	4 New Che (375 Comp
- New Mechanism	-	New Mechanism	-	New Mecha
- Improves pancreas function	-	- Blocks A.G.E. cascade	-	- Breaks
- Increases insulin production	-	- Improves kidney function	-	- Restor
- Restores insulin sensitivity	-	Effect additive to ACE Inhibitors	-	- Restor Activity drug

Lead Compounds:

ALT-4037 ----- Pre-Clinical Lead Type II Diabetes	Pimagedine ----- Phase II/III Diabetic Disease	ALT-711 ----- Phase II C Cardiovasc
	ALT-946	

-----  
Pre-Clinical Lead

We incurred research and development expenditures of \$6,022,000, \$10,598,000 and \$24,592,000 for the years ended December 31, 2000, 1999 and 1998, respectively.

5

6

#### 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 in a Phase IIa trial the ability to reverse tissue damage and restore function to the cardiovascular system.

Additionally, we are evaluating development of the breaker class for several other indications where A.G.E.s and A.G.E. crosslinking lead 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 four distinct chemical classes of A.G.E. crosslink breakers, and have a library of more than 375 compounds.

#### ALT-711

Through its unique mechanism of action, ALT-711 is the first compound that breaks A.G.E.-derived crosslinks between proteins, both in vitro and in vivo. The compound is under Phase II clinical evaluation in cardiovascular disease, as well as in various pre-clinical models to assess its potential in a variety of disease states.

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 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 this primate study, administration of ALT-711 every other day for three weeks was found to significantly reduce aortic stiffness with the maximum improvement in vessel wall flexibility occurring at the six-week evaluation after the end of treatment with ALT-711. Baseline weight, fasting blood glucose, creatinine and cholesterol did not change after treatment. 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. This decrease was accompanied by an overall improvement in cardiac function. Reductions in blood pressure that have been observed in animal models of diabetic hypertension suggest that ALT-711 also may prove beneficial in the treatment of systolic hypertension in the elderly or in the diabetic.

ALT-711 is a small, easily synthesized compound with a rapid mode of action. It is well absorbed from an oral tablet formulation. Since June 1998, five Phase I safety and dose escalation studies have been conducted. These

## Edgar Filing: ALTEON INC /DE - Form 10-K

trials have shown the drug to be well tolerated.

In April 2000, we initiated a Phase IIa clinical trial of ALT-711 at nine clinical sites in the United States to evaluate effects of the compound on the cardiovascular system. This trial 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 cardiovascular, 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 210 mg 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.

In January 2001, we announced that these study results showed that patients who received ALT-711 experienced a statistically significant (p[less than, equal to] 0.05) and clinically meaningful reduction in the arterial pulse pressure, defined as the difference between systolic and diastolic blood pressures. Results also showed a clinically meaningful increase in large artery compliance, an indicator of greater vascular flexibility and volume capacity, using a traditional measurement of the ratio of stroke volume to pulse pressure. Additionally, the drug was well tolerated. This Phase IIa data was accepted to be presented at the Special Sessions Presentation of "Late Breaking Clinical Trials" at the American College of Cardiology Annual Scientific Session in March 2001.

6

7

Based on the positive results of this trial, we plan to initiate a Phase IIB efficacy trial of ALT-711. The timing and extent of ALT-711's clinical development will be determined by our ability to secure additional financing.

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

A.G.E.-formation inhibitors are designed to prevent glucose/protein formation and crosslinking. We believe that 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 800 compounds. Further development of the A.G.E. inhibitor class of compounds is subject to further funding.

### Pimagedine

Pimagedine is our lead compound in the A.G.E.-formation inhibitor class. We conducted a randomized double-blind, placebo-controlled, multi-center, Phase II/III clinical trial to evaluate the safety and efficacy of Pimagedine in Type 1 diabetic patients with overt nephropathy, the ACTION I trial. The primary objective of the trial was to evaluate the safety and efficacy of Pimagedine in preserving kidney function in Type 1 patients. The trial enrolled 690 patients at 56 investigational sites in the United States and Canada. Patients were treated for a minimum of two years and received twice daily oral doses of Pimagedine, adjusted for kidney function. Under this protocol, Pimagedine treatment was in addition to the best available therapeutic regimen chosen by the treating physicians.

In November 1998, we announced results of an analysis of data from the ACTION I trial. 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



## Edgar Filing: ALTEON INC /DE - Form 10-K

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.

In addition to evaluating oral Pimagedine in overt nephropathy, we have completed acute toxicity studies in animals with an intravenous formulation of Pimagedine. Animal studies have demonstrated that Pimagedine, when given prior to or after indication of stroke by occlusion of the middle cerebral artery, reduced the volume of tissue death by 30%. We have filed an investigational new drug application ("IND") with the United States Food and Drug Administration ("FDA").

We are actively exploring partnering and regulatory pathways for the continued development of Pimagedine and expect to pursue development if funding is obtained.

### ALT-946

ALT-946 is the pre-clinical lead candidate in our A.G.E.- formation inhibitor class of compounds. A study of ALT-946 in diabetic rats demonstrated that ALT-946 had a protective effect on the kidneys, and that ALT-946 was more potent than Pimagedine in inhibiting A.G.E. crosslinking, both in vitro and in vivo. We continue to evaluate ALT-946 in pre-clinical testing.

### 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.

7

8

### ALT-4037

ALT-4037 has been identified as the pre-clinical lead in the glucose lowering agent class of compounds. ALT-4037 is a novel compound that lowers glucose and lipids, restores normal pancreatic sensing of glucose, stimulates greater production of insulin and restores insulin sensitivity in skeletal muscle and fat in animal models of Type 2 diabetes. Additional development is subject to further funding.

### CORPORATE STRATEGIC ALLIANCES

#### Yamanouchi

We granted to Yamanouchi Pharmaceutical Co., Ltd. ("Yamanouchi") an exclusive license to commercialize our A.G.E.-related technology in Japan, South Korea, Taiwan and The People's Republic of China (the "Yamanouchi Territory") in exchange for royalty payments on net sales, if any. Yamanouchi has the right to terminate the agreement upon 90 days' prior written notice. This license expires as to each product in each licensed country upon the later of 15 years from the

## Edgar Filing: ALTEON INC /DE - Form 10-K

date of the agreement, the expiration of the last patent applicable to the product or five years after the first commercial sale of the product in the country. Pursuant to the license agreement, we granted to Yamanouchi the right to manufacture Pimagedine bulk material for sale in the Yamanouchi Territory.

Roche

In December 1994, we entered into an exclusive licensing arrangement with Roche Diagnostics GmbH ("Roche") for our technology for diagnostic applications. Under this alliance, we will be entitled to receive royalties based on net sales of research and commercial assays developed by Roche and based on our A.G.E. technology. Roche received exclusive worldwide rights to the technology for diagnostic applications outside the Yamanouchi Territory. The agreement gives Roche discretion over commercial development of diagnostic applications. Roche may terminate the license agreement upon 90 days' prior written notice.

Under the agreement, Roche agreed to develop immunoassays to detect A.G.E.-hemoglobin, ApoB-A.G.E. and A.G.E.-serum protein/peptides. Development of reagents and formats for the A.G.E. competitive ELISA and a procedure for measuring hemoglobin-A.G.E. was completed in 1998. This research assay is currently being evaluated at a number of institutes and medical universities in Germany. Continuation of the program to adapt these reagents to automated clinical assays is contingent upon FDA approval of Pimagedine and would advance along with any product launch of Pimagedine.

Gamida

In November 1995, we entered into clinical testing and distribution agreements with Gamida for Life ("Gamida"). Under these agreements, Gamida conducted, at its own expense, a Phase II multi-site clinical trial in Israel, in accordance with the protocol developed by us, to evaluate Pimagedine in patients with diabetes and elevated serum cholesterol levels. Gamida will receive the exclusive right to distribute Pimagedine, if successfully developed and approved for marketing, in Israel, Bulgaria, Cyprus, Jordan and South Africa. The distribution agreement is for a term ending 10 years after the date of regulatory approval for the sale of Pimagedine in Israel; thereafter, it will be automatically renewed for successive three-year periods unless terminated by either party on the last day of the initial or renewal term.

IDEXX

In June 1997, we entered into a license and supply agreement with IDEXX Laboratories, Inc. ("IDEXX"), pursuant to which we licensed Pimagedine to IDEXX as a potential therapeutic in companion animals (dogs, cats and horses) and its A.G.E. diagnostics technology for companion animal use. IDEXX will be responsible for the development, licensing and marketing of Pimagedine and A.G.E. diagnostics for such use on a worldwide basis. We will be entitled to receive milestone payments and royalties on sales of the licensed products. To date, IDEXX has not developed any such products.

8

9

HemoMax

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. Under the agreement, HemoMax will fund the pre-clinical development of compounds arising from the technology, and we will directly manage the development programs. HemoMax has granted us an exclusive right of first refusal to acquire

## Edgar Filing: ALTEON INC /DE - Form 10-K

the HemoMax technology. In addition, based on the achievement of certain milestones, we will receive 15% ownership of HemoMax. While this technology is not currently a part of our main technology platform, we entered into this relationship because it represents an opportunity to participate in the development of and potentially acquire a technology that complements our cardiovascular activities with ALT-711.

### ACADEMIC RESEARCH AND LICENSE AGREEMENTS

Washington University, St. Louis

In June 1995, we obtained an exclusive, worldwide, royalty-bearing license from Washington University for patents covering the use of Pimagedine as an inhibitor of inducible nitric oxide synthase ("iNOS"). The agreement requires us to pay certain licensing fees upon the attainment of development milestones as well as a royalty on net sales or a share of sub-licensing profits on products covered by the patents. The license also covers patents developed through any subsequent research collaboration between the parties that we agree to fund.

The Rockefeller University

Pursuant to an agreement with Rockefeller University, we have exclusive, 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."

The Picower Institute for Medical Research

Pursuant to an agreement with The Picower Institute, a not-for-profit biomedical science institution, we have received an exclusive worldwide, royalty-bearing license for certain commercial health care applications of A.G.E.-related inventions. See "--Patents, Trade Secrets and Licenses."

### 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 "--Corporate Strategic Alliances."

### MARKETING AND SALES

We plan to market and sell our products, if successfully developed and approved, directly or through co-promotion or other licensing arrangements with third parties. Such arrangements may be exclusive or nonexclusive and may provide for marketing rights worldwide or in a specific market.

For certain of our products, we have licensed exclusive marketing rights, formed joint marketing arrangements or granted distribution rights

## Edgar Filing: ALTEON INC /DE - Form 10-K

within specified territories with its corporate partners, Yamanouchi, Roche, Gamida and IDEXX. See "--Corporate Strategic Alliances."

9

10

### 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, 2000, our patent estate of owned and/or licensed patent rights consisted of 98 issued patents and one allowed United States patent application, none of which expire prior to 2005, and 30 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 four issued United States patents and three issued foreign patents, including one from the European Patent Office, as well as 22 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.

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 appreciation 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. In consultation with us, The Picower Institute is responsible for the worldwide filing and prosecution of patent applications and maintenance of patents for such inventions. We will contribute 50% of the cost of such activities.

## Edgar Filing: ALTEON INC /DE - Form 10-K

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

10

11

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 its 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 regulation by the FDA in the United States 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

## Edgar Filing: ALTEON INC /DE - Form 10-K

marketing in the United States generally involves (i) pre-clinical new drug laboratory and animal tests, (ii) submission to the FDA of an 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 I, when the drug is initially given to human subjects, the product is tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase II 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 II/III 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

11

12

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 manufacturing 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

## Edgar Filing: ALTEON INC /DE - Form 10-K

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 regulation 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

We believe 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. We are aware of several biotechnology companies that are developing A.G.E.-formation inhibitors. We have no knowledge of any company that has an A.G.E. crosslink breaker compound in clinical development. 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.

A broad range of drugs is under development that could reduce or eliminate the market for any product developed by us. 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 or obsolete. 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). ISH, 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 ISH patients, treatments approved for essential hypertension are currently being prescribed to treat hypertension in these patients. However, these agents are of limited value where stiffness of the large arteries is the underlying pathology.

Results of the DCCT showed that tight glucose control reduced the incidence of diabetic complications. Numerous companies are pursuing other methods to manage glucose control and to reduce the incidence of diabetic complications. In addition, several companies have initiated research with drugs that inhibit vascularization as a potential treatment of diabetic retinopathy. In the event one or more of these initiatives are successful, the market for some of our products may be reduced or eliminated.

#### 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:



## Edgar Filing: ALTEON INC /DE - Form 10-K

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; President, American College of Clinical Pharmacology.

Leslie Z. Benet, Ph.D., Professor UCSF, School of Pharmacy, Department of Biopharmaceutical Sciences; Chairman of the Board, AvMax, Inc.; former Chairman, Department of Biopharmaceutical Sciences of UCSF.

Michael A. Brownlee, M.D., Anita and Jack Saltz Professor of Diabetes Research, Departments of Medicine and Pathology, Albert Einstein College of Medicine.

Edward D. Frohlich, M.D., Distinguished Scientist of the Alton Ochsner Medical 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.

13

14

Richard J. Glasscock, M.D., M.A.C.P., Professor Emeritus, UCLA School of Medicine; Past-President, National Kidney Foundation; Past-President, American Society of Nephrology.

Jan Lessem, M.D., Ph.D., F.A.C.C., Chief Medical Officer and Vice President, Clinical Research and Development, OraPharma, Inc.; former Vice President and Corporate Officer, Drug Strategy and Medical Director, Takeda America, Inc.; former Director of Clinical Investigations, SmithKline Beecham Pharmaceuticals.

Lawrence Resnick, M.D., Professor of Medicine, Division of Hypertension, New York Presbyterian Hospital/Weill Medical College of Cornell Medical Center.

Mark E. Williams, M.D., Director of Dialysis, Joslin Diabetes Center; Chairman, National Scientific Council on Diabetic Kidney Disease, National Kidney Foundation.

### EMPLOYEES

As of February 28, 2001, we employed 26 persons (eight of whom held a Ph.D., M.D. or other advanced degree), of whom 13 were engaged in research and development and 13 were engaged in administration and management. 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

## Edgar Filing: ALTEON INC /DE - Form 10-K

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.

WE MAY NOT BE ABLE TO OBTAIN SUFFICIENT ADDITIONAL FUNDING TO MEET OUR NEEDS OR TO ALLOW US TO CONTINUE THE RESEARCH, PRODUCT DEVELOPMENT, PRE-CLINICAL TESTING AND CLINICAL TRIALS OF OUR PRODUCT CANDIDATES.

We anticipate that our existing available cash and cash equivalents and short-term investments will be adequate to satisfy our working capital requirements for our current operations into 2002. We will require substantial new funding in order to continue the research, product development, pre-clinical testing and clinical trials of our product candidates, including ALT-711 and Pimagedine. We will also require additional funding for operating expenses, the pursuit of regulatory approvals for our product candidates and the establishment of marketing and sales capabilities. Our future capital requirements will depend on many factors, including continued scientific progress in our research and development programs, the size and complexity of these programs, progress with pre-clinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patent claims, competing technological and market developments, the establishment of additional collaborative arrangements, the cost of manufacturing arrangements, commercialization activities and the cost of product in-licensing and strategic acquisitions, if any. We cannot be certain that our cash reserves and other liquid assets will be adequate to satisfy our capital and operating requirements.

We intend to seek funding through arrangements with corporate collaborators and through public or private sales of our securities, including equity securities, when and if conditions permit. In addition, we may pursue opportunities to obtain debt financing, including capital leases, in the future. We cannot be certain, however, that additional funding will be available on reasonable terms, if at all. Any additional equity financing would be dilutive to our stockholders. If adequate funds are not available, we may be required to curtail significantly or eliminate one or more of our research and development programs. If we obtain funds through arrangements with collaborative partners or others, we may be required to relinquish rights to certain of our technologies or product candidates.

14

15

WE MAY NOT SUCCESSFULLY DEVELOP OR DERIVE REVENUES FROM ANY PRODUCTS.

All of our product candidates are in research or clinical development. We cannot be certain that we will 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.

We have not yet requested or received regulatory approval for any product from the FDA or any other regulatory body. 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 results from pre-clinical studies and early clinical trials may not be predictive of results that will be obtained in large-scale testing, and we cannot be certain

## Edgar Filing: ALTEON INC /DE - Form 10-K

that any clinical trials we undertake will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or will result in marketable products.

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 cannot be certain that we will undertake additional clinical trials or that our product development efforts will be successfully completed, that required regulatory approvals can be obtained or that any products, if introduced, will be successfully marketed or achieve customer acceptance. We do not expect any of our products, including ALT-711 and Pimagedine, to be commercially available for a number of years, if at all.

WE MAY NEVER GENERATE PROFITS.

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 cannot be certain that we will realize product revenues on a timely basis, if at all.

At December 31, 2000, we had an accumulated deficit of \$134,011,000. We anticipate that we will incur substantial, potentially greater losses in the future. We cannot be certain that our products under development will be successfully developed or that our products, if successfully developed, will 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 cannot be certain that we will obtain required regulatory approvals, or successfully develop, manufacture, commercialize and market product candidates or that we will ever achieve product revenues or profitability.

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 an amendment to the Accounting Principals Board Opinion No. 25 ("APB Opinion No. 25"), "Accounting for Stock Issued to Employees." This amendment requires us to record compensation expense, which is adjusted every quarter, for increases or decreases in the fair market 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.

WE MAY NOT BE ABLE TO FORM AND MAINTAIN THE COLLABORATIVE RELATIONSHIPS THAT OUR BUSINESS STRATEGY REQUIRES.

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 have established collaborative arrangements with Yamanouchi, Gamida,

## Edgar Filing: ALTEON INC /DE - Form 10-K

Roche and IDEXX with respect to the development of drug therapies and diagnostics utilizing our scientific platforms. To succeed, we will have to

15

16

develop additional relationships. We are seeking to establish new collaborative relationships to provide the funding necessary for continuation of our product development, but we cannot be certain that such effort will be successful. If we are unable to enter into or manage additional collaborations, our programs may suffer and we may be unable to develop products.

OUR DEPENDENCE ON COLLABORATIVE RELATIONSHIPS MAY LEAD TO DELAYS IN PRODUCT DEVELOPMENT AND DISPUTES OVER RIGHTS TO TECHNOLOGY.

We will, in some cases, be dependent upon outside partners to conduct pre-clinical testing and clinical trials and to provide adequate funding for our development programs. Our corporate partners 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 agreements 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.

We cannot be certain that disputes will not arise in the future with respect to the ownership of rights to any technology we develop with third parties. These and other possible disagreements between us and collaborators could lead to delays in the collaborative research, development or commercialization of product candidates or could require or result in litigation or arbitration, which would be time-consuming and expensive and would have a material adverse effect on our business, financial condition and results of operations.

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

WE MAY NOT BE ABLE TO PROTECT THE PROPRIETARY RIGHTS THAT ARE CRITICAL TO OUR SUCCESS.

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.

We cannot be certain that competitors will not 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 which impact A.G.E. or A.G.E. crosslink formation.

## Edgar Filing: ALTEON INC /DE - Form 10-K

The degree of patent protection afforded to pharmaceutical inventions is uncertain and our potential products are subject to this uncertainty. Pimagedine is not a novel compound and is not covered by a composition-of-matter patent. The patents covering Pimagedine are use patents containing claims covering therapeutic indications and the use of Pimagedine to inhibit A.G.E. formation. Competitors may develop and commercialize Pimagedine or Pimagedine-like products for indications outside of the protection provided by the claims of our use patents. Physicians, pharmacies and wholesalers could then substitute for our Pimagedine products. Substitution for our Pimagedine products would have a material adverse effect on our business, financial condition and results of operations. Use patents may afford a lesser degree of protection in certain foreign countries due to their patent laws. In addition, although we have several patent applications pending to protect proprietary technology and potential products, we cannot be certain that these patents will be issued, that the claims of any patents which do issue will provide any significant protection of our technology or products, or that we will 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

16

17

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. We cannot be certain that relevant inventions will not be developed by a person not bound by an invention assignment agreement. We cannot be certain that binding agreements will not be breached, that we would have adequate remedies for such breach, or that our trade secrets will not otherwise become known to or be independently discovered by competitors.

WE CANNOT BE CERTAIN THAT REGULATORY APPROVALS WILL BE OBTAINED FOR OUR PRODUCTS.

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 cannot be certain that regulatory approval will be obtained for any drugs we develop. Moreover, regulatory approval may entail limitations on the indicated uses of the drug. Further, even if regulatory approval is obtained, 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 and

## Edgar Filing: ALTEON INC /DE - Form 10-K

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 cannot be certain that we will be able to obtain FDA approval for any products. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude our licensees or marketing partners from marketing our products or limit the commercial use of such products and will have a material adverse effect on our business, financial condition and results of operations.

WE MAY NOT BE ABLE TO COMPETE SUCCESSFULLY WITH BIOTECHNOLOGY COMPANIES AND ESTABLISHED PHARMACEUTICAL COMPANIES IN THE DEVELOPMENT AND MARKETING OF CURES AND THERAPIES FOR DIABETES, CARDIOVASCULAR DISEASES AND THE OTHER CONDITIONS FOR WHICH WE SEEK TO DEVELOP PRODUCTS.

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 a cure for diabetes or the reduction of the incidence of diabetes and its complications. For example, a number of companies are investigating islet cell transplantation as a possible cure for Type 1 diabetes. Results of a study conducted by the National Institutes of Health, known as the DCCT, published in 1993, showed that tight glucose control reduced the incidence of diabetic complications. Several pharmaceutical companies have introduced new products for glucose control for the management of hyperglycemia in Type 2 diabetes. In addition, several large companies have initiated or expanded research, development and licensing efforts to build a diabetic pharmaceutical franchise focusing on diabetic nephropathy, neuropathy, retinopathy and related conditions. An example of this is research seeking anti-angiogenesis drugs for the potential treatment of diabetic retinopathy. It is possible that one or more of these initiatives may reduce or eliminate the market for some of our products.

17

18

In addition, a broad range of cardiovascular drugs are under development by many pharmaceutical and biotechnology companies. It is possible that one or more of these initiatives may reduce or eliminate the market for some of our products.

EFFORTS TO REDUCE HEALTH CARE COSTS MAY AFFECT OUR OPERATIONS.

Our business, financial condition and results of operations may be materially adversely affected by the continuing efforts of government and third-party payers to contain or reduce the costs of health care through various means. For example, 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

## Edgar Filing: ALTEON INC /DE - Form 10-K

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 health care products, and third-party payers, including Medicare, are increasingly challenging the prices charged for medical products and services. We cannot be certain that any third-party insurance coverage will be available to patients for any products developed by us. Government and other third-party payers are increasingly attempting to contain health care 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.

WE HAVE NO EXPERIENCE IN MARKETING OR SALES AND MAY HAVE TO RELY ON OTHERS TO MARKET AND SELL ANY PRODUCTS WE MAY DEVELOP, WHICH MAY IMPAIR OUR ABILITY TO DELIVER PRODUCTS.

For certain of our products, we have licensed exclusive marketing rights to our corporate partners or formed collaborative marketing arrangements within specified territories in return for royalties to be received on sales, a share of profits or beneficial transfer pricing. These agreements are terminable at the discretion of our partners upon as little as 90 days' prior written notice. If the licensee or marketing partner terminates an agreement or fails to market a product successfully, our business, financial condition and results of operations may be adversely affected.

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 cannot be certain that we will develop successfully marketing and sales experience, or that we will be able to enter into marketing and sales agreements with others on acceptable terms, if at all, or that any such arrangements, if entered into, will not 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, and we cannot be certain that their efforts will be successful.

WE HAVE NO EXPERIENCE IN MANUFACTURING PRODUCTS AND MAY HAVE TO RELY ON OTHERS TO MANUFACTURE ANY PRODUCTS WE MAY DEVELOP, WHICH MAY IMPAIR OUR ABILITY TO DEVELOP OR DELIVER PRODUCTS.

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 cannot be certain that we will be able to enter into agreements for the manufacture of future products with manufacturers whose facilities and

## Edgar Filing: ALTEON INC /DE - Form 10-K

procedures comply with cGMP and other regulatory requirements. Our current

18

19

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.

### USE OF ANY PRODUCTS WE DEVELOP MAY RESULT IN LIABILITY CLAIMS.

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 Pimagedine, may expose us to liability claims resulting from the use of products or product candidates. These claims might be made directly by 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 cannot be certain that we will be able to maintain insurance or, if maintained, that insurance can be acquired 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 cannot be certain that we will be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future or that insurance coverage and our resources would be sufficient to satisfy any liability resulting from product liability claims. A successful product liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

### WE MAY BE UNABLE TO ATTRACT AND RETAIN THE KEY PERSONNEL ON WHOM OUR SUCCESS DEPENDS.

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 cannot be certain that we will be able to attract and retain personnel on acceptable terms given the competition between pharmaceutical and health care 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.

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. 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 and results of operations.

### 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.



Edgar Filing: ALTEON INC /DE - Form 10-K

ITEM 3. LEGAL PROCEEDINGS.

On July 13, 2000 and August 8, 2000, Colby S. Parks and Marion H. Parks filed suits against us in the United States District Court for the Middle District of North Carolina and the Superior Court of Chatham County, North Carolina, respectively, claiming unspecified damages for injuries Mr. Parks allegedly sustained as a result of his participation in one of our Pimagedine clinical trials. Our liability insurance carrier is defending these actions.

On October 20, 2000, Charles L. Grimes, one of our stockholders, and his wife, Jane Gillespie Grimes, filed a complaint against us in the Court of Chancery in Delaware, claiming breach of an alleged oral agreement with us which would have purportedly entitled Mr. Grimes to purchase 10% of our private placement of \$6,235,000 of common stock and warrants in September 2000. We believe the suit is without merit and intend to defend it vigorously.

19

20

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.

In our quarterly report on Form 10-Q for the quarter ended September 30, 2000, we reported that in September 2000, we had entered into an agreement to sell 2,834,088 shares of common stock (the "Shares") and warrants to purchase 1,133,636 shares of common stock (the "Warrants") to the parties named therein in a private placement. We indicated that the closing of the sale of one-half of the Shares and Warrants was completed on September 29, 2000, and that there would be a subsequent closing of the sale of the remainder of the Shares and Warrants. This subsequent closing of the remaining one-half of the Shares and Warrants was completed on November 28, 2000.

Our Common Stock traded on the American Stock Exchange ("Amex") since August 7, 2000, under the symbol "ALT." Prior to August 7, 2000, our Common Stock was traded on the Over-the-Counter Bulletin Board ("OTCBB") under the symbol "ALTN." The following table sets forth, for the calendar periods indicated, the range of high and low sale prices for our Common Stock on Amex or OTCBB, as applicable:

2000	High	Low
----	-----	-----
First Quarter.....	\$ 5.0000	\$ 0.9062
Second Quarter.....	3.6250	1.5000
Third Quarter.....	3.5625	2.1250
Fourth Quarter.....	8.3125	2.8750
1999	High	Low
----	-----	-----

Edgar Filing: ALTEON INC /DE - Form 10-K

First Quarter.....	\$ 1.6875	\$ 0.6875
Second Quarter.....	1.0625	0.6250
Third Quarter.....	1.4375	0.5625
Fourth Quarter.....	1.3438	0.5000

As of February 28, 2001, there were 318 holders of the Common Stock. On February 28, 2001, the last sale price reported on the Amex for the Common Stock was \$4.35 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 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.

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, 2000, has been derived from our audited financial statements.

	Years Ended December		
	2000	1999	1998
	(in thousands, except per		
STATEMENT OF OPERATIONS DATA:			
Revenues:			
Investment income .....	\$ 570	\$ 835	\$ 1,321
Other income .....	--	600	--
	-----	-----	-----
Total revenues .....	570	1,435	1,321
Expenses:			
Research and development .....	6,022	10,598	24,592
Elimination of previously accrued loss contingency .....	--	--	(1,771)
General and administrative .....	4,422	4,357	4,842
Non-cash stock compensation .....	1,244	--	--
Interest .....	--	--	4
	-----	-----	-----
Total expenses .....	11,688	14,955	27,667
	-----	-----	-----

## Edgar Filing: ALTEON INC /DE - Form 10-K

Loss before income tax benefit .....	(11,118)	(13,520)	(26,346)
Income tax benefit .....	1,548	2,588	--
	-----	-----	-----
Net loss .....	(9,570)	(10,932)	(26,346)
Preferred stock dividends and discount amortization .....	2,945	2,707	2,207
	-----	-----	-----
Net loss applicable to common stockholders .....	\$ (12,515)	\$ (13,639)	\$ (28,553)
	=====	=====	=====
Basic and diluted loss per share to common stockholders .....	\$ (0.63)	\$ (0.72)	\$ (1.57)
	=====	=====	=====
Weighted average common shares used in computing basic and diluted loss per share	19,861	19,055	18,211
	=====	=====	=====

### BALANCE SHEET DATA:

Cash, cash equivalents and short-term investments .....	\$ 9,955	\$ 12,370	\$ 24,132
Working capital .....	9,754	10,425	20,093
Total assets .....	13,389	15,021	27,652
Long-term capital lease obligations .....	--	--	--
Accumulated deficit .....	(134,011)	(121,496)	(107,857)
Stockholders' equity .....	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 engaged in the discovery and development of oral drugs for the treatment of diseases of aging and diabetes. Our product candidates represent novel approaches to some of the largest pharmaceutical markets, such as cardiovascular and kidney diseases. Two of our compounds are in clinical development; several others are undergoing pre-clinical testing. These pharmaceutical candidates were developed as a result of our understanding of the Advanced Glycosylation End-product ("A.G.E.") pathway, a fundamental pathological process and inevitable consequence of aging that may result in many medical disorders.

Our lead compound, ALT-711, is initially being developed for cardiovascular indications, including ISH. We recently completed a Phase IIa trial to evaluate the effect of ALT-711 on cardiovascular compliance. Based on the positive results of this trial, we plan to initiate a Phase IIb efficacy trial of ALT-711.

We are pursuing development of other compounds from our library of A.G.E. crosslink breakers and A.G.E.-formation inhibitors in additional aging- and diabetes-related pathologies.

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.

## Edgar Filing: ALTEON INC /DE - Form 10-K

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 \$134,011,000 as of December 31, 2000, 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, a follow-on offering of Common Stock completed in 1995, and private placements of common and preferred equity securities, revenue from present and 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 Losses carryforwards.

In September 2000, we entered into an agreement with several investors pursuant to which we sold them, 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 an aggregate purchase price of \$6,235,000. The exercise price of the Warrants is \$3.40 per share, while the term is seven years.

In March 2000, the Financial Accounting Standards Board ("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 expense resulting from the repricing and included in net loss for the year ended December 31, 2000, is \$1,244,000.

In 2000 and 1999, we sold \$14.1 million and \$27.6 million, respectively, of our gross State net operating loss carryforwards and \$590,000 and \$645,000, 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 allowed 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 in 2000 and 1999 were \$1,548,000 and \$2,588,000, 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 2000 were received on January 8, 2001.

Our business is subject to significant risks including, but not limited to, (i) our 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 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

## Edgar Filing: ALTEON INC /DE - Form 10-K

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."

22

23

### RESULTS OF OPERATIONS

Years Ended December 2000, 1999, 1998

#### Revenues

Total revenues for 2000, 1999 and 1998 were \$570,000, \$1,435,000 and \$1,321,000, respectively. Revenues were derived from interest earned on cash and cash equivalents and short-term investments, and in 1999, the \$600,000 payment under an option agreement with Taisho Pharmaceutical Co., Ltd., pursuant to which they were granted an option by us (which expired without being exercised) to acquire a license to ALT-711 in certain territories. The decrease in revenues in 2000 over 1999 was attributed to a decrease in cash and cash equivalents and short-term investment balances and the absence of the option payment in 2000.

#### Operating Expenses

Total expenses decreased to \$11,688,000 in 2000, from \$14,955,000 in 1999 and \$27,667,000 in 1998, and consisted primarily of research and development expenses. Research and development expenses were \$6,022,000 in 2000, \$10,598,000 in 1999 and \$24,592,000 in 1998. Research and development expenses decreased in 2000, from 1999, by \$4,576,000, or 43.2%. This decrease was primarily related to the closure of the ACTION I and ESRD trials and decreased personnel-related expenses, offset by increased expenses related to the ALT-711 Phase IIa costs. Research and development expenses decreased in 1999, from 1998, by \$13,994,000, or 56.9%, due to the decreased expenses related to the closure of the ACTION I and ESRD trials and personnel-related expenses.

General and administrative expenses were \$4,422,000 in 2000, relatively unchanged from \$4,357,000 in 1999 and \$4,842,000 in 1998. In January 2000, and March 2000, we completed a downsizing of our associates. We undertook the downsizing to reduce operating expenses in order to preserve our existing capital resources for research and development programs.

Non-cash stock compensation expense totaled \$1,244,000 in 2000, which resulted from certain stock options being repriced.

#### Net Loss

At December 31, 2000, we had available Federal net operating loss carryforwards, which expire in various amounts from the years 2006 through 2020, of approximately \$125.9 million for income tax purposes and State net operating loss carryforwards, which expire in the years 2001 through 2007, of approximately \$81.8 million. In addition, we had Federal research and development credit carryforwards of approximately \$4.9 million and State research and development tax credit carryforwards of approximately \$2.2 million. We had net losses of \$9,570,000 in 2000, \$10,932,000 in 1999 and \$26,346,000 in 1998.

### LIQUIDITY AND CAPITAL RESOURCES

We had cash, cash equivalents and short-term investments at December 31, 2000, of \$9,955,000 compared to \$12,370,000 at December 31, 1999. This is a decrease in cash, cash equivalents and short-term investments for the twelve

## Edgar Filing: ALTEON INC /DE - Form 10-K

months ended December 31, 2000, of \$2,415,000. This consisted of \$8,986,000 of cash used in operations, consisting primarily of research and development expenses, personnel and related costs and facility expenses and approximately \$62,000 of capital expenditures. This was offset by \$6,636,000 of financing activities related to a private placement of common stock and proceeds from stock option exercises. As of December 31, 2000, we had invested \$7,444,000 in capital equipment and leasehold improvements.

In September 2000, we entered into an agreement with several investors pursuant to which we sold them, 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 an aggregate purchase price of \$6,235,000. The exercise price of the Warrants is \$3.40 per share, while the term is seven years.

In 2000 and 1999, we sold \$14.1 million and \$27.6 million, respectively, of our gross State net operating loss carryforwards and \$590,000 and \$645,000, respectively, of our State research and development tax credit carryforwards under the Program. The Program allowed qualified technology and biotechnology business in New

23

24

Jersey to sell unused amounts of net operating loss carryforwards and defined research and development tax credits for cash. The proceeds in 2000 and 1999 were \$1,548,000 and \$2,588,000, 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 2000 were received on January 8, 2001.

We anticipate that our existing available cash and cash equivalents and short-term investments will be adequate to satisfy our working capital requirements for our current operations into 2002.

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

Our current priorities are the evaluation and possible continued development of ALT-711, our lead A.G.E. Crosslink Breaker candidate, and the continued development of Pimagedine. We are focusing our resources on the development of ALT-711. 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. We have also decided to pursue the continued development of Pimagedine and are actively seeking one or

## Edgar Filing: ALTEON INC /DE - Form 10-K

more corporate partners. We believe that additional development of this compound and other product candidates will require us to find sources of funding.

Effective August 7, 2000, our Common Stock was approved for listing on the American Stock Exchange under the symbol "ALT."

In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 101 ("SAB 101"), "Revenue Recognition in Financial Statements." SAB 101 summarizes certain of the SEC's views in applying generally accepted accounting principles to revenue recognition in financial statements. The adoption of SAB 101 had no impact on the accompanying financial statements.

### 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 U.S. government, government agencies, financial institutions and corporations with strong credit ratings. The table below presents principal amounts and related weighted average interest rates expected by maturity date for our investment portfolio. There are no maturities after 2001, and our exposure is limited based on the short-term nature of these investments.

	2001
	----
Assets	
Cash equivalents:	
Fixed rate .....	\$3,600,328
Average interest rate ..	6.72%
Short-term investments:	
Fixed rate .....	\$6,354,479
Average interest rate ..	6.64%
Total investment securities:	\$9,954,807
Average interest rate ..	6.66%

24

25

### 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 28.

b) The unaudited quarterly financial data for the two-year period ended December 31, 2000 is as follows:

	Loss Before Income Tax	Net Loss Applicable to Common	Basic/Diluted
--	---------------------------	-------------------------------------	---------------

Edgar Filing: ALTEON INC /DE - Form 10-K

	Revenues	Expenses	Benefit	Stockholders	Loss Per Share
	-----	-----	-----	-----	-----
	(in thousands, except per share amounts)				
2000					
First Quarter	\$ 166	\$ 2,762	\$ (2,596)	\$ (3,305)	\$ (0.17)
Second Quarter	143	2,402	(2,259)	(2,983)	(0.15)
Third Quarter	110	3,339	(3,229)	(3,977)	(0.20)
Fourth Quarter	151	3,185	(3,034)	(2,250)	(0.11)
	-----	-----	-----	-----	-----
Total Year	\$ 570	\$ 11,688	\$ (11,118)	\$ (12,515)	\$ (0.63)
1999					
First Quarter	\$ 278	\$ 5,623	\$ (5,345)	\$ (5,992)	\$ (0.32)
Second Quarter	227	4,240	(4,013)	(4,681)	(0.25)
Third Quarter	370	2,489	(2,119)	(2,808)	(0.15)
Fourth Quarter	560	2,602	(2,043)	(158)	(0.00)
	-----	-----	-----	-----	-----
Total Year	\$ 1,435	\$ 14,954	\$ (13,520)	\$ (13,639)	\$ (0.72)

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

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 2001 Annual Meeting of Stockholders to be held on June 5, 2001.

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 2001 Annual Meeting of Stockholders to be held on June 5, 2001.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

The 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 2001 Annual Meeting of Stockholders to be held on June 5, 2001.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Not applicable.



Edgar Filing: ALTEON INC /DE - Form 10-K

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(a) Financial Statements:

Our audited financial statements, financial statement schedules and the Report of Independent Public Accountants are appended to this Annual Report on Form 10-K. Reference is made to the "Index to Financial Statements and Schedules" on page 28.

(b) Reports on Form 8-K.

On December 14, 2000, we filed a current report on Form 8-K, dated December 6, 2000, announcing the appointment of a Medical Director.

On November 8, 2000, we filed a current report on Form 8-K, dated October 17, 2000, regarding the grant of a patent.

On October 20, 2000, we filed a current report on Form 8-K, dated October 10, 2000, announcing that we entered into an agreement with HemoMax, LLC.

On October 5, 2000, we filed a current report on Form 8-K, dated September 29, 2000, announcing that we entered into an agreement for the private placement of common stock and warrants.

(c) Exhibits.

The exhibits required to be filed are listed on the Index to Exhibits 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 1st day of March 2001.

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
-----	-----	----
/s/ Mark Novitch ----- Mark Novitch	Chairman of the Board	March 1,

Edgar Filing: ALTEON INC /DE - Form 10-K

/s/ Kenneth I. Moch ----- Kenneth I. Moch	President and Chief Executive Officer (principal executive officer)	March 1,
/s/ Elizabeth O'Dell ----- Elizabeth O'Dell	Vice President, Finance and Administration, Secretary and Treasurer (principal finance and accounting officer)	March 1,
/s/ Edwin Bransome, Jr. M.D. ----- Edwin Bransome, Jr. M.D.	Director	March 1,
/s/ Marilyn G. Breslow ----- Marilyn G. Breslow	Director	March 1,
/s/ Alan J. Dalby ----- Alan J. Dalby	Director	March 1,
/s/ David McCurdy ----- David McCurdy	Director	March 1,
/s/ George M. Naimark, Ph.D. ----- George M. Naimark, Ph.D.	Director	March 1,

28  
 Form 10-K - Item 14(a)(1)  
 Alteon Inc.  
 Index to Financial Statements and Schedules

	Page ----
Report of Independent Public Accountants - Arthur Andersen LLP .....	29
Financial Statements:	
Balance Sheets at December 31, 2000 and 1999 .....	30
Statements of Operations for the years ended December 31, 2000, 1999 and 1998 .....	31
Statements of Stockholders' Equity for the years ended December 31, 2000, 1999 and 1998 .....	32

Edgar Filing: ALTEON INC /DE - Form 10-K

Statements of Cash Flows for the years ended December 31, 2000, 1999 and 1998 .....	33
Notes to Financial Statements .....	34

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Alteon Inc.:

We have audited the accompanying balance sheets of Alteon Inc. (a Delaware corporation) as of December 31, 2000 and 1999, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2000. 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, 2000 and 1999, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States.

ARTHUR ANDERSEN LLP

Roseland, New Jersey  
January 15, 2001

ALTEON INC.  
BALANCE SHEETS

ASSETS

December 31,  
2000

December  
1999

Edgar Filing: ALTEON INC /DE - Form 10-K

-----		
Current Assets:		
Cash and cash equivalents .....	\$ 3,600,328	\$ 5,33
Short-term investments .....	6,354,479	7,03
Other current assets .....	1,735,660	24
-----		
Total current assets .....	11,690,467	12,61
Property and equipment, net .....	1,696,082	2,39
Deposits and other assets .....	2,815	
-----		
Total assets .....	\$ 13,389,364	\$ 15,02
=====		
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable .....	\$ 304,779	\$ 43
Accrued expenses .....	1,631,579	1,76
-----		
Total current liabilities .....	1,936,358	2,19
-----		
Stockholders' Equity:		
Preferred Stock, \$0.01 par value, 1,993,329 shares authorized, and 912 and 839 of Series G and 2,739 and 2,518 of Series H shares issued and outstanding, as of December 31, 2000 and December 31, 1999, respectively .....	37	
Common Stock, \$0.01 par value, 40,000,000 shares authorized, and 22,399,660 and 19,189,701 shares issued and outstanding, as of December 31, 2000 and December 31, 1999, respectively	223,997	19
Additional paid-in capital .....	145,241,265	134,12
Accumulated deficit .....	(134,011,423)	(121,49
Accumulated other comprehensive (loss)/income .....	(870)	
-----		
Total stockholders' equity .....	11,453,006	12,82
-----		
Total liabilities and stockholders' equity .....	\$ 13,389,364	\$ 15,02
=====		

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

Edgar Filing: ALTEON INC /DE - Form 10-K

30

31

ALTEON INC.  
STATEMENTS OF OPERATIONS

	Year ended December 31,		
	2000	1999	1998
<b>Revenues:</b>			
Investment income .....	\$ 570,444	\$ 834,661	\$ 1,300,000
Other income .....	--	600,000	--
<b>Total revenues .....</b>	<b>570,444</b>	<b>1,434,661</b>	<b>1,300,000</b>
<b>Expenses:</b>			
Research and development .....	6,022,315	10,598,008	24,500,000
Elimination of previously accrued loss contingency .....	--	--	(1,700,000)
General and administrative .....	4,422,146	4,356,447	4,800,000
Non-cash stock compensation .....	1,243,669	--	--
Interest .....	--	--	--
<b>Total expenses .....</b>	<b>11,688,130</b>	<b>14,954,455</b>	<b>27,600,000</b>
Loss before income tax benefit .....	(11,117,686)	(13,519,794)	(26,300,000)
Income tax benefit .....	1,547,763	2,588,210	--
<b>Net loss .....</b>	<b>(9,569,923)</b>	<b>(10,931,584)</b>	<b>(26,300,000)</b>
Preferred stock dividends and discount amortization .....	2,945,451	2,707,844	2,200,000
<b>Net loss applicable to common stockholders .....</b>	<b>\$ (12,515,374)</b>	<b>\$ (13,639,428)</b>	<b>\$ (28,500,000)</b>
Basic and diluted loss per share to common stockholders .....	\$ (0.63)	\$ (0.72)	\$ (0.80)
Weighted average common shares used in computing basic and diluted loss per share .....	19,860,847	19,054,750	18,200,000

The accompanying notes are an integral part of these statements.

Edgar Filing: ALTEON INC /DE - Form 10-K

31

32

ALTEON INC.  
STATEMENTS OF STOCKHOLDERS' EQUITY

	Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amount
Balances at				
DECEMBER 31, 1997 .....	942	\$ 9	17,922,319	\$ 17,922,319
Net loss .....	--	--	--	--
Change in unrealized gains/(losses)	--	--	--	--
Comprehensive loss .....	--	--	--	--
Issuance of Series H preferred stock valued at \$10,000 per share to Genentech, Inc., net of transaction costs .....	2,254	23	--	--
Issuance of Series G and H preferred stock dividends .....	133	1	--	--
Conversion of Series G preferred stock to common stock .....	(243)	(2)	822,204	--
Preferred stock discount amortization .....	--	--	--	--
Exercise of employee stock options .....	--	--	70,217	--
Deferred compensation expense in connection with the issuance of non-qualified stock options and options granted to non- employees .....	--	--	--	--
DECEMBER 31, 1998 .....	3,086	31	18,814,740	18,814,740
Net loss .....	--	--	--	--
Change in unrealized gains/(losses)	--	--	--	--
Comprehensive loss .....	--	--	--	--
Issuance of Series G and H preferred stock dividends .....	271	3	--	--
Exercise of employee stock options .....	--	--	374,961	--
Deferred compensation expense in connection with the issuance of non-qualified stock options and options granted to non- employees .....	--	--	--	--
DECEMBER 31, 1999 .....	3,357	34	19,189,701	19,189,701
Net loss .....	--	--	--	--
Change in unrealized gains/(losses)	--	--	--	--
Comprehensive loss .....	--	--	--	--

Edgar Filing: ALTEON INC /DE - Form 10-K

Issuance of Series G and H preferred stock dividends .....	294	3	--	
Exercise of employee stock options .....	--	--	375,871	
Private placement of common stock and warrants .....	--	--	2,834,088	2
Compensation expense related to variable plan employee stock options .....	--	--	--	
Deferred compensation expense in connection with the issuance of non-qualified stock options and options granted to non-employees .....	--	--	--	
DECEMBER 31, 2000 .....	<u>3,651</u>	<u>\$ 37</u>	<u>22,399,660</u>	<u>\$ 22</u>

	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	-----	-----	-----	-----
Balances at				
DECEMBER 31, 1997 .....	\$ 105,585,019	\$ (79,303,374)	\$ (5,941)	\$ 26,4
Net loss .....	--	(26,346,042)	--	(26,3
Change in unrealized gains/(losses)	--	--	7,709	-----
Comprehensive loss .....	--	--	--	(26,3
Issuance of Series H preferred stock valued at \$10,000 per share to Genentech, Inc., net of transaction costs .....	22,543,706	--	--	22,5
Issuance of Series G and H preferred stock dividends .....	1,327,768	(1,327,768)	--	
Conversion of Series G preferred stock to common stock .....	(8,220)	--	--	
Preferred stock discount amortization .....	879,437	(879,437)	--	
Exercise of employee stock options .....	195,451	--	--	1
Deferred compensation expense in connection with the issuance of non-qualified stock options and options granted to non-employees .....	481,872	--	--	4
DECEMBER 31, 1998 .....	<u>131,005,033</u>	<u>(107,856,621)</u>	<u>1,768</u>	<u>23,3</u>
Net loss .....	--	(10,931,584)	--	(10,9
Change in unrealized gains/(losses)	--	--	(475)	-----
Comprehensive loss .....	--	--	--	(10,9
Issuance of Series G and H preferred stock dividends .....	2,707,841	(2,707,844)	--	
Exercise of employee stock options .....	162,691	--	--	1

Edgar Filing: ALTEON INC /DE - Form 10-K

Deferred compensation expense in connection with the issuance of non-qualified stock options and options granted to non- employees .....	253,948	--	--	2
DECEMBER 31, 1999 .....	134,129,513	(121,496,049)	1,293	12,8
Net loss .....	--	(9,569,923)	--	(9,5
Change in unrealized gains/(losses)	--	--	(2,163)	
Comprehensive loss .....	--	--	--	(9,5
Issuance of Series G and H preferred stock dividends .....	2,945,448	(2,945,451)	--	
Exercise of employee stock options .....	500,786	--	--	5
Private placement of common stock and warrants .....	6,103,151	--	--	6,1
Compensation expense related to variable plan employee stock options .....	1,243,669	--	--	1,2
Deferred compensation expense in connection with the issuance of non-qualified stock options and options granted to non- employees .....	318,698	--	--	3
DECEMBER 31, 2000 .....	\$ 145,241,265	\$ (134,011,423)	\$ (870)	\$ 11,4

The accompanying notes are an integral part of these statements.

32

33

ALTEON INC.  
STATEMENTS OF CASH FLOWS

	Year ended December 31	
	2000	1999
Cash flows from operating activities:		
Net loss .....	\$ (9,569,923)	\$ (10,931,584)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization .....	765,601	743,820
Amortization of deferred compensation .....	318,698	253,948
Non-cash compensation expense related to variable plan employee stock options .....	1,243,669	--
Changes in operating assets and liabilities:		
Other current assets .....	(1,486,677)	25,162
Other assets .....	--	257,265
Accounts payable and accrued expenses .....	(257,844)	(2,119,073)



Edgar Filing: ALTEON INC /DE - Form 10-K

Net cash used in operating activities .....	(8,986,476)	(11,770,462)
	-----	-----
Cash flows from investing activities:		
Capital expenditures .....	(62,377)	(157,969)
Purchases of marketable securities .....	(11,550,202)	(54,461,475)
Sales and maturities of marketable securities .....	12,227,817	60,719,408
Restricted cash .....	--	--
	-----	-----
Net cash provided by (used in) investing activities	615,238	6,099,964
	-----	-----
Cash flows from financing activities:		
Net proceeds from issuance of common stock .....	6,636,037	166,441
Net proceeds from issuance of preferred stock .....	--	--
Payments under capital lease obligations .....	--	--
	-----	-----
Net cash provided by financing activities .....	6,636,037	166,441
	-----	-----
Net decrease in cash and cash equivalents .....	(1,735,201)	(5,504,057)
Cash and cash equivalents, beginning of period .....	5,335,529	10,839,586
	-----	-----
Cash and cash equivalents, end of period .....	\$ 3,600,328	\$ 5,335,529
	=====	=====
Supplemental disclosures of cash flow information:		
Cash paid for interest .....	\$ --	\$ --
	=====	=====

The accompanying notes are an integral part of these statements.

33

34

ALTEON INC.  
NOTES TO FINANCIAL STATEMENTS

NOTE 1 -- SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Business

Alteon Inc. ("Alteon" or the "Company") is a product-based biopharmaceutical company engaged in the discovery and development of oral drugs for the treatment of diseases of aging and diabetes. 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 Glycosylation 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 A.G.E. Crosslink Breaker compound, ALT-711, is initially being developed for cardiovascular indication, including isolated systolic hypertension ("ISH"). Alteon recently completed a Phase IIa trial to evaluate the effect of ALT-711 on cardiovascular compliance. Based on the positive

## Edgar Filing: ALTEON INC /DE - Form 10-K

results of this trial, the Company plans to initiate a Phase IIb efficacy trial of ALT-711. The Company is seeking a corporate partner to help fund the continued development of its lead A.G.E.-Formation Inhibitor, Pimagedine, based on the results of a Phase II/III trial of Pimagedine in Type 1 diabetic patients with overt nephropathy. Alteon is also pursuing the development of a novel series of glucose lowering agent compounds.

The Company's business is subject to significant risks including, but not limited to, (i) its ability to obtain funding, (ii) its uncertainty of future profitability, (iii) the risks inherent in its research and development efforts, including clinical trials, (iv) uncertainties associated with obtaining and enforcing its patents and with the patent rights of others, (v) the lengthy, expensive and uncertain process of seeking regulatory approvals, (vi) uncertainties regarding government reforms and product pricing and reimbursement levels, (vii) technological change and competition, (viii) manufacturing uncertainties and (ix) 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. Alteon will require substantial additional funding in order to continue the research, product development, pre-clinical testing and clinical trials of its product candidates. If adequate funding is not available, the Company may be required to curtail significantly one or more of its research or development programs and other Company activities.

### Pervasiveness 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.

34

35

### ALTEON INC. NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

#### 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 market value, as determined by quoted market value. As of December 31, 2000, short-term investments were invested in debt instruments of the U.S. government, government agencies, financial institutions and corporations with strong credit ratings. They consist of the following:

December 31,	
2000	1999
-----	-----

Edgar Filing: ALTEON INC /DE - Form 10-K

U.S. government agency funds...	\$2,651,255	\$ --
Corporate obligations .....	3,703,224	7,034,258
	-----	-----
	\$6,354,479	\$7,034,258
	=====	=====

The amortized cost of short-term investments was \$6,353,732 and \$7,033,844 at December 31, 2000 and December 31, 1999, respectively. Gross unrealized gains or losses are not significant.

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.

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 under Accounting Principles Board Opinion No. 25 ("APB Opinion No. 25") and related interpretations.

Net Loss Per Share

Basic 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 loss per share is the same as basic loss per share, as the inclusion of common stock equivalents would be antidilutive.

Comprehensive Income/(Loss)

The only comprehensive income/(loss) items the Company has are unrealized gains/(losses) on available-for-sale investments and net loss.

Recently Issued Accounting Standards

In June 2000, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard No. 138 ("SFAS 138"), "Accounting for Certain Derivative Instruments and Certain Hedging Activities, an Amendment of FASB Statement No. 133." SFAS No. 138 was issued to address a limited number of issues causing implementation difficulties for entities that apply SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," issued in June 1998. SFAS No. 133 and SFAS No. 138 require that all derivatives be measured at fair value and recognized as assets or liabilities on the balance sheet. Changes in the fair value of derivatives should be recognized in either net income/(loss) or other comprehensive income/(loss), depending on the designated

## Edgar Filing: ALTEON INC /DE - Form 10-K

purpose of the derivative. The Company is required to and will adopt SFAS No. 133 and SFAS No. 138 in the first quarter of 2001. Based on the Company's current activities, the Company does not believe that adoption of these pronouncements will have a material impact on the Company's results of operations, cash flows or financial position.

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 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. On February 2, 1999, the Company repriced certain stock options (See Note 7). The total non-cash stock compensation expense resulting from the repricing for the year ended December 31, 2000, is \$1,244,000, which includes research and development charges of \$353,000 and general and administrative charges of \$891,000.

In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 101 ("SAB 101"), "Revenue Recognition in Financial Statements." SAB 101 summarizes certain of the SEC's views in applying generally accepted accounting principles to revenue recognition in financial statements. The adoption of SAB 101 had no impact on the accompanying financial statements.

### Reclassifications

Certain prior year amounts have been reclassified to conform to current year presentation.

### NOTE 2 -- PROPERTY AND EQUIPMENT

	December 31,	
	2000	1999
Laboratory equipment .....	\$ 1,167,780	\$ 1,261,640
Furniture and equipment .....	686,560	682,124
Computer equipment .....	374,589	360,713
Leasehold improvements .....	5,215,069	5,215,069
	7,443,998	7,519,546
Less: Accumulated depreciation & amortization	(5,747,916)	(5,120,241)
	\$ 1,696,082	\$ 2,399,305

Depreciation and amortization expense was \$765,601, \$743,820 and \$678,773 for the years ended December 31, 2000, 1999 and 1998, respectively.

## Edgar Filing: ALTEON INC /DE - Form 10-K

### NOTE 3 -- COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT

In December 1997, Alteon and Genentech, Inc. ("Genentech") entered into a stock purchase agreement and a development collaboration and license agreement providing for the development and marketing of Pimagedine, a second-generation A.G.E.-Formation Inhibitor. Pursuant to the stock purchase agreement, Genentech purchased Common Stock, Series G Preferred Stock and Series H Preferred Stock for an aggregate purchase price of \$37,544,000 (See Note 7). Genentech's obligations to purchase shares of Alteon's stock terminated December 31, 1998. Pursuant to a letter agreement dated February 11, 1999 between Alteon and Genentech, the development collaboration and license agreement terminated effective June 30, 1999.

### NOTE 4 -- OTHER DEVELOPMENT AGREEMENTS

In 1989, Alteon and Yamanouchi Pharmaceutical Co., Ltd. ("Yamanouchi") formed a strategic alliance to develop and commercialize the Company's A.G.E. technology. Under this arrangement, the parties agreed to collaborate on further research and development, and the Company granted to Yamanouchi an exclusive license to commercialize the Company's technology in Japan, South Korea, Taiwan and The People's Republic of China.

In June 1995, the Company obtained an exclusive, worldwide, royalty-bearing license from Washington University for patents covering the use of Pimagedine as an inhibitor of inducible nitric oxide synthase. The agreement requires the Company to pay certain licensing fees upon the attainment of development milestones as well as a royalty on net sales or a share of sub-licensing profits of products covered by the patents. The license also covers patents developed through any subsequent research collaboration between the parties, which Alteon agrees to fund.

In August 1999, Alteon and Taisho Pharmaceutical Co., Ltd. ("Taisho") entered into an agreement under which Taisho was granted an exclusive option through December 31, 1999, to acquire a license to Alteon's lead A.G.E. Crosslink Breaker, ALT-711, for Japan, South Korea, Taiwan and The People's Republic of China for a non-refundable option fee of \$600,000. This amount is reflected in other income in the statement of operations. The option expired on December 31, 1999.

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. Under the agreement, HemoMax will fund the pre-clinical development of compounds arising from the technology, and Alteon will directly manage the development programs. HemoMax has granted Alteon an exclusive right of first refusal to acquire the HemoMax technology. In addition, based on the achievement of certain milestones, Alteon will receive 15% ownership of HemoMax. While this technology is not currently a part of our main technology platform, we entered into this relationship because it represents an opportunity to participate in the development of and potentially to acquire a technology that complements our cardiovascular activities with ALT-711.

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

## Edgar Filing: ALTEON INC /DE - Form 10-K

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.

37

38

ALTEON INC.  
NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

NOTE 5 -- ACCRUED EXPENSES

	December 31,	
	2000	1999
Accrued clinical trial expense .....	\$ 848,745	\$ 923,756
Accrued professional fees .....	291,000	145,769
Accrued payroll and related expenses	167,680	402,288
Accrued rent .....	155,585	210,498
Accrued patent fees .....	111,529	20,000
Other .....	57,040	60,891
	\$1,631,579	\$1,763,202
	\$1,631,579	\$1,763,202

The Company's headquarters and research facility rent is being expensed on a straight-line basis over the 10-year lease period (See Note 6).

NOTE 6 -- CONTINGENCIES AND COMMITMENTS

Contingencies

In December 1990, the Company and Marion Merrell Dow, Inc., which was subsequently acquired by an affiliate of Hoechst AG and renamed Hoechst Marion Roussel, Inc. ("HMRI"), formed a strategic alliance to develop and commercialize the Company's A.G.E. technology for therapeutics in the areas of diabetic and aging complications. In 1996, HMRI ended the collaboration as a result of HMRI's continuing prioritization of its new product pipeline, and the Company regained all rights granted to HMRI covering the Company's technology. In June 1998, the Company and HMRI resolved various open issues arising from the termination of their collaboration. As a result, the previously established accrual in the amount of \$1.8 million has been eliminated and credited to the statement of operations.

Commitments

The Company leases its headquarters and research facility and related equipment and furniture under non-cancelable operating leases. As of December 31, 2000, future minimum rentals under operating leases that have initial or remaining non-cancelable terms in excess of one year are as follows:

Operating  
Leases

Edgar Filing: ALTEON INC /DE - Form 10-K

	-----
2001 .....	\$ 536,500
2002 .....	536,500
2003 .....	447,000
Thereafter...	--
	-----
	\$1,520,000
	=====

Rent expense for each of the years in the three-year period ended December 31, 2000, was \$586,294, \$573,962 and \$584,510, respectively.

38

39

ALTEON INC.  
NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

NOTE 7 -- STOCKHOLDERS' EQUITY

Common/Preferred Stock Issuances

In September 2000, Alteon entered into an agreement with several investors pursuant to which we sold them, 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 an aggregate purchase price of \$6,235,000. The exercise price of the Warrants is \$3.40 per share, while the term is seven years.

In December 1997, the Company and 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 (See Note 3). 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, 2000 and 1999, respectively, approximately \$2,945,000 and \$2,708,000 of Preferred Stockholder Dividends and amortization of Preferred Stock conversion discount were recorded. Series G Preferred Stock and Series H Preferred Stock Dividends are payable quarterly in shares 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 a 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.

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 Common Stock may be granted under the first plan and options to purchase up to 4,000,000 shares of common stock may be granted under the second plan.

The plans are administered by a committee of the Board of Directors, which may grant either non-qualified 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

Edgar Filing: ALTEON INC /DE - Form 10-K

antidilution and change in control rights, as defined.

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

	Options	Exercise Price Range Per Share	Weighted Average Exercise Price Per Share
Balance, December 31, 1997	3,659,440		\$ 6.51
Granted .....	1,232,950	0.88 - 8.50	1.98
Exercised .....	(70,217)	0.30 - 8.63	2.79
Canceled .....	(22,913)	3.88 - 15.00	8.72
Balance, December 31, 1998	4,799,260		\$ 5.39
Granted .....	1,928,701	0.78 - 1.125	0.99
Exercised .....	(374,961)	0.30 - 0.60	0.44
Canceled .....	(1,277,804)	0.81 - 15.00	3.88
Balance, December 31, 1999	5,075,196		\$ 3.40
Granted .....	1,083,420	1.63 - 7.00	4.57
Exercised .....	(375,871)	0.60 - 5.13	1.34
Canceled .....	(550,326)	0.60 - 9.50	1.12
Balance, December 31, 2000	5,232,419		\$ 4.03

39

40

ALTEON INC  
NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

The following table summarizes information regarding stock options outstanding at December 31, 2000:

Range of Exercise Prices	Number of Shares	Options Outstanding at December 31, 2000	Options Exercised December 31, 2000
		Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
\$0.7810 - \$ 1.0630	1,880,218	6.56	\$ 0.9590
\$1.1250 - \$ 3.8750	1,424,125	8.78	\$ 2.5223
\$4.3600 - \$ 9.2500	1,457,387	5.51	\$ 7.2395
\$9.5000 - \$15.0000	470,689	2.99	\$10.8932
	5,232,419	6.55	\$ 4.0274
			Number of Shares Exercisable
			1,277,322
			847,890
			1,041,595
			470,689
			3,637,496

The weighted average fair value of the options granted was \$2.54,



## Edgar Filing: ALTEON INC /DE - Form 10-K

\$0.53 and \$1.71 during 2000, 1999 and 1998, respectively. Included in options at December 31, 2000, are 835,000 options granted to certain executives with option prices ranging from \$.875 per share to \$3.56 per share. Such options vest upon the earlier of five years after grant or upon achievement of certain Company milestones.

The Company accounts for its stock option plans under APB Opinion No. 25, under which no compensation cost (excluding those options granted below fair market value) has been recognized. Had compensation costs for these plans been determined consistent with FASB Statement No. 123, the Company's pro forma net loss and loss per share applicable to common stockholders for 2000, 1999 and 1998 would have been \$13.7 million, \$13.9 million and \$30.5 million and, \$0.69, \$0.73 and \$1.67, respectively. The 2000 pro forma net loss and loss per share applicable to common stockholders reflects a benefit for the reversal of previously recognized pro forma compensation costs on options forfeited in 2000. Consistent with FASB Statement No. 123, the Company elected not to estimate these forfeitures in the prior period pro forma compensation cost calculation. Because FASB Statement No. 123 has not been applied to options granted prior to January 1, 1995, the resulting pro forma compensation cost may not be representative of that to be expected in future years.

Under FASB Statement No. 123, the fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions used for grants in 2000, 1999 and 1998, respectively: risk free interest rates ranging 5.24% to 6.64%, 4.73% to 6.07% and 4.32% to 5.63%, respectively; expected life of 2.02 years over the vesting periods; expected dividend yield of 0%; and expected volatility of 70%.

In February 1999, the Board of Directors approved the repricing of 1,063,000 stock options outstanding as of February 2, 1999 (See Note 1).

### NOTE 8 -- 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. The Company made contributions of \$30,530 and \$49,000 for the years ended December 31, 2000 and 1999, respectively.

40

41

### ALTEON INC. NOTES TO FINANCIAL STATEMENTS - (CONTINUED)

### NOTE 9 -- 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 for Medical Research ("The Picower Institute"), The Rockefeller University, Cerami Consulting Corporation and the Kenneth S. Warren Laboratories, Inc. The Company paid to the organizations \$0, \$243,000 and \$731,000 in 2000, 1999, and 1998, respectively. In addition, the Company paid patent maintenance fees for technology related to the organizations of \$120,000, \$73,000 and \$207,000 in 2000, 1999 and 1998, 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

## Edgar Filing: ALTEON INC /DE - Form 10-K

revenues associated with certain technologies developed. Effective May 17, 1999, the Company terminated its consulting agreement with Cerami Consulting Corporation and its research agreement with Kenneth S. Warren Laboratories, Inc. In addition, Dr. Cerami resigned from the Company's Board of Directors on April 19, 1999.

Prior to 2000, the Company had a Scientific Advisory Board. The Chairman and two other Scientific Advisory Board members provided consulting services to the Company. Consulting fees paid to these members totaled \$55,000 and \$89,000 in 1999 and 1998, respectively.

### NOTE 10 -- INCOME TAXES

At December 31, 2000, the Company had available Federal net operating loss carryforwards, which expire in the years 2006 through 2020, of approximately \$125.9 million for income tax purposes and State net operating loss carryforwards, which expire in the years 2000 through 2007, of approximately \$81.8 million. In addition, the Company has Federal research and development tax credit carryforwards of approximately \$4.9 million and State research and development tax credit carryforwards of approximately \$2.2 million. 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,	
	2000	1999
Net operating loss carryforwards	\$ 47,700,000	\$ 42,900,000
Research and development credit	7,100,000	7,000,000
Other temporary differences ....	2,400,000	4,700,000
	57,200,000	54,600,000
Gross deferred tax assets .....	57,200,000	54,600,000
Valuation allowance .....	(57,200,000)	(54,600,000)
	\$ --	\$ --
Net deferred tax assets .....	\$ --	\$ --

A valuation allowance was established since the realization of the deferred tax assets is uncertain. In 2000 and 1999, Alteon sold \$14.1 million and \$27.6 million, respectively, of our gross State net operating loss carryforwards and \$590,000 and \$645,000, 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 allowed 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 sales prices in 2000 and 1999 were \$1,548,000 and \$2,588,000, 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 2000 were received on January 8, 2001. Accordingly, as of December 31, 2000, \$1,548,000 is included in other current assets.

# Edgar Filing: ALTEON INC /DE - Form 10-K

41

42

## EXHIBIT INDEX

Exhibit No. -----	Description of Exhibit -----
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).
3.2	Certificate of the Voting Powers, Designations, Preference and Relative Participating, Optional and Other Special Rights and Qualifications, Limitations or Restrictions of Series F Preferred Stock of the Company.
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).
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).
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).
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).
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).
3.8	Certificate of Retirement dated November 20, 2000, of Alteon Inc.
3.9	By-laws, as amended. (Incorporated by reference to Exhibit 3.7 to the Company's Report on Form 10-Q filed on May 12, 1999).
4.1	Stockholders' Rights Agreement dated as of July 27, 1995, between Alteon Inc. and Registrar and Transfer Company, as Rights Agent.
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).
4.3	Registration Rights Agreement dated as of April 24, 1997, between Alteon Inc. and the investors named on the signature

## Edgar Filing: ALTEON INC /DE - Form 10-K

page thereof. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 9, 1997).

- 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).
- 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).
- 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).
- 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).
- 43
- 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).
- 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).
- 10.2+ Amended 1995 Stock Option Plan. (Incorporated by reference to Exhibit 10.2 to the Company's Report on Form 10-Q filed May 12, 1999).
- 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 (File Number 33-42574), which became effective on November 1, 1991).
- 10.4 Amendment and Assignment of Research and Option Agreement dated as of September 25, 1987, among Telos Development Corporation ("Telos"), The Rockefeller University ("The Rockefeller"), the Company and Anthony Cerami. (Incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File Number 33-42574), which became effective on November 1, 1991).
- 10.5 License Agreement dated as of September 25, 1987, among Telos, Applied Immune Sciences, Inc., the Company and The Rockefeller, as amended by letter agreement dated September 25, 1987, and letter agreement dated August 15, 1991. (Incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File Number 33-42574), which became effective on November 1, 1991).
- 10.6\* License Agreement dated as of June 16, 1989, between the Company and Yamanouchi Pharmaceutical Co., Ltd. ("Yamanouchi"). (Incorporated by reference to Exhibit 10.17 to the Company's

## Edgar Filing: ALTEON INC /DE - Form 10-K

Registration Statement on Form S-1 (File Number 33-42574), which became effective on November 1, 1991).

- 10.7\* Research and License Agreement dated as of September 5, 1991, between the Company and The Picower Institute for Medical Research. (Incorporated by reference to Exhibit 10.29 to the Company's Registration Statement on Form S-1 (File Number 33-42574), which became effective on November 1, 1991).
- 10.8 Lease Agreement dated January 11, 1993, between Ramsey Associates and the Company.
- 10.9\* License Agreement dated as of December 30, 1994, between the Company and Corange International Limited.
- 10.10\* Research Collaboration and License Agreement dated as of June 2, 1995, between Washington University and the Company.
- 10.11 Distribution Agreement dated September 25, 1995, between the Company and Eryphile BV.
- 10.12+ Employment Agreement dated as of October 21, 2000, between the Company and Elizabeth O'Dell.
- 10.13+ Alteon Inc. Change in Control Severance Benefits Plan.
- 10.14 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).
- 10.15\* 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).
- 44
- 10.16 Stock Purchase Agreement dated as of December 1, 1997, between Alteon Inc. and Genentech, Inc. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 10, 1997).
- 10.17+ Amended and Restated Employment Agreement dated as of December 15, 1998, between the Company 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).
- 10.18 Letter Agreement dated February 11, 1999, between the Company and Genentech, Inc. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 19, 1999).
- 10.19+ Consulting Agreement dated as of December 15, 1998, between the Company and Mark Novitch, M.D., as amended by letter agreement dated as of January 18, 2001.
- 10.20+ Employment Agreement dated as of March 14, 2000, between the Company and Robert deGroof, Ph.D. (Incorporated by reference to

## Edgar Filing: ALTEON INC /DE - Form 10-K

Exhibit 10.1 to the Company's Report on Form 10-Q filed on May 12, 2000).

- 10.21 Common Stock and Warrants Purchase Agreement dated as of September 29, 2000, among Alteon Inc. and EGM Medical Technology Fund, L.P., EGM Technology Offshore Fund, Narragansett I, L.P., Narragansett Offshore, Ltd., S.A.C. Capital Associates, LLC, SDS Merchant Fund, LP and Herriot Tabuteau. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 5, 2000).
- 10.22\* Development Services Agreement dated September 25, 2000. (Incorporated by reference to Exhibit 10.2 to the Company's Report on Form 10-Q filed on November 13, 2000).
- 23.1 Consent of Independent Public Accountants.

-----  
\* 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.