

ATHEROGENICS INC  
Form 10-K  
March 15, 2004

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**Form 10-K**

(Mark One)

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

**For the fiscal year ended December 31, 2003**

**OR**

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

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

**Commission file number 0-31261**

**AtheroGenics, Inc.**

(Exact name of Registrant as specified in its charter)

**Georgia**

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

**58-2108232**

*(I.R.S. Employer Identification Number)*

**8995 Westside Parkway,  
Alpharetta, Georgia 30004**

*(Address of principal executive offices, including zip code)*

**(678) 336-2500**

*(Registrant's telephone number, including area code)*

Securities registered pursuant to Section 12(b) of the Exchange Act:

**None**

Securities registered pursuant to Section 12(g) of the Exchange Act:

**Common Stock, No Par Value  
Common Stock Purchase Rights**

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

## Edgar Filing: ATHEROGENICS INC - Form 10-K

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

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

The aggregate market value of the 28,918,490 shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price as reported on the Nasdaq National Market as of the last business day of AtheroGenics' most recently completed second fiscal quarter (June 30, 2003), was approximately \$431,753,056. AtheroGenics has no nonvoting common equity.

The number of shares outstanding of the registrant's common stock, as of March 8, 2004: 36,973,755.

### **Documents Incorporated by Reference:**

**Portions of the proxy statement filed pursuant to Regulation 14A under the Securities Exchange Act of 1934 with respect to the 2004 Annual Meeting of Shareholders are incorporated herein by reference in Part III.**

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**PART I**

**Item 1. Business**

**Overview**

AtheroGenics is a research-based pharmaceutical company incorporated in the State of Georgia in 1993. We are focused on the discovery, development and commercialization of novel drugs for the treatment of chronic inflammatory diseases, including heart disease (atherosclerosis), rheumatoid arthritis, organ transplant rejection and asthma. We have developed a proprietary vascular protectant, or v-protectant, technology platform to discover drugs to treat these types of diseases. Based on our v-protectant platform, we have four drug development programs in the clinic and are pursuing a number of other preclinical programs.

Our first v-protectants are drug candidates that block the production of proteins that are necessary to initiate and maintain inflammation. For example, one of these proteins, VCAM-1, binds to white blood cells that accumulate at the site of inflammation and directs these cells in their migration from the bloodstream into the tissue. We believe that v-protectants can suppress chronic inflammation by blocking production of VCAM-1 without undermining the body's ability to protect itself against infection.

AGI-1067 is our v-protectant candidate that is most advanced in clinical development. AGI-1067 is designed to benefit patients with coronary heart disease, which is atherosclerosis of the blood vessels of the heart. Atherosclerosis is a common disease that results from inflammation and the build-up of plaque in arterial blood vessel walls. More than 13 million people in the United States currently have been diagnosed with coronary heart disease. There are no medications available for physicians to treat directly the underlying chronic inflammation associated with coronary heart disease. Instead, physicians treat risk factors, such as high cholesterol and high blood pressure, to slow the progression of the disease. The anti-inflammatory mechanism of AGI-1067 represents a novel, direct therapeutic approach that may be suitable as a chronic treatment for all patients with coronary heart disease, including those without traditional risk factors.

We have completed a successful 305-patient Phase II clinical trial, called CART-1 (Canadian Antioxidant Restenosis Trial), that demonstrated the safety and effectiveness of AGI-1067 for the treatment of post-angioplasty restenosis, a condition that affects many patients with coronary heart disease. In addition, CART-1 data also showed that after only six weeks of therapy, there was an apparent anti-atherosclerotic effect in blood vessels adjacent to the angioplasty site, but not involved in the angioplasty. A recent analysis of the CART-1 trial offers additional data on the impact of AGI-1067 on plaque burden, a measure of disease in coronary blood vessels. In the treatment groups receiving the two highest doses of AGI-1067, plaque burden decreased by 1.6% and 1.9%, respectively, a therapeutic effect that we believe is consistent with reversing coronary artery disease. The trial also demonstrated that AGI-1067 was well tolerated, with no increase in adverse events versus placebo. Based on the results of a subsequent End of Phase II meeting with the U.S. Food and Drug Administration (FDA), we proceeded to develop a Phase III clinical trial protocol to evaluate AGI-1067 for the treatment of atherosclerosis. The Phase III protocol has received a Special Protocol Assessment from the FDA. A Special Protocol Assessment is written confirmation from the FDA that the protocol is adequately designed to support a New Drug Application for the drug in the specified treatment area.

We are currently conducting a Phase IIb clinical trial called CART-2, which is a 500-patient study that examines the effect of 12 months of AGI-1067 therapy on atherosclerosis and post-angioplasty restenosis. We recently completed enrollment in CART-2 and expect to complete the treatment phase of CART-2 in mid-2004, after which we will proceed with data analysis and disclosure of the results.

In June 2003, we initiated a pivotal Phase III trial, referred to as ARISE (Aggressive Reduction of Inflammation Stops Events), which is being conducted in cardiac centers in the United States, Canada, the United Kingdom and South Africa. ARISE will evaluate the impact of AGI-1067 on important outcome measures such as death due to coronary disease, myocardial infarction, stroke, coronary re-vascularization and unstable angina in patients who have coronary heart disease. The study will assess the incremental benefits of AGI-1067 versus the current standard of care therapies in this patient population. As such, all patients in the trial, including those on placebo, will be receiving other appropriate heart disease medications, including statins and other cholesterol-lowering therapies, high blood pressure medications and anti-clotting agents. ARISE will enroll 4,000 patients who will be followed for an average of 18 months or until a minimum of 1,160 primary events, or outcome measures, have occurred.

AGIX-4207, our second v-protectant candidate, is a novel oral agent being developed for the treatment of the signs and symptoms of rheumatoid arthritis. We have completed a Phase II clinical trial that evaluated safety, tolerability and the effect of AGIX-4207 on biological markers of inflammation in rheumatoid arthritis patients. Data from this trial demonstrated that treatment



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with AGIX-4207 was safe and well tolerated by all patients. In the trial, AGIX-4207 significantly inhibited an increase in the erythrocyte sedimentation rate, an important biomarker of disease activity, versus patients on placebo. The effect of AGIX-4207 on the other biomarkers tested was not statistically significant although some showed trends toward benefit.

We have commenced enrollment for a 275-patient Phase II clinical trial of AGIX-4207, called OSCAR (Oral Suppression of Cellular Inflammation Attenuates Rheumatoid Arthritis). OSCAR will evaluate the impact of various doses of AGIX-4207 versus placebo on clinical efficacy, biomarkers, and safety in patients with rheumatoid arthritis. We expect to complete the enrollment and treatment phases of OSCAR in the second quarter of 2004, after which we will proceed with data analysis and disclosure of the results.

AGIX-4207 I.V., our third v-protectant candidate, is an intravenous drug designed to treat rheumatoid arthritis patients in whom the rapid attainment of target drug levels in the blood is desirable. We have completed a Phase I clinical trial that assessed the safety and tolerability of AGIX-4207 I.V. in healthy volunteers. The results from this trial demonstrated that single infusions of AGIX-4207 I.V. were well tolerated and adverse events were generally mild and not considered clinically significant.

Our fourth v-protectant candidate, AGI-1096, is a novel antioxidant and selective anti-inflammatory agent which is being developed to address the accelerated inflammation of grafted blood vessels, known as transplant arteritis, common in chronic organ transplant rejection. We have completed a Phase I clinical trial that assessed the safety and tolerability of AGI-1096 in healthy volunteers. The results of the AGI-1096 clinical trial data demonstrated the drug was well tolerated at all oral doses, with no drug-related adverse events. We recently announced a collaboration with Fujisawa Pharmaceutical Co., Ltd. to further develop AGI-1096.

We have identified additional potential v-protectant candidates to treat other chronic inflammatory diseases, including asthma. We are evaluating these v-protectants to determine lead drug candidates for clinical development. We plan to develop these v-protectants rapidly and may seek regulatory fast track status, if available, to expedite development and commercialization. We will continue to expand upon our v-protectant technology platform using functional genomics to identify novel therapeutic gene targets. Functional genomics is the process by which one uses scientific models and techniques to discover and modify genes, measure the consequences of the modifications, and reliably determine the function of those genes.

## **Business Strategy**

Our objective is to become a leading pharmaceutical company focused on discovering, developing and commercializing novel drugs for the treatment of chronic inflammatory diseases. The key elements of our strategy include the following:

*Continue aggressive development program for AGI-1067.* We intend to rapidly develop AGI-1067 for the treatment and prevention of atherosclerosis in patients with coronary heart disease. We are currently enrolling patients in the ARISE Phase III clinical trial for the treatment of atherosclerosis in patients with coronary heart disease.

*Extend our v-protectant technology platform into additional therapeutic areas that address unmet medical needs.* We believe that our v-protectants have the potential for treating a wide variety of other chronic inflammatory diseases. These indications include: rheumatoid arthritis, asthma, chronic organ transplant rejection and other diseases. We are currently enrolling patients in the OSCAR Phase II clinical trial with our v-protectant compound, AGIX-4207, for the treatment of rheumatoid arthritis. We completed Phase I clinical trials with positive results for both AGIX-4207 I.V., an intravenously administered drug for the treatment of rheumatoid arthritis, and for AGI-1096, a v-protectant developed for the prevention of chronic organ transplant rejection.

*Expand our clinical product candidate portfolio.* In addition to our existing discovery programs, we intend to acquire rights to other product candidates and technologies that complement our existing product candidate lines or that enable us to capitalize on our scientific and clinical development expertise. We plan to expand our product candidate portfolio by in-licensing or acquiring product candidates, technologies or companies.

*Commercialize our products.* We plan to collaborate with large pharmaceutical companies to commercialize products that we develop to target patient or physician populations in broad markets. In contrast, we plan to develop a sales force to commercialize those of our products that we develop to target appropriate patient or physician populations in narrow markets.



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**Inflammation and Disease**

Inflammation is a normal response of the body to protect tissues from infection, injury or disease. The inflammatory response begins with the production and release of chemical agents by cells in the infected, injured or diseased tissue. These agents cause redness, swelling, pain, heat and loss of function. Inflamed tissues generate additional signals that recruit white blood cells to the site of inflammation. White blood cells destroy any infective or injurious agent, and remove cellular debris from damaged tissue. This inflammatory response usually promotes healing but, if uncontrolled, may become harmful.

The inflammatory response can be either acute or chronic. Acute inflammation lasts at most only a few days. The treatment of acute inflammation, where therapy includes the administration of aspirin and other non-steroidal anti-inflammatory agents, provides relief of pain and fever for patients. In contrast, chronic inflammation lasts weeks, months or even indefinitely and causes tissue damage. In chronic inflammation, the inflammation becomes the problem rather than the solution to infection, injury or disease. Chronically inflamed tissues continue to generate signals that attract white blood cells from the bloodstream. When white blood cells migrate from the bloodstream into the tissue they amplify the inflammatory response. This chronic inflammatory response can break down healthy tissue in a misdirected attempt at repair and healing. Diseases characterized by chronic inflammation include, among others:

- atherosclerosis, including coronary heart disease;
- rheumatoid arthritis;
- organ transplant rejection; and
- asthma.

Atherosclerosis is a common cardiovascular disease that results from inflammation and the buildup of plaque in arterial blood vessel walls. Plaque consists of inflammatory cells, cholesterol and cellular debris. Atherosclerosis, depending on the location of the artery it affects, may result in a heart attack or stroke.

Atherosclerosis of the blood vessels of the heart is called coronary artery disease or heart disease. It is the leading cause of death in the United States, claiming more lives each year than all forms of cancer combined. Recent estimates suggest that over 13 million Americans are diagnosed with some form of atherosclerosis. When atherosclerosis becomes severe enough to cause complications, physicians must treat the complications themselves, including angina, heart attack, abnormal heart rhythms, heart failure, kidney failure, stroke, or obstructed peripheral arteries. Many of the patients with established atherosclerosis are treated aggressively for their associated risk factors, as with statins, which have been repeatedly shown to slow the progression of atherosclerosis and prevent future adverse events such as heart attack, stroke, and death. Other risk factors associated with atherosclerosis include elevated triglyceride levels, high blood pressure, smoking, diabetes, obesity and physical inactivity. Many atherosclerosis patients also experience symptoms of angina and/or a history of acute coronary syndromes, such as myocardial infarctions and unstable angina. In addition, most of these patients have high-cholesterol, and as a result, the current treatment focuses primarily on cholesterol reduction. Additionally, these patients are routinely treated with anti-hypertensives and anti-platelet drugs to help prevent the formation of blood clots. There are currently no medications available for physicians to treat directly the underlying chronic inflammation of atherosclerosis.

Rheumatoid arthritis is a common form of arthritis that is characterized by inflammation of the membrane lining the joint, which causes pain, stiffness, warmth, redness and swelling. The inflamed joint lining, the synovium, can invade and damage bone and cartilage. Inflammatory cells release enzymes that may digest bone and cartilage. The involved joint can lose its shape and alignment, resulting in pain and loss of movement. When the immune system works properly, it is the body's defense against bacteria, viruses and other foreign cells. In an immune disorder like rheumatoid arthritis, the immune system works improperly and attacks the body's own joints and other organs. In rheumatoid arthritis, white blood cells move from the bloodstream into the joint tissues. Fluid containing inflamed cells accumulates in the joint. The white cells in the joint tissue and fluid produce many substances, including enzymes, antibodies and other molecules that attack the joint and can cause damage. In the United States, approximately one percent of the population, or 2.1 million people, have rheumatoid arthritis. The cause of rheumatoid arthritis is not yet known, and the disease differs from person to person. Anyone can get rheumatoid arthritis, including children and the elderly. However, the disease usually begins in the young- to middle-adult years. Among people with rheumatoid arthritis, women outnumber men three-to-one. The disease occurs in all ethnic groups and in all parts of the world.

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Current treatment methods for rheumatoid arthritis focus on relieving pain, reducing inflammation, stopping or slowing joint damage, and improving patient function and well-being, and include non-steroidal anti-inflammatory drugs, corticosteroids, and drugs designed to slow the progression of disease, termed disease modifying anti-rheumatic drugs, or DMARDs. DMARDs can cause serious side effects, and include drugs that were originally designed to treat cancer, such as methotrexate. Modern treatments with two new DMARDs developed by other companies, Enbrel® (etanercept) and Remicade® (infliximab), have substantially improved the quality of life for people with rheumatoid arthritis. These drugs prove that blocking the activity of tumor necrosis factor, a molecule that stimulates a broad range of cellular activities implicated in the inflammation process, improves rheumatoid arthritis. However, both of these drugs must be injected and both increase the risk of severe infection.

Organ transplantation takes place when an organ from a donor is surgically removed and placed in a recipient patient whose own organ has failed because of disease or infection. Except for transplants between identical twins, all transplant donors and recipients are immunologically incompatible. This biological incompatibility is a barrier that causes the recipient's immune system to try to destroy or reject the new organ. A patient's white blood cells produce special proteins called antibodies that are created specifically to latch onto the transplanted organ. While attached to the organ, the antibodies alert the rest of the immune system to attack the organ slowly and continuously. The current treatment for prevention of organ transplant rejection focuses on the use of powerful immunosuppressive drugs such as cyclosporin A, tacrolimus and rapamycin (sirolimus). These drugs, which are initiated during the acute rejection phase, need to be taken continuously after the transplant procedure, often cause side effects, and may fail to prevent long-term rejection of the transplant. Immunosuppressants may also impair the recipient's immune system in order to reduce the immune response against the transplant. The Scientific Registry of Transplant Recipients reports that even with the use of immunosuppressants, patients run the risk of losing a donated organ during the first three years following transplantation, and roughly 50 percent of patients have functioning organ transplants after approximately ten years.

Asthma is a common chronic inflammatory disease of the bronchial tubes, which are the airways in the lungs. Asthma is marked by episodic airway attacks that are caused by many stresses, including allergy, cold air, ozone or exercise. Asthma therapy has concentrated on the use of inhaled corticosteroids to reduce chronic inflammation and bronchodilators to provide symptomatic relief. Asthmatic patients, however, continue to experience flare-ups, or exacerbations, that are not prevented nor effectively treated by these medicines.

Many physicians are only now becoming aware of the key role of chronic inflammation in diverse diseases such as atherosclerosis and asthma for which existing anti-inflammatory treatments are incomplete and limited in use. As more physicians recognize that a wide range of chronic diseases are inflammatory in nature, we believe that these physicians will require safer and more effective anti-inflammatory treatments. We believe that one of these therapeutic approaches will be the administration of drugs designed to block the migration of white blood cells through blood vessel walls into inflamed tissues, unless the inflammation is due to infection.

### **V-Protectant Technology**

We have developed a proprietary v-protectant technology platform for the treatment of chronic inflammatory diseases. This platform is based on the work of our scientific co-founders R. Wayne Alexander, M.D., Ph.D. and Russell M. Medford, M.D., Ph.D. In 1993, Drs. Alexander and Medford discovered a novel mechanism within arterial blood vessel walls that could control the excessive accumulation of white blood cells without affecting the body's ability to fight infection. V-protectant technology exploits the observation that the endothelial cells that line the interior wall of the blood vessel play an active role in recruiting white blood cells from the blood to the site of chronic inflammation. V-protectants are drugs that block harmful effects of oxygen and other similar molecules, collectively called oxidants. Scientists have known for some time that some oxidants can damage cells, but have more recently determined that these same oxidants may also act as signals to modify gene activity inside cells. This change in gene activity leads to the production of proteins that initiate or maintain inflammation. The protein products of these cells, including VCAM-1, attract white blood cells to the site of chronic inflammation. We believe that an excess number of VCAM-1 molecules on the surface of cells is a disease state. We also believe that AGI-1067 and other v-protectants can act as antioxidants and can block the specific type of inflammation caused by oxidants acting as signals. We believe that v-protectants will provide this anti-inflammatory benefit without undermining the body's ability to protect itself against infection.

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The table below summarizes our therapeutic programs, their target indication or disease and their development status.

<b>Therapeutic Program</b>	<b>Disease/Indication</b>	<b>Development Status</b>
<b>V-PROTECTANTS</b>		
AGI-1067	Atherosclerosis	Phase III clinical trial
AGIX-4207	Rheumatoid arthritis	Phase II clinical trial
AGIX-4207 I.V	Exacerbations of rheumatoid arthritis	Phase I clinical trial
AGI-1096	Transplant rejection	Phase I clinical trial
Oral product candidate	Chronic asthma	Pre-IND
<b>FUNCTIONAL GENOMICS PROGRAM</b>	Inflammatory diseases	Research
<b>MEKK TECHNOLOGY PLATFORM</b>	Inflammatory diseases	Research

We have established therapeutic programs for product development using lead candidates we select from among our compound libraries. These programs seek to exploit the value of the products early and to expand their use broadly. We continue to test compounds to identify back-up and second-generation product candidates. We are also pursuing novel discovery targets in chronic inflammation.

*AGI-1067*

Our lead v-protectant product candidate, AGI-1067, is a novel small molecule that was designed to treat atherosclerosis of the blood vessels of the heart, or coronary artery disease. We believe that AGI-1067 may treat all areas of the coronary artery susceptible to atherosclerosis in a way that cannot be achieved with any existing therapy.

AGI-1067 was studied preclinically in multiple species to establish its therapeutic properties. Dosed orally, AGI-1067 blocked VCAM-1 expression, prevented atherosclerosis and showed potent anti-oxidant activity. Based upon the successful completion of preclinical testing, AGI-1067 was studied in seven Phase I clinical trials in more than 150 men and women, including healthy volunteers and patients up to the age of 85, to assess tolerability and potential for interaction with other drugs. In addition, we have given AGI-1067 in combination with other drugs commonly used in patients with atherosclerosis. In these clinical trials the subjects tolerated AGI-1067 well, with no dose or use-limiting side effects. These positive results supported our progress to Phase II clinical trials.

In November 2001, data from our first Phase II trial, called CART-1, presented at the American Heart Association 2001 Scientific Sessions suggested that AGI-1067 had a direct anti-atherosclerotic effect on coronary blood vessels, consistent with reversing the progression of coronary artery disease.

CART-1 was a 305-patient clinical trial that compared three oral doses of AGI-1067 in the amounts of 70 mg, 140 mg and 280 mg, given for six weeks, to placebo and probucol, a drug that has been shown to prevent restenosis. The primary endpoint of the trial was the size of the luminal area, or coronary artery opening, as measured by intravascular ultrasound, or IVUS, six months after angioplasty. CART-1 results showed that the study met its primary endpoint, achieving statistical significance for both the AGI-1067 dose response and for 280 mg AGI-1067 vs. placebo.

In addition, an early direct benefit on coronary heart disease was evident at two weeks as shown by a dose response improvement of the luminal area at the site of angioplasty for patients who received AGI-1067. This direct benefit was maintained at the angioplasty site at the six-month follow-up, as measured by repeat angiography. A recent analysis of the CART-1 trial offers additional data on the impact of AGI-1067 on plaque burden, a measure of disease in coronary blood vessels. In the treatment groups

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receiving the two highest doses of AGI-1067, plaque burden decreased by 1.6% and 1.9%, respectively, a therapeutic effect that we believe is consistent with reversing coronary artery disease.

In July 2003, we completed enrollment in CART-2, a 500-patient Phase IIb clinical trial that examines the effect of 12 months of AGI-1067 therapy on atherosclerosis and post-angioplasty restenosis. We expect to complete the treatment phase of CART-2 in mid-2004, after which we will proceed with data analysis and disclosure of the results.

Based on the results of a subsequent End of Phase II meeting with the FDA in 2002, AtheroGenics accelerated the development of a Phase III clinical trial protocol to evaluate AGI-1067 for the treatment of atherosclerosis. This protocol was submitted to the FDA in November 2002. The protocol was accepted in March 2003 and we are currently enrolling patients in our Phase III clinical trial.

The Phase III ARISE trial is being conducted in cardiac centers throughout the United States, Canada, South Africa and the United Kingdom. ARISE will evaluate the impact of AGI-1067 on important clinical outcome measures including death due to coronary heart disease, myocardial infarction, stroke, coronary re-vascularization and unstable angina in patients who have coronary heart disease. The study will also assess the incremental benefits of AGI-1067 over the current standard of care in this patient population. As such, all patients in the trial, including those on placebo, will be receiving other appropriate heart disease medications, including statins and other cholesterol-lowering therapies, high blood pressure medications and anti-clotting agents. ARISE will enroll 4,000 patients who will be followed for an average of 18 months or until a minimum of 1,160 primary events, or outcome measures, have occurred.

*AGIX-4207*

Rheumatoid arthritis is a chronic, progressively debilitating inflammatory disease that affects articular, or rotating, joints resulting in significant pain, stiffness and swelling and leads to degradation of the joint tissue. According to the Arthritis Foundation, there are 2.1 million people with rheumatoid arthritis in the United States. Approximately 70 percent of patients with rheumatoid arthritis are young and middle-aged women.

Physicians treat rheumatoid arthritis in a stepwise fashion, starting with the occasional to regular use of anti-inflammatory agents such as aspirin or ibuprofen, and proceeding to treatment with DMARDs, which can potentially be toxic. The newer DMARDs target the modulation of tumor necrosis factor (TNF), tissue repair and proliferation. The recent successful introduction of new drugs for rheumatoid arthritis has highlighted both the market potential and the size and scope of the unmet medical need of these patients. These drugs are partially effective and may cause serious side effects. AGIX-4207 is a selective modulator of TNF induced genes and is being tested as a medication that would be taken orally, once a day. This selective nature of AGIX-4207 may decrease chronic inflammation in rheumatoid arthritis with fewer side effects.

In March 2001, we commenced a Phase I clinical trial to assess the safety and tolerability of AGIX-4207 in healthy volunteers. In February 2002, we received results from the Phase I clinical trial demonstrating that AGIX-4207 is well tolerated over the single and multiple dose ranges studied. Adverse events were generally mild and not considered clinically significant.

In September 2002, we commenced a Phase II clinical trial to evaluate the safety of orally administered AGIX-4207 in patients, and its effect on biomarkers of inflammation. The trial evaluated 27 patients, who were being treated for rheumatoid arthritis with the prescribed dosing regimen of Remicade®, every six-to-eight weeks, and met American College of Rheumatology response criteria. In July 2003, we received the results from this clinical trial and the data demonstrated that treatment with AGIX-4207 was safe and well tolerated by all patients. In the trial, AGIX-4207 significantly inhibited an increase in the erythrocyte sedimentation rate, an important biomarker of disease activity, versus patients on placebo. In addition, no serious adverse events, discontinuations from therapy or new laboratory abnormalities were noted in patients who received the drug. In October 2003, we initiated the enrollment in a Phase II clinical trial called OSCAR, a multi-center, randomized, double-blind, placebo-controlled trial of approximately 275 patients. The patients are being randomized into four groups and treated with one of three doses of AGIX-4207 or placebo, administered orally, once a day, for 12 weeks. Patients who have been treated with DMARDs prior to screening will not be included in the trial. The primary endpoint, a reduction in the clinical signs and symptoms of disease in patients with rheumatoid arthritis, will be measured after 12 consecutive weeks of treatment using the American College of Rheumatology ACR 20 composite score. The ACR 20 is a standard measurement of response utilized to evaluate improvement of signs and symptoms in rheumatoid arthritis patients. The trial will also assess a variety of secondary endpoints, including ACR 50 and ACR 70 scores, biological markers, safety and tolerability and time to initiation of rescue medication.

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We have also developed an intravenously-dosed v-protectant drug candidate, AGIX-4207 I.V., to treat rheumatoid arthritis patients in whom the rapid attainment of target drug levels in the blood is desirable. These populations may include patients with flare-ups or exacerbations of the disease, patients who are intolerant of protein-based parenteral TNF inhibitors, hospitalized patients with rheumatoid arthritis who undergo elective or emergency surgical procedures and risk causing flare-ups, as well as patients who are unable to take oral medication. An exacerbation is a sudden worsening of the patient's arthritis or condition that usually requires hospitalization and intensive therapy. We have completed a Phase I clinical trial to assess the safety and tolerability of AGIX-4207 I.V. in healthy volunteers. The results demonstrated that single infusions of AGIX-4207 I.V. were well tolerated in healthy volunteers at all the doses studied, including those doses that reached targeted blood levels. There was no dose-related increase in adverse events, and the drug had a safety profile similar to placebo.

*AGI-1096*

Organ transplant rejection is caused when patients' immune systems recognize transplanted organs as foreign and, therefore, reject them. Acute rejection occurs soon after transplantation, while chronic rejection may take years. Recent industry sources report there are approximately 200,000 organ transplant recipients in the United States who are at risk of chronic organ transplant rejection. Chronic rejection is a major factor contributing to organ shortage.

Physicians treat these patients with powerful immunosuppressants to block all immune and inflammatory reactions that could cause organ transplant rejection. These immunosuppressive therapies, however, may place patients at increased risk for infection. The vascular protection provided by our drug candidate may protect organs from rejection beyond the first year without increasing the risk of infection.

AGI-1096 is an anti-inflammatory agent designed to both diminish the organ transplant response to inflammation and directly protect the blood vessels to the transplanted organ through its v-protectant activity. AGI-1096 inhibits the expression of certain inflammatory proteins, including VCAM-1, in endothelial cells lining the inside surfaces of blood vessel walls. We have completed a Phase I clinical trial of AGI-1096 in healthy volunteers that demonstrated AGI-1096 was well-tolerated over the escalating single oral doses studied. Adverse events were generally mild and not considered clinically significant. Subjects reached targeted blood levels for AGI-1096 that were equivalent to those seen in successful pre-clinical models of organ transplant rejection. In January 2004, we announced a collaboration with Fujisawa Pharmaceutical Co., Ltd. to conduct preclinical and early stage clinical development trials, with Fujisawa funding all development costs during the term of the agreement. Fujisawa will also receive an option to negotiate for late stage development and commercial right to AGI-1096.

*AGI-Series for Respiratory Diseases*

According to the American Lung Association, approximately 20 million adults and children in the United States currently suffer from asthma. Current therapies that target the underlying disease include corticosteroids and several classes of drugs that relieve symptoms but are not effective for chronic inflammation. None of these drugs, including inhaled corticosteroids, are particularly effective for treating exacerbations of asthma, which remain a major unmet medical problem. We believe that v-protectants may reduce the inflammation associated with chronic asthma. We further believe that our v-protectant may be useful in the treatment of up to 1.8 million patients annually who develop acute exacerbations of asthma and seek emergency room treatment in the United States.

We are evaluating classes of chemical compounds as potential treatments for asthma and other respiratory diseases. We will evaluate these compounds for regular treatment of chronic respiratory diseases or for exacerbations. We will test our compounds for delivery by the oral, intravenous or inhaled route of administration.

In June 2001, we entered into a worldwide exclusive license agreement with National Jewish Medical and Research Center to discover and develop novel therapeutics for the treatment of inflammation and asthma. We plan to use these new technologies to discover and develop additional drug candidates for the treatment of asthma and other diseases.

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### **Discovery Research Program**

We have built a robust Discovery Research Program using our demonstrated expertise in functional genomics, molecular biology, cell biology, physiology, pharmacology, biochemistry and medicinal chemistry.

Our Discovery Research Program has four main objectives:

*To discover and develop v-protectants with enhanced potency and improved therapeutic properties.* We are synthesizing novel compounds and testing them in a variety of biochemical and cell-based assays to discover and develop new, small molecule v-protectants. We believe that these v-protectants will have improved therapeutic properties and applicability across a wide range of chronic inflammatory diseases. We have identified several novel series of highly potent v-protectants.

*To identify novel anti-inflammatory therapeutic targets utilizing functional genomics.* One part of our drug discovery platform is a set of techniques that connects our knowledge of genes, which code for proteins, to agents that modify gene activity. This collection of methods, called functional genomics, enables us to select targets efficiently. Our targets for therapy may be the gene, the protein, another substance in the body that links to the protein, or the agent that induces the change. For example, oxidants are agents that induce changes in gene activity. We believe our functional genomics program will enable us to identify novel genes and their protein products that are critical to the chronic inflammatory disease process. We plan to progress these genes and proteins into targets for novel classes of drugs.

*To develop new classes of v-protectant drugs based on the new therapeutic targets identified by our functional genomics program.* We are identifying enzymes and other molecular targets that either control or are controlled by oxidant signals. We believe these discoveries will enable our chemists to synthesize the next generation of v-protectants. We intend to use these enzymes and other molecular targets for both internal efforts and as strategic collaboration assets.

*To develop a second broad platform for the discovery and development of a new class of anti-inflammatory drug candidates.* As a result of entering into the license agreement with National Jewish Medical and Research Center in June 2001, we plan to expand our research program in the future to include the discovery and development of new drug candidates through the exploitation of the licensed technology.

### **Patents and Intellectual Property**

We have established a patent portfolio of owned and in-licensed patents that cover our lead compounds and their use. It is our goal to pursue both broad and specific patent protection in the key areas of our research and development both in the United States and internationally, and to identify value-added exclusive in-licensing opportunities.

#### *V-Protectant Technology*

We have license agreements with Emory University and The Regents of the University of California covering aspects of our v-protectant technology. These agreements obligate us to make milestone payments upon attainment of agreed-upon goals and royalty payments on the sale of licensed products and technology. The licenses with Emory University and The Regents of the University of California also require us to be diligent in commercializing the licensed technologies within certain time periods.

Under our license agreement with Emory University, Emory University granted to us an exclusive license to make, use and sell methods and products covered by certain patents and patent applications owned by Emory University relating generally to the treatment and diagnosis of VCAM-1 related diseases. The license agreement requires us to make royalty payments to Emory University based on certain percentages of net revenue we derive from sales of products covered by the licensed patents or patent applications, and from sublicensing of the licensed patents or patent applications. The license agreement also requires us to make milestone payments to Emory University upon the occurrence of certain product development events. Milestone payments for AGI-1067 could total \$250,000 if all milestone objectives are met. We must indemnify Emory University for all claims and/or losses caused or contributed to by AtheroGenics arising out of our use of the license. We have procured commercial general liability insurance in specified amounts customary in the industry naming Emory University as an insured.

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The Emory license agreement will terminate when all patent rights licensed under the agreement expire. Emory University may terminate the agreement if, after Emory gives notice to us, we fail to make a payment, we fail to render progress reports, we incur specified financial problems, we decide to no longer develop licensed products under the agreement, or we breach a material term of the agreement. We may terminate the agreement upon advance notice to Emory, or if Emory University violates certain material terms of the agreement.

Under our license agreement with The Regents of the University of California, we received a license to make, use and sell diagnostic and therapeutic methods and products using monoclonal antibodies in atherosclerosis and other diseases, which are claimed in applicable patent applications owned by The Regents of the University of California in the U.S. and Canada. We must make milestone payments to The Regents of the University of California upon occurrence of various product development events of up to \$45,000 for each therapeutic application and \$35,000 for each diagnostic application. In addition, we must pay to The Regents of the University of California a percentage of the net revenue we receive from the sale of products covered by the patents and patent applications and from our sublicensing the licensed patents and patent applications. The Regents of the University of California may terminate the agreement upon proper notice for violation of material terms of the agreement. The agreement expires in 2018, when the last patent covered by the license expires. We may terminate the agreement at any time upon prior notice to The Regents of the University of California. We must indemnify The Regents of the University of California for all losses and claims arising out of our use of the license. In addition, we have procured commercial liability insurance in specified amounts customary in the industry naming the University of California as an insured.

As part of our v-protectant technology patent portfolio, we also purchased U.S. Patent No. 5,262,439 under an agreement with Dr. Sampath Parthasarathy. We believe the cost of this agreement to us is immaterial.

*AGI-1067 Patent Portfolio*

Our patent coverage on AGI-1067 is based on patent filings that we own and patent filings exclusively licensed from Emory University. We own one issued patent, U.S. Patent No. 5,262,439, which expires in 2012, and related filings in Japan, Canada and Europe that generically cover the compound AGI-1067 as a member of a class of related compounds. We own another patent, U.S. Patent No. 6,147,250, that protects through 2018 the specific compound AGI-1067 and its use to treat VCAM-1 mediated diseases including, among others, atherosclerosis, post-angioplasty restenosis and coronary artery disease. We also own U.S. Patent No. 6,121,319, which covers the use of a class of compounds including AGI-1067 to treat VCAM-1 mediated diseases. Applications corresponding to U.S. Patent No. 6,147,250 and U.S. Patent No. 6,121,319 have also been filed in foreign patent offices. The patents that we have exclusively licensed from Emory University include the use of a substance that inhibits a class of oxidant signals to treat diseases mediated by VCAM-1.

*AGIX-4207 Patent Portfolio*

Our patent coverage on AGIX-4207 is based on patent filings that we own and patent filings exclusively licensed from Emory University. We own U.S. Patent No. 6,548,699, and associated non-U.S. patent filings which describe AGIX-4207 and its use to treat rheumatoid arthritis, other inflammatory conditions and other disorders mediated by VCAM-1. This patent and its associated non-U.S. counterparts will expire in 2018.

*AGI-1096 Patent Portfolio*

Our patent coverage on AGI-1096 is based on patent filings that we own and patent filings exclusively licensed from Emory University. We own U.S. Patent No. 6,617,352 and associated non-U.S. patent filings which describe AGI-1096 and its use to treat disorders mediated by VCAM-1. We also own U.S. Patent No. 6,670,398 which claims method of using AGI-1096 for treating transplant organ rejection. These patents and any associated non-U.S. counterparts will expire in 2018.

*Other V-Protectant Compounds*

Certain patent applications in the United States and non-U.S. countries cover the use of a number of compounds identified in our research program to act as v-protectants, and specifically for use in treating cardiovascular and inflammatory disease. In addition we have exclusively licensed patents from Emory University that cover the use of a class of compounds which act as v-protectants.

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*MEKK Technology*

In June 2001, we entered into a worldwide exclusive license agreement with National Jewish Medical and Research Center. Under the agreement, National Jewish granted us an exclusive license under several of its U.S. and foreign patents and patent applications and related technical information to make, use and sell diagnostics and therapeutics for the treatment of human diseases, including inflammation and asthma. Under the terms of the agreement with National Jewish, we may grant sublicenses of our rights to others.

Under the agreement with National Jewish, we have assumed responsibility for all future costs associated with research and development of products developed from the licensed technology. We have also assumed responsibility for the costs of filing, prosecuting and maintaining the licensed patent rights. We granted National Jewish a warrant to purchase up to 40,000 shares of our common stock at an exercise price of \$6.00 per share, subject to a vesting period. Under the agreement, we paid an upfront payment in connection with the execution of the agreement and will pay milestone payments to National Jewish upon the achievement of certain clinical and regulatory milestones. Upfront and milestone payments could aggregate up to approximately \$800,000. If we fail to meet various performance milestones by certain dates, some or all of the licensed technology will revert to National Jewish. We must also pay a royalty to National Jewish on net sales of licensed products. If we sublicense the licensed technology, we must pay to National Jewish a percentage of the amounts paid to us by the sublicensee.

We may terminate the license agreement with National Jewish at any time upon at least 90 days prior written notice. If we terminate the agreement in this manner, all licensed patent rights and related technology revert to National Jewish. Either party to the agreement may also terminate it upon a material, uncured breach by the other, or upon the bankruptcy or insolvency of the other. We must indemnify National Jewish for all losses and claims arising out of our use of the license. We will procure commercial liability insurance in amounts customary in the industry as required by the agreement.

Our patent position, like that of many pharmaceutical companies, is uncertain and involves complex legal and factual questions for which important legal principles are unresolved or unclear. We may not develop or obtain rights to products or processes that are patentable. Even if we do obtain patents, they may not adequately protect the technology we own or in-license. In addition, others may challenge, seek to invalidate, infringe or circumvent any patents we own or in-license, and rights we receive under those patents may not provide competitive advantages to us.

Our commercial success will depend in part on our ability to manufacture, use, sell and offer to sell our product candidates and proposed product candidates without infringing patents or other proprietary rights of others. We may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our product candidates or proposed product candidates. For example, U.S. patent applications do not publish until 18 months from their effective filing date. Further, we may not be aware of published or granted conflicting patent rights. Any conflicts resulting from patent applications and patents of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. If others obtain patents with conflicting claims, we may be required to obtain licenses to these patents or to develop or obtain alternative technology. We may not be able to obtain any licenses or other rights to patents, technology or know-how necessary to conduct our business as described in this report. Any failure to obtain such licenses or other rights could delay or prevent us from developing or commercializing our product candidates and proposed product candidates, which could materially affect our business.

Litigation or patent interference proceedings may be necessary to enforce any of our patents or other proprietary rights, or to determine the scope and validity or enforceability of the proprietary rights of others. The defense and prosecution of patent and intellectual property claims are both costly and time consuming, even if the outcome is favorable to us. Any adverse outcome could subject us to significant liabilities, require us to license disputed rights from others, or require us to cease selling our future products.

*Trademarks*

The U.S. Patent and Trademark Office issued a Certificate of Registration for the trademark OXYKINE on April 10, 2001. The Patent and Trademark Office issued a Certificate of Registration for the trademark AATHEROGENICS and design on November 7, 2000 and issued one for the trademark AGI on September 19, 2000. On February 3, 2003, we applied for the trademark V-PROTECTANT.

On January 30, 2002, Applied Genetics Incorporated Dermatics filed with the United States Patent and Trademark Office a petition to cancel the trademark AGI. Applied Genetics has not requested any monetary damages. We filed an answer to the



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petition on March 11, 2002. On July 12, 2002, the United States Patent and Trademark Office issued a suspension of the cancellation proceeding to allow the parties to negotiate a settlement. A settlement agreement has been reached between both parties and is pending approval with the Patent Office.

### **License Agreement with Schering-Plough**

In October 1999, we entered into a worldwide exclusive license agreement with Schering-Plough. Under the agreement we granted to Schering-Plough an exclusive license under our patents and know-how to make, use and sell AGI-1067 and other specified compounds for the treatment of restenosis, coronary artery disease and atherosclerosis. Schering-Plough paid us an initial nonrefundable licensing fee of \$5,000,000 upon signing the agreement and, pursuant to the terms of the agreement, had assumed responsibility for all costs going forward associated with the development, manufacturing and commercialization of products containing AGI-1067 and any other licensed compound.

In October 2001, we reacquired the rights to AGI-1067 and related technology and terminated the exclusive license agreement between us and Schering-Plough to permit us to expedite the development of the compound. With the termination of this license agreement, Schering-Plough has no further rights to the technology or financial obligations to us.

### **Manufacturing**

We have entered into an arrangement with a third party manufacturer for the supply of AGI-1067 bulk drug substance and another third party manufacturer for the formulated drug product. The supplier of the bulk drug substance for AGI-1067 operates under current Good Manufacturing Practice guidelines using cost-effective and readily available materials and reliable processes. The starting material used in the manufacturing process of AGI-1067 is probucol, which was once widely used in North America as a cholesterol-lowering agent, but has since been withdrawn from the North American market due to lack of efficacy. Under the terms of our arrangement, our bulk drug supplier will manufacture sufficient quantities to support development activities for the foreseeable future. After manufacture, a third party supplier formulates AGI-1067 into the drug product under current Good Manufacturing Practice guidelines. We anticipate that this supplier will be able to provide sufficient formulated drug product to complete our ongoing and currently planned clinical trials.

We plan to establish manufacturing agreements with third parties that comply with Good Manufacturing Practice guidelines for bulk drug substance and oral or intravenous formulations of our v-protectant product candidates, including AGIX-4207, AGIX-4207 I.V. and AGI-1096.

### **Sales and Marketing**

We plan to collaborate with large pharmaceutical companies to commercialize product candidates which are for patient or physician populations in broad markets. We believe that collaborating with large companies that have significant marketing and sales capabilities provides for optimal penetration into broad markets, particularly those areas that are highly competitive. In contrast, we plan to develop a sales force to commercialize the products targeted at appropriate patient and physician populations in narrow markets. By using our own sales and marketing organization, we believe we can retain a higher percentage of the profits generated from the sale of our products.

### **Competition**

Developments by others may render our product candidates obsolete or noncompetitive. We face intense competition from other companies for collaborative arrangements with pharmaceutical, biotechnology and medical device companies for establishing relationships with academic and research institutes and for licenses to proprietary technology. These competitors, either alone or in collaboration, may succeed in developing technologies or products that are more effective than ours.

We believe pharmaceutical, biotechnology and medical device companies, as well as academic and research institutions and government agencies, have drug discovery and development programs related to our named therapeutic areas of interest. Many of these companies and institutions, including Pfizer Inc., Amgen Inc., Johnson & Johnson, and Novartis AG, have targeted indications that overlap significantly with our targets and have substantially greater resources than we do. They may, therefore, succeed in commercializing products before we do that compete with us on the basis of efficacy, safety and price.

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Our ability to compete is predicated on three related factors:

First, our scientists and their collaborators have pioneered the basic discoveries and research methodologies linking oxidant signals to vascular cell inflammation. These discoveries and research methodologies form the foundation for our proprietary drug discovery programs relating to chronic inflammation.

Second, our scientific expertise, coupled with our expertise in clinical drug development, has enabled us to be the first company to conduct clinical trials of an orally-administered, small molecule v-protectant .

Third, we believe our scientific, development and licensing expertise strongly positions us to acquire promising technologies and products discovered outside AtheroGenics.

**Governmental Regulation**

We plan to develop prescription-only drugs for the foreseeable future. The U.S. Food and Drug Administration is the regulatory agency that is charged with the protection of people in the United States who take prescription medicines. Every country has a regulatory body with a similar mandate. In addition, the European Union has vested centralized authority in the European Medicines Evaluation Agency and Committee on Proprietary Medicinal Products to standardize review and approval across member nations.

Regulatory agencies have established guidelines and regulations for the drug development process. This process involves several steps. First, the drug company must generate sufficient preclinical data to support initial human testing. In the United States, the drug company must submit an Investigational New Drug application prior to human testing. The Investigational New Drug application contains adequate data on product candidate chemistry, toxicology and metabolism and, where appropriate, animal research testing to support initial safety evaluation in humans. In addition, the drug company provides to the FDA a clinical plan, including proposed use and testing in subjects comprising healthy volunteers and patients.

Clinical trials for a new product candidate usually proceed through four phases:

Phase I clinical trials explore safety, blood levels, metabolism and the potential for interaction with other drugs. Phase I typically proceeds from healthy volunteers into patients with the target disease and comprises up to approximately 200 total subjects.

Phase II clinical trials establish a dose for future testing and marketing in an adequate number of patients with the target disease. The clinical trials may include hundreds of patients who have the target disease and who are receiving a range of background medications. In addition, Phase II clinical trials verify the mechanisms of action proposed preclinically.

Phase III clinical trials usually include two adequate and well controlled studies in the target population. For most chronic diseases, drug companies study a few thousand patients to assure a broadly applicable assessment of safety and efficacy.

At the successful conclusion of Phase III, drug companies may submit a product license application, called a New Drug Application in the United States. Upon accepting the submission, the FDA or non-U.S. regulatory authorities review the file for completeness, accuracy and adherence to regulations. These authorities may use internal and external consultants and may convene an expert committee to advise on the safety, effectiveness and usefulness of the proposed new product candidate prior to final regulatory judgment. The final step to registration is approval of the package insert or label that defines what the drug company may promote to physicians who may use the new drug.

Phase IV clinical trials provide additional information to support marketing of the drug for its approved indication. Phase IV clinical trials may generate data to support promotion of the new drug in comparison with other approved drugs and to support healthcare economics claims. In addition, every pharmaceutical company is responsible for post-marketing surveillance for safety in the marketplace.

We must meet regulatory standards prior to exposing subjects to any drug candidate. We remain responsible for any of these development activities whether we perform them internally or contract them to a third party. The FDA may audit us or our third party

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contractors at any time to ascertain compliance with standards. The FDA may halt all ongoing work if it determines that we or our contractors have deviated significantly from these standards. These standards include:

Good Manufacturing Practices, which govern process chemistry, formulation, labeling and handling of a drug throughout its life cycle;

Good Laboratory Practices, which govern the use of a drug in animal studies to support establishment of safety or the disposition and metabolism of the administered drug, and handling of human or other biological samples for drug assays; and

Good Clinical Practices, which govern the exposure of human subjects under our protocols. Good Clinical Practices set standards for the constitution and activities of institutional review boards that are charged with assuring that the appropriate person gives informed consent prior to study participation and protecting patients whether they receive an experimental drug, an approved drug, or an inactive look-alike called a placebo.

Advertising is subject to FDA approval in the United States and national review elsewhere. In addition, state and local governments and other federal agencies may control marketing if the drug substance, formulation, package, intended use or disposal is subject to local regulation.

The FDA has expanded its expedited review process in recognition that certain severe or life-threatening diseases and disorders have only limited treatment options. Fast track designation expedites the development process but places greater responsibility on a drug company during Phase IV clinical trials. The drug company may request fast track designation for one or more indications at any time during the Investigational New Drug application process, and the FDA must respond within 60 days. Fast track designation allows the drug company to develop product candidates and to request an accelerated or priority review of the New Drug Application based on clinical effectiveness in a smaller number of patients. If the FDA accepts the submission as a priority review, the time for New Drug Application review and approval is reduced from one year to six months. We plan to request fast track designation as appropriate for internal drug development programs.

## **Research and Development**

Our research and development expenses in 2003, 2002 and 2001 were \$45.7 million, \$22.8 million and \$16.9 million, respectively. We plan to increase significantly our research and development expenses as we continue to invest in our clinical programs. We are proceeding with the ARISE Phase III clinical trial for AGI-1067. This trial will enroll 4,000 patients and we expect the total cost of the trial will be approximately \$45 million. The expense associated with this trial, when combined with our other operating activities and on-going preclinical and clinical programs, is estimated to result in net cash usage in 2004 of \$63 million to \$67 million.

## **Employees**

We currently have 97 full-time employees, including 77 in research and development. The employee group includes 27 employees with Ph.D.s, six with M.D.s and 19 with Masters degrees. We believe that our employee relations are good.

## **Available Information**

Our internet website is located at [www.atherogenics.com](http://www.atherogenics.com). Copies of our reports filed under Section 13(a) or 15(d) of the Exchange Act, including annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to these reports may be accessed from our website, free of charge, as soon as reasonably practicable after these reports are electronically filed with or furnished to the Securities and Exchange Commission. The reference to our website address does not constitute incorporation by reference of the information contained on the website and this information should not be considered part of this document.

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**Advisory Boards**

We have established advisory boards to provide guidance and counsel on aspects of our business. These boards are convened once a year and individual members are contacted as required. Members of these boards provide input on product research and development strategy, education and publication plans. The names and members of these boards are as follows:

**Scientific Advisory Board:**

R. Wayne Alexander, M.D., Ph.D., <i>Chairman</i>	R. Bruce Logue Professor and Chairman of the Department of Medicine, Emory University School of Medicine
Victor J. Dzau, M.D.	Hersey Professor of the Theory and Practice of Medicine and Chairman, Department of Medicine, Harvard Medical School and Physician in Chief and Director of Research, Brigham and Women's Hospital
Erwin W. Gelfand, M.D.	Chairman, Department of Pediatrics, National Jewish Medical and Research Center
David G. Harrison, M.D.	Bernard Marcus Professor of Medicine, Director, Division of Cardiology, Emory University School of Medicine
Gary L. Johnson, Ph.D.	Professor and Chair, Department of Pharmacology, University of North Carolina
Dennis Liotta, Ph.D.	Samuel Candler Dobbs Professor of Chemistry, Emory University School of Medicine, Department of Chemistry
Robert M. Nerem, Ph.D.	Director, Georgia Tech/Emory Center (GTEC) for the Engineering of Living Tissues and Director, Parker H. Petit Institute for Bioengineering and Bioscience at Georgia Institute of Technology
Robert D. Rosenberg, M.D., Ph.D.	Chief, Molecular Medicine Unit, Beth Israel Deaconess Medical Center, Whitehead Professor of Biology, Massachusetts Institute of Technology and William B. Castle Professor of Medicine, Harvard Medical School

**Clinical Advisory Board:**

William Virgil Brown, M.D.	Chief of Medicine and Primary Care, Veterans Affairs Medical Center, Emory University School of Medicine
Harvey M. Golomb, M.D.	Chairman and Professor Lowell T. Coggeshall, Professor in Medical Sciences, The University of Chicago
Joseph L. Witzum, M.D.	Professor of Medicine Director, La Jolla Specialized Center of Research in Molecular Medicine and Atherosclerosis

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### **Forward-Looking Statements and Risks Related to Our Company and Business**

*The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by or on behalf of AtheroGenics. AtheroGenics and its representatives may from time to time make written or verbal forward-looking statements, including statements contained in this report and our other filings with the Securities and Exchange Commission and in our reports to our shareholders. Generally, the words, believe, expect, intend, estimate, anticipate, will and similar expressions identify forward-looking statements. All statements which address operating performance, events or developments that we expect or anticipate will occur in the future, including projections of our future results of operations or of our financial condition, research, development and commercialization of our product candidates, and anticipated trends in our business, are forward-looking statements within the meaning of the Reform Act. The forward-looking statements are and will be based on our then current views and assumptions regarding future events and operating performance, and speak only as of their dates. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.*

*The following are some of the factors that could affect our financial performance or could cause actual results to differ materially from those expressed or implied in our forward-looking statements:*

***If AGI-1067 fails in clinical trials, we may not be able to generate future revenues or become profitable.***

AGI-1067 is our lead compound. This compound could fail in clinical trials if we are unable to show it is effective or if it causes unacceptable side effects in the patients we treated. Failure in clinical trials for AGI-1067 would have a material adverse effect on our ability to generate revenue or become profitable.

***We have a history of operating losses, and we may not generate revenue or achieve profitability in the future.***

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to complete successfully the development of our product candidates, conduct preclinical tests in animals and clinical trials in human beings, obtain the necessary regulatory approvals, and manufacture and market the resulting drugs. We have experienced operating losses since we began operations in 1994. As of December 31, 2003, we had an accumulated deficit of approximately \$142.5 million. We expect to incur additional operating losses over the next several years and expect cumulative losses to increase substantially as our research and development, preclinical, clinical, manufacturing and marketing efforts expand. Except for an initial licensing fee and research and development revenue paid to us under a license agreement that has since been terminated, we have had no significant revenue to date.

***If we need additional financing and cannot obtain it, we may not be able to develop or market our products.***

We may encounter increased costs due to unanticipated changes in our product development or commercialization plans. If these costs exceed our available funds, we will need to seek additional financing. If additional funds are not available, we may need to delay clinical studies, curtail operations or obtain funds through collaborative arrangements that may require us to relinquish rights to certain of our products or potential markets.

***If we do not successfully develop our other product candidates, we will have limited ability to generate revenue.***

All of our other programs, AGIX-4207, AGIX-4207 I.V. and AGI-1096, are in early stages of development, and subject to the risks of failure inherent in developing drug products based on new technologies. We do not expect any of our potential product candidates to be commercially available until at least 2006. Our drug discovery efforts may not produce any other proprietary product candidates.

***If we fail to demonstrate adequately the safety and efficacy of a product candidate, we will not be able to commercialize that product candidate.***

We cannot assure you that any product candidate we develop, alone or with others, will prove safe and effective in clinical trials and will meet all of the applicable regulatory requirements needed to receive regulatory approval. If we fail to adequately demonstrate safety and efficacy for any product candidate, we will not be able to commercialize that product candidate. Our failure to produce a product candidate will materially adversely affect our revenue opportunities. We will need to conduct significant research, preclinical testing and clinical trials before we can file product approval applications with the FDA and similar regulatory authorities in other countries. Preclinical testing and clinical trials are long, expensive and uncertain processes. We may spend several years completing our testing for any particular product candidate, and failure can occur at any stage.



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The FDA or we may suspend our clinical trials at any time if either of us believes that we are exposing the subjects participating in these trials to unacceptable health risks. The FDA or institutional review boards at the medical institutions and healthcare facilities where we sponsor clinical trials may suspend any trial indefinitely if they find deficiencies in the conduct of these trials. We must conduct clinical trials in accordance with the FDA's Good Clinical Practices. The FDA and these institutional review boards have authority to oversee our clinical trials and the FDA may require large numbers of test subjects. In addition, we must manufacture the product candidates that we use in our clinical trials under the FDA's Good Manufacturing Practices.

Even if we achieve positive results in early clinical trials, these results do not necessarily predict final results. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after achieving positive results in earlier trials. Negative or inconclusive results or adverse medical events during a clinical trial could cause the FDA or us to terminate a clinical trial or require that we repeat it.

Also, even if the FDA approves a New Drug Application for any of our product candidates, the resulting product may not be accepted in the marketplace. Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend any of our products. In addition, after approval and use in an increasing number of patients, our products could show side effect profiles that limit their usefulness or require their withdrawal although the drugs did not show the side effect profile in Phase I through Phase III clinical trials.

***We may experience delays in our clinical trials that could adversely affect our financial results and our commercial prospects.***

We do not know whether planned clinical trials will begin on time or whether we will complete any of our clinical trials on schedule or at all. Product development costs to us and our collaborators will increase if we have delays in testing or approvals or if we need to perform more or larger clinical trials than planned. Significant delays may adversely affect our financial results and the commercial prospects for our products, and delay our ability to become profitable. We typically rely on third party clinical investigators at medical institutions and healthcare facilities to conduct our clinical trials and, as a result, we may face additional delaying factors outside our control.

***Because we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates, we cannot predict the timing of any future revenue from these product candidates.***

We cannot commercialize any of our product candidates, including AGI-1067, AGIX-4207, AGIX-4207 I.V. and AGI-1096, to generate revenue until the appropriate regulatory authorities have reviewed and approved the applications for the product candidates. We cannot assure you that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for any product candidate we or our collaborators develop. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. Regulatory approval processes outside the United States include all of the risks associated with the FDA approval process. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

***If we do not comply with applicable regulatory requirements in the manufacture and distribution of our products, we may incur penalties that may inhibit our ability to commercialize our products and adversely affect our revenue.***

Our failure to comply with applicable FDA or other regulatory requirements including manufacturing, quality control, labeling, safety surveillance, promoting and reporting may result in criminal prosecution, civil penalties, recall or seizure of our products, total or partial suspension of production or an injunction, as well as other regulatory action against our potential products or us. Discovery of previously unknown problems with a product, supplier, manufacturer or facility may result in restrictions on the sale of our products, including a withdrawal of such products from the market.

***Our failure to protect adequately or enforce our intellectual property rights or secure rights to third party patents could materially adversely affect our proprietary position in the marketplace or prevent the commercialization of our products.***

Our patent position, like that of many pharmaceutical companies, is uncertain and involves complex legal and factual questions for which important legal principles are unresolved. In addition, we may not be able to obtain patent rights on products, treatment methods or manufacturing processes that we may develop or to which we may obtain license or other rights. Even if we do

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obtain patents, they may not adequately protect the technology we own or in-license. In addition, others may challenge, seek to invalidate, infringe or circumvent any patents we own or in-license, and rights we receive under those patents may not provide competitive advantages to us.

Our commercial success will depend in part on our ability to manufacture, use, sell and offer to sell our product candidates and proposed product candidates without infringing patents or other proprietary rights of others. We may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our product candidates or proposed product candidates. For example, U.S. patent applications do not publish until 18 months from their priority date. Further, we may not be aware of published or granted conflicting patent rights. Any conflicts resulting from patent applications and patents of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. If others obtain patents with conflicting claims, we may need to obtain licenses to these patents or to develop or obtain alternative technology. We may not be able to obtain any licenses or other rights to patents, technology or know-how necessary to conduct our business as described in this report. Any failure to obtain such licenses could delay or prevent us from developing or commercializing our drug candidates or proposed product candidates, which would adversely affect our business.

Litigation or patent interference proceedings may be necessary to enforce any of our patents or other proprietary rights, or to determine the scope and validity or enforceability of the proprietary rights of others. The defense and prosecution of patent and intellectual property claims are both costly and time consuming, even if the outcome is favorable to us. Any adverse outcome could subject us to significant liabilities, require us to license disputed rights from others, or require us to cease selling our future products.

Our commercial success will also depend on our ability to manufacture, use, sell and offer to sell our product candidates and proposed product candidates without breaching our agreements with our patent licensees. We have obtained exclusive licenses to technologies from Emory University, covering aspects of our v-protectant technology; The Regents of the University of California, covering aspects of our diagnostic technology; and National Jewish, covering aspects of our MEKK technology platform. Our exclusive license with Emory University requires us to take steps to commercialize the licensed technology in a timely manner. If we fail to meet these obligations, Emory University can convert our exclusive license to a non-exclusive license, can grant others non-exclusive rights in the licensed technology or can require us to sublicense aspects of the licensed technology. Our license agreement with The Regents of the University of California also includes a requirement that we develop the licensed technology within certain time limits. If we fail to meet these time limits, they can terminate our license. Further, The Regents of the University of California are primarily responsible for patent prosecution of the technology we license from them, and we are required to reimburse them for the costs they incur in performing these activities. As a result, we do not have the ability to control these activities. Our license agreement with National Jewish requires us to develop the licensed technology in a timely manner. If we fail to meet these obligations, some or all of the licensed technology may revert to National Jewish.

We also rely upon trade secrets, proprietary know-how and technological advances which we seek to protect through agreements with our collaborators, employees and consultants. These persons and entities could breach our agreements, for which we may not have adequate remedies. In addition, others could become aware of our trade secrets or proprietary know-how through independent discovery or otherwise.

***If our competitors develop and market anti-inflammatory products that are more effective, have fewer side effects or are less expensive than our current or future product candidates, we may have limited commercial opportunities.***

Our competitors include large pharmaceutical and medical device companies and more established biotechnology companies. These competitors have significant resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals and marketing. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. It is possible that any of these competitors could develop technologies or products that would render our technologies or product candidates obsolete or non-competitive, which could adversely affect our revenue potential.

***Third parties' failure to synthesize and manufacture our product candidates to our specifications could delay our clinical trials or hinder our commercialization prospects.***

We currently have no manufacturing facilities to synthesize or manufacture our product candidates, nor do we intend to develop these capabilities in the near future. Our reliance on third parties for these services exposes us to several risks that could delay our clinical trials or hinder our commercialization prospects. These risks include the following:



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*A finding that a third party did not comply with applicable governmental regulations.* Manufacturers of pharmaceutical products are subject to continual review and periodic inspections by regulatory agencies. Failure of one of our third party manufacturers to comply with applicable regulatory requirements, whether or not related to our product candidates, could result in sanctions against our potential products, including recall or seizure, total or partial suspension of production or injunction.

*A failure to synthesize and manufacture our product candidates in accordance with our product specifications.* For example, a starting material used in the manufacturing process of AGI-1067 is probucol, which physicians previously prescribed as a cholesterol-lowering agent but which its manufacturer withdrew from the market for efficacy reasons. The occurrence of a rare side effect with chronic dosing of probucol requires that we maintain a very low maximal amount of probucol in the manufacture of AGI-1067.

*A failure to deliver product candidates in sufficient quantities or in a timely manner.* Any failure by our third party manufacturers to supply our requirements for clinical trial materials or commercial product, or supply these materials in a timely manner could jeopardize the scheduled initiation or completion of these clinical trials and could have a material adverse effect on our ability to generate revenue.

In addition, our continued dependence on third parties for the synthesis and manufacture of our future products may subject us to costs outside of our control, which could adversely affect our future profitability and our ability to commercialize products on a timely and competitive basis.

***If we are unable to create sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will not be able to commercialize our future product candidates.***

We currently have no sales, marketing or distribution capabilities. Therefore, in order to commercialize our product candidates, we must either develop our own sales, marketing and distribution capabilities or collaborate with a third party to perform these functions. We have no experience in developing, training or managing a sales force and will incur substantial additional expenses in doing so. The cost of establishing and maintaining a sales force may exceed its cost effectiveness. In addition, we will compete with many companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete successfully against these companies.

To the extent we seek sales, marketing and distribution alliances for our future products, we face risks including the following:

we may not be able to find collaborators, enter into alliances on favorable terms or enter into alliances that will be commercially successful;

any collaborator might, at its discretion, limit the amount of resources and time it devotes to marketing our products; and

any collaborator may terminate its agreement with us and abandon our products at any time for any reason, regardless of the terms of the agreement.

***Our failure to attract, retain and motivate skilled personnel and cultivate key academic collaborations could materially adversely affect our research and development efforts.***

We are a small company with 97 full-time employees. If we are unable to continue to attract, retain and motivate highly qualified management and scientific personnel and to develop and maintain important relationships with leading academic institutions and scientists, we may not be able to achieve our research and development objectives. Competition for personnel and academic collaborations is intense. Loss of the services of any of our key scientific personnel and, in particular, Dr. Russell M. Medford, our President and Chief Executive Officer, could adversely affect progress of our research and development programs. Dr. Medford is the only employee with whom we currently have an employment agreement, although we are in the process of entering into employment agreements with our other senior executives.

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*Our failure to obtain an adequate level of reimbursement or acceptable prices for our products could diminish our revenues.*

Our ability to commercialize our future products successfully, alone or with collaborators, will depend in part on the extent to which reimbursement for the products will be available from:

government and health administration authorities;

private health insurers; and

other third party payors.

Government and other third party payors increasingly are attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs. Third party private health insurance coverage may not be available to patients for any of our future products.

The continuing efforts of government and other third party payors to contain or reduce the costs of healthcare through various means may limit our commercial opportunity. For example, in some countries other than the United States, pricing and profitability of prescription pharmaceuticals are subject to government control. In the United States, we expect proposals to implement similar government control to continue. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we or any potential collaborators could receive for any of our future products and could adversely affect our profitability.

*If plaintiffs bring product liability lawsuits against us, we may incur substantial financial loss or may be unable to obtain future product liability insurance at reasonable prices, if at all, either of which could diminish our ability to commercialize our future products.*

The testing and marketing of medicinal products entail an inherent risk of product liability. Clinical trial subjects, consumers, healthcare providers, or pharmaceutical companies or others selling our future products could bring product liability claims against us. We cannot assure you that we will be able to acquire or maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us.

*Our quarterly operating results may fluctuate, causing volatility in our stock price.*

Our product candidates are now in research and various stages of development or clinical trials. Accordingly, we do not receive any revenues from sales of these product candidates. Our results of operations historically have fluctuated on a quarterly basis, which we expect to continue. Our results of operations at any given time will be based primarily on the following factors:

the status of development of our various product candidates;

whether we enter into collaboration agreements and the timing and accounting treatment of payments, if any, to us under those agreements;

whether and when we achieve specified development or commercialization milestones; and

the addition or termination of research programs or funding support.

We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of future performance. These fluctuating results may cause the price of our stock to fluctuate, perhaps substantially.

*Conversion of our \$100 million principal amount, 4.5% convertible notes will dilute the ownership interest of existing shareholders and could adversely affect the market price of our common stock.*

The conversion of some or all of our outstanding 4.5% convertible notes will dilute the ownership interests of existing shareholders. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the notes may encourage short selling by market participants.

**Table of Contents****Item 2. Properties**

Our scientific and administration facility encompasses approximately 27,000 square feet in Alpharetta, Georgia. We lease our facility pursuant to a long-term lease agreement that expires in 2009 and our remaining aggregate commitment under this long-term, non-cancelable lease is approximately \$6 million. This lease may be extended at our option to 2019.

In November 2001, we leased a facility in Norcross, Georgia encompassing approximately 5,800 square feet. We lease this laboratory facility pursuant to a long-term lease agreement that expires in 2004 and our remaining aggregate commitment under this long-term, non-cancelable lease is approximately \$103,000. We have the option to renew this lease under mutually agreeable terms.

**Item 3. Legal Proceedings**

We are not currently a party to any legal proceedings.

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

None.

**PART II****Item 5. Market for Registrant's Common Equity and Related Shareholder Matters****Common Stock Information**

Our common stock is traded on the Nasdaq National Market under the symbol AGIX. The following table sets forth the range of high and low reported last sale price per share of our common stock as quoted on the Nasdaq National Market for each period indicated.

	Common Stock	
	High	Low
	_____	_____
<b>Year ended December 31, 2003</b>		
First quarter	\$ 9.84	\$ 6.41
Second quarter	15.11	8.79
Third quarter	18.65	12.12
Fourth quarter	18.43	13.15
<b>Year ended December 31, 2002</b>		
First quarter	\$ 7.71	\$ 5.51
Second quarter	8.35	6.27
Third quarter	7.47	4.71
Fourth quarter	7.41	5.65

As of March 1, 2004, there were approximately 5,600 holders of our common stock. This number includes beneficial owners of our common stock whose shares are held in the names of various dealers, clearing agencies, banks, brokers and other fiduciaries.

**Dividend Policy**

We have never declared or paid any dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance our operations and do not anticipate paying any cash dividends on our capital stock in the foreseeable future.



**Table of Contents****Item 6. Selected Financial Data**

The selected financial data set forth below should be read in conjunction with our financial statements and the related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations, included in this annual report. The historical results are not necessarily indicative of the operating results to be expected in the future.

	Year Ended December 31,				
	2003	2002	2001	2000	1999
<b>Statement of Operations Data:</b>					
Revenues:					
License fees	\$	\$	\$ 1,111,111	\$ 3,333,333	\$ 555,556
Research and development			2,398,429	4,826,370	791,653
Total revenues			3,509,540	8,159,703	1,347,209
Operating expenses:					
Research and development *	45,721,087	22,838,066	16,884,027	12,815,788	9,041,345
General and administrative *	5,504,650	4,070,189	3,979,813	3,035,559	2,593,017
Amortization of deferred stock compensation	1,365,898	1,976,872	2,652,031	7,972,728	85,480
Total operating expenses	52,591,635	28,885,127	23,515,871	23,824,075	11,719,842
Operating loss	(52,591,635)	(28,885,127)	(20,006,331)	(15,664,372)	(10,372,633)
Interest and other income	1,258,216	962,040	2,366,748	1,714,850	342,178
Interest expense	(1,954,402)	(42,420)			(402,795)
Net loss	\$(53,287,821)	\$(27,965,507)	\$(17,639,583)	\$(13,949,522)	\$(10,433,250)
Basic and diluted net loss per share	\$ (1.49)	\$ (1.00)	\$ (0.68)	\$ (1.30)	\$ (4.27)
Shares used in computing basic and diluted net loss per share	35,770,994	27,978,705	26,010,347	10,747,773	2,443,237
* Exclusive of amounts recorded as amortization of deferred stock compensation which was allocable as follows:					
Research and development	\$ 939,873	\$ 908,061	\$ 940,053	\$ 1,856,932	\$ 23,649
General and administrative	\$ 426,025	\$ 1,068,811	\$ 1,711,978	\$ 6,115,796	\$ 61,831

The following table contains a summary of our balance sheet data for the five years ended December 31, 2003.

	December 31,				
	2003	2002	2001	2000	1999
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 72,058,249	\$ 32,132,329	\$ 28,682,050	\$ 26,463,070	\$ 13,409,450
Short-term investments	59,525,679	2,538,802	29,757,945	27,518,169	
Working capital	124,848,687	30,009,013	55,056,263	52,422,951	9,651,239

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Total assets	138,836,746	37,952,044	62,255,278	57,598,951	15,717,214
Long-term obligations, less current portion	100,083,622	572,492		84,907	61,854
Deferred stock compensation	(505,708)	(1,243,786)	(2,975,314)	(5,930,880)	(1,809,680)
Accumulated deficit	(142,531,315)	(89,243,494)	(61,277,987)	(43,638,404)	(29,688,882)
Total shareholders' equity (deficit)	30,377,006	32,493,713	58,294,812	54,271,686	(29,288,600)

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

*The following discussion should be read in conjunction with our financial statements and related notes included in this annual report. In this report, AtheroGenics, we, us and our refer to AtheroGenics, Inc.*

#### **Overview**

Since our operations began in 1994, we have focused on the discovery, development and commercialization of novel drugs for the treatment of chronic inflammatory diseases, such as atherosclerosis, rheumatoid arthritis and asthma. Based on our proprietary vascular protectant, or v-protectant, technology platform, we have advanced four drug development programs into clinical trials. Our lead compound, AGI-1067, is being evaluated in the Phase III clinical trial called ARISE (Aggressive Reduction of Inflammation Stops Events) as an oral therapy for the treatment of atherosclerosis. AGIX-4207, our second clinical compound, is a novel, oral agent being tested in a Phase II clinical trial called OSCAR (Oral Suppression of Cellular Inflammation Attenuates Rheumatoid Arthritis) as a treatment for rheumatoid arthritis. AGIX-4207 I.V. is an intravenous rheumatoid arthritis treatment that has completed a Phase I clinical trial. AGI-1096 is a novel, oral agent that is being developed for the prevention of organ transplant rejection in collaboration with Fujisawa Pharmaceutical Co., Ltd. In addition to these compounds, we are progressing on a number of other preclinical programs.

To date, we have devoted substantially all of our resources to research and development. We have not derived any commercial revenues from product sales and, excluding the effect of certain license fees of a non-recurring nature, expect to incur significant losses in most years prior to deriving any such product revenue. We have funded our operations primarily through sales of equity and debt securities.

We have incurred significant losses since we began operations and, as of December 31, 2003, had an accumulated deficit of \$142.5 million. We cannot assure you whether or when we will become profitable. We expect to continue to incur significant operating losses over the next several years as we continue to incur increasing research and development costs. We expect that losses will fluctuate from quarter to quarter and that these fluctuations may be substantial. Our ability to achieve profitability depends upon our ability, alone or with others, to complete the successful development of our product candidates, to obtain required regulatory clearances, and to manufacture and market our future products.

#### **Critical Accounting Policies**

We have identified the following policies as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations are discussed throughout Management's Discussion and Analysis of Financial Condition and Results of Operations.

##### *Use of Estimates*

The preparation of the financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

##### *Research and Development Accrual*

As part of the process of preparing our financial statements, we are required to estimate expenses that we believe we have incurred, but have not yet been billed for. This process involves identifying services and activities that have been performed by third-party vendors on our behalf and estimating the level to which they have been performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of expenses for which we accrue based on estimates we make include fees for professional services, such as those provided by certain clinical research organizations and investigators in conjunction with clinical trials, and fees owed to contract manufacturers in conjunction with the manufacture of clinical trial materials. We must sometimes estimate the date on which certain services commence and/or the level of services performed on or before a given date and the cost of such services. We make these estimates based upon the facts and circumstances known to us at the time and in accordance with generally accepted accounting principles.

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*Revenue Recognition*

License fees, which are nonrefundable, are recognized when the related license agreements specify that no further efforts or obligations are required of us. We had committed to perform certain research and development activities as part of a license agreement, which has been terminated; accordingly, the upfront license payment was amortized over the anticipated time period to conduct these activities. Revenues under research and development arrangements were recognized as the research and development activities were performed pursuant to the terms of the related agreements. These revenues were billed quarterly and the related payments were not refundable.

*Stock-Based Compensation*

We have elected to follow Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ), in accounting for our stock-based employee compensation plans, rather than the alternative fair value accounting method provided for under Statement of Financial Accounting Standards ( SFAS ) No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ), as SFAS 123 requires the use of option valuation models that were not developed for use in valuing employee stock options. We account for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees, in accordance with SFAS 123 and Emerging Issues Task Force ( EITF ) Issue No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* ( SFAS 148 ), an amendment to SFAS 123, requires disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements.

In connection with the grant of certain options to employees, we have recorded non-cash deferred stock compensation of approximately \$14 million since 1999, representing the difference between the exercise price and the deemed fair value of our common stock on the dates these stock options were granted. Deferred stock compensation is included as a reduction of shareholders' equity and is being amortized to expense using the graded vesting method. The graded vesting method provides for vesting of each portion of the overall award over its respective vesting period, and results in higher vesting in earlier years than straight-line vesting.

In connection with the grant of certain options and warrants to non-employees during 2001 and 2002, we recorded non-cash deferred stock compensation of approximately \$1.3 million. The fair value of the options and warrants for purposes of this calculation was determined by using the Black-Scholes option valuation model. The fair value of the options and warrants is re-measured at each measurement date, based on the then current fair value of our common stock.

**Results of Operations**

**Comparison of Years Ended December 31, 2003 and 2002**

*Revenues*

There were no revenues during 2003 or 2002. We may receive revenues in the future related to potential licensing agreements with pharmaceutical companies for our compounds or programs.

*Expenses*

*Research and Development.* Research and development expenses, excluding amortization of deferred stock compensation, were \$45.7 million in 2003, compared to \$22.8 million in 2002. The increase of \$22.9 million, or 100%, is primarily due to increased expenditures for the AGI-1067 ARISE Phase III clinical trial and the AGIX-4207 OSCAR Phase II clinical trial, such as manufacturing activities for clinical drug supply, study monitoring and payments to clinical investigators. Also contributing to the increase are the ongoing patient related costs for the AGI-1067 CART-2 Phase IIb clinical trial.

We expect that research and development expenses will continue to increase in 2004. This increase will be primarily related to activities surrounding the AGI-1067 ARISE Phase III clinical trial.

*General and Administrative.* General and administrative expenses, excluding amortization of deferred stock compensation, were \$5.5 million in 2003, compared to \$4.1 million in 2002. The increase of \$1.4 million, or 35%, is primarily due to an increase in directors and officers insurance premiums, consulting fees and business development expenses related to partnering activities.





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*Amortization of Deferred Stock Compensation.* Amortization of deferred stock compensation was \$1.4 million in 2003, compared to \$2.0 million in 2002. The decrease in 2003 compared to 2002 is primarily due to the deferred stock compensation being amortized using the graded vesting method, which results in higher amortization in the earlier years, partially offset by re-measuring options and warrants granted to consultants based on our current, higher fair market value.

*Interest and Other Income*

Interest and other income is primarily comprised of interest income earned on our cash and short-term investments. Interest and other income was \$1.3 million in 2003, compared to \$962,040 in 2002. The increase is due to the increased amount of invested funds received from our follow-on offering in February 2003 and our convertible debt offering in August 2003.

*Interest Expense*

Interest expense was \$2.0 million in 2003 compared to \$42,420 in 2002. The increase in interest expense is primarily comprised of interest expense resulting from our \$100 million long-term convertible debt, issued in August 2003.

*Income Taxes*

As of December 31, 2003, we had net operating loss carryforwards and research and development credit carryforwards of \$129.5 million and \$4.0 million, respectively, available to offset future regular and alternative taxable income. The net operating loss carryforwards and the research and development credit carryforwards will expire between 2010 and 2024. Because of our lack of earnings history, the resulting deferred tax assets have been fully offset by a valuation allowance. The utilization of the loss and credit carryforwards to reduce future income taxes will depend on our ability to generate sufficient taxable income prior to the expiration of the net operating loss carryforwards and research and development credit carryforwards. We have completed an analysis of Internal Revenue Code Section 382 limitations on the cumulative net operating loss carryforward. The annual limitations are not expected to prevent utilization of the net operating loss carryforward due to significant increases in value indicated by the successive issuances of our stock.

**Comparison of Years Ended December 31, 2002 and 2001**

*Revenues*

There were no revenues during 2002, compared to \$3.5 million in 2001. Revenue in 2001 reflected the amortization of a \$5.0 million license fee payment and research and development revenue attributable to a license agreement that was terminated in October 2001.

*Expenses*

*Research and Development.* Research and development expenses, excluding amortization of deferred stock compensation, were \$22.8 million in 2002, compared to \$16.9 million in 2001. The increase of \$6.0 million, or 35%, was primarily due to increased expenditures for the Phase II clinical trials for AGI-1067 and AGIX-4207 for items such as patient costs and clinical drug supply. Also contributing to the increase were start-up expenditures related to organizing the ARISE Phase III clinical trial, which were primarily related to commercial formulation, manufacturing bulk drug supply and the hiring of additional employees in preparation for the planned clinical trials.

*General and Administrative.* General and administrative expenses, excluding amortization of deferred stock compensation, were \$4.1 million in 2002, compared to \$4.0 million in 2001. The increase of \$90,376, or 2%, reflects an increase in business development activities offset in part by lower expenditures for professional fees.

*Amortization of Deferred Stock Compensation.* Amortization of deferred stock compensation was \$2.0 million in 2002, of which \$908,061 was attributable to research and development expenses and \$1.1 million was attributable to general and administrative expenses. In 2001, amortization of deferred stock compensation was \$2.7 million, of which \$940,053 was attributable to research and development expenses and \$1.7 million was attributable to general and administrative expenses. The decrease in 2002 compared to 2001 was due to the deferred stock compensation being amortized using the graded vesting method, which results in higher amortization in the earlier years. The decrease was partially offset by re-measuring options and warrants granted to consultants to current fair market value, in accordance with EITF Issue No. 96-18.

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### *Interest and Other Income*

Interest income was \$962,040 in 2002, compared to \$2.4 million in 2001. The decrease in interest income was a reflection of lower investment balances and lower average interest rates.

### *Interest Expense*

Interest expense was \$42,420 in 2002 was due to the interest on the equipment loan facility.

### *Income Taxes*

As of December 31, 2002, we had net operating loss carryforwards and research and development credit carryforwards of \$76.3 million and \$2.3 million, respectively, available to offset future regular and alternative taxable income.

## **Liquidity and Capital Resources**

Since inception, we have financed our operations primarily through sales of equity securities, convertible notes and payments received from a licensing agreement. At December 31, 2003, we had cash, cash equivalents and short-term investments of \$131.6 million, compared with \$34.7 million and \$58.4 million at December 31, 2002 and 2001, respectively. Working capital at December 31, 2003 was \$124.8 million, compared to \$30.0 million and \$55.1 million at December 31, 2002 and 2001, respectively. The increase in cash, cash equivalents, short-term investments and working capital for the year ended December 31, 2003 is primarily due to funds received from our follow-on stock offering in February 2003 of approximately \$48.4 million and our convertible debt offering in August 2003 of approximately \$96.7 million. The decrease in cash, cash equivalents, short-term investments and working capital for the year ended 2002 from 2001 is due to the use of funds for operating purposes.

Net cash used in operating activities was \$48.6 million in 2003 compared to \$24.2 million in 2002 and \$12.8 million in 2001. The increase in the use of cash in operating activities is principally due to funding a net loss of \$53.3 million and an increase in prepaid expense of \$1.0 million, partially offset by an increase in the research and development accrual of \$2.0 million and accrued liabilities of \$1.6 million. The increase in cash needed to fund the net loss is primarily attributable to expenditures for our ARISE Phase III clinical trial and our CART-2 Phase IIb clinical trial for AGI-1067, and the implementation of our OSCAR Phase II clinical trial for AGIX-4207, as well as other ongoing product development activities. The increase in prepaid expense is due to pre-payments made to contractors for the ARISE clinical trial which is being expensed when service is performed. As a result of our ongoing Phase III ARISE clinical trial for AGI-1067 and the expected increase in cash usage, we anticipate that prepaid expenses and the research and development accrual may fluctuate more significantly than in previous periods. We anticipate net cash usage in 2004 for ARISE and our other on-going preclinical and clinical programs, as well as our other operating activities, to be in a range of \$63.0 million to \$67.0 million, subject to the impact of a corporate partnering arrangement for AGI-1067.

Net cash used in investing activities was \$57.5 million in 2003 compared to net cash provided by investing activities of \$26.5 million in 2002 and \$3.8 million used in investing activities in 2001. Net cash used in investing activities during 2003 consisted primarily of net purchases of available-for-sale securities. Net cash provided by investing activities during 2002 consisted primarily of the sales of available-for-sale securities, with the proceeds reinvested in interest-bearing cash equivalents. Net cash used in investing activities during 2001 consisted primarily of net purchases of available-for-sale securities, and purchases of equipment and leasehold improvements.

Net cash provided by financing activities was \$146.1 million in 2003 compared to \$1.2 million in 2002 and \$18.8 million in 2001. Net cash provided by financing activities in 2003 consisted of primarily of \$48.4 million received from our follow-on stock offering in February 2003 and \$96.7 million received from our convertible debt offering in August 2003. Net cash provided by financing activities in 2002 consisted primarily of proceeds from an equipment loan facility and exercise of common stock options. Net cash provided by financing activities in 2001 consisted primarily of \$18.8 million received from the private placement of our common stock in June 2001.

In March 2002, we entered into a revolving credit facility with Silicon Valley Bank (the Bank) for up to a maximum amount of \$5.0 million to be used for working capital requirements. The revolving credit facility was not used, and as such, we terminated it in December 2003. We also entered into an equipment loan facility, as modified in June 2003, with the Bank for up to a maximum amount of \$2.5 million to be used to finance existing and new equipment purchases. The borrowing period under the

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equipment loan facility, as modified, expired on September 30, 2003. At December 31, 2003, there was an outstanding balance of approximately \$563,000 on the equipment loan facility and the weighted average interest rate was 7.7% per year.

In February 2003, we completed a public offering of approximately 8.3 million shares of common stock (including the exercise of the underwriters' over-allotment option) that raised net proceeds of approximately \$48.4 million.

In August 2003, we issued \$100 million in aggregate principal amount of 4.5% convertible notes due 2008 through a Rule 144A private placement to qualified institutional buyers. These notes initially are convertible into our common stock at a conversion rate of 65.1890 shares per \$1,000 principal amount of notes, or approximately \$15.34 per share. Net proceeds were approximately \$96.7 million. We intend to use the net proceeds from the sale of the notes for research and development activities, including clinical trials, process development and manufacturing support, and for general corporate purposes, including working capital. Pending these uses, the net proceeds have been invested in interest-bearing, investment grade securities. As of December 31, 2003, we have recorded \$1.7 million of interest expense related to the notes, which is due March 1, 2004.

We have a contract with an organization that is currently conducting our Phase II and Phase III clinical trials for AGI-1067. We will be required to pay a percentage of the remaining balance of the contract in the unlikely event that we terminate the contract. As of December 31, 2003, the termination fee would have been approximately \$1.0 million had we elected to terminate at that time.

The following table summarizes our long-term contractual obligations as of December 31, 2003:

	Total	Payments Due by Period			Thereafter
		2004	2005-2006	2007-2008	
Contractual obligations					
Operating leases, net of sublease income	\$ 5,723,230	\$ 1,063,794	\$ 2,152,011	\$ 2,314,723	\$ 192,702
Long-term debt	100,563,061	479,439	83,622	100,000,000	
Total contractual obligations	\$ 106,286,291	\$ 1,543,233	\$ 2,235,633	\$ 102,314,723	\$ 192,702

Based upon the current status of our product development and commercialization plans, we believe that our existing cash and cash equivalents will be adequate to satisfy our capital needs for at least the next 12 months. However, our actual capital requirements will depend on many factors, including:

- the status of product development;
- the time and cost involved in conducting clinical trials and obtaining regulatory approvals;
- the costs of filing, prosecuting and enforcing patent and other intellectual property claims;
- competing technological and market developments; and
- our ability to establish new licensing agreements.

We have historically accessed the capital markets from time to time to raise adequate funds for operating needs and cash reserves. Although we believe we have adequate cash for at least the next 12 months, we may access capital markets when we believe market conditions or company needs merit doing so.

**Table of Contents****Item 7A. *Quantitative and Qualitative Disclosures about Market Risk***

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the fair value of the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the fair value of the principal amount of our investment will probably decline. To minimize this risk in the future, we intend to continue to maintain our portfolio of cash equivalents and short-term investments in a variety of securities, including commercial paper, all of which have a minimum investment rating of A1/P1, money market funds, and government and non-government debt securities. The average duration of all of our investments has generally been less than one year. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments.

The following table summarizes the maturity of the debt and projected annual average interest rates on our equipment loan facility and convertible notes as of December 31, 2003.

	2004	2005-2006	2007-2008	Total	Value as of December 31, 2003
Long-term debt-fixed rate					
Maturity	\$ 479,439	\$ 83,622	\$ 100,000,000	\$ 100,563,061	\$ 123,813,061
Average interest rate	7.7%	7.7%	4.5%		

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

**ATHEROGENICS, INC.  
INDEX TO FINANCIAL STATEMENTS**

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**REPORT OF INDEPENDENT AUDITORS**

**The Board of Directors and Shareholders  
AtheroGenics, Inc.**

We have audited the accompanying balance sheets of AtheroGenics, Inc. as of December 31, 2003 and 2002, and the related statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2003. 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 AtheroGenics, Inc. at December 31, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

Atlanta, Georgia  
February 10, 2004

**Table of Contents****ATHEROGENICS, INC.  
BALANCE SHEETS**

	December 31,	
	2003	2002
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 72,058,249	\$ 32,132,329
Short-term investments	59,525,679	2,538,802
Prepaid expenses	1,144,006	166,995
Notes receivable and other current assets	496,871	56,726
	<u>133,224,805</u>	<u>34,894,852</u>
Equipment and leasehold improvements, net of accumulated depreciation and amortization	2,520,790	2,825,267
Other assets	3,091,151	231,925
	<u>138,836,746</u>	<u>37,952,044</u>
Total assets	\$ 138,836,746	\$ 37,952,044
<b>Liabilities and Shareholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,778,187	\$ 1,959,295
Accrued research and development costs	2,961,085	945,506
Accrued liabilities	2,118,500	589,345
Accrued compensation	1,038,907	957,056
Current portion of equipment loan facility	479,439	434,637
	<u>8,376,118</u>	<u>4,885,839</u>
Total current liabilities	8,376,118	4,885,839
Convertible notes payable	100,000,000	
Equipment loan facility, net of current portion	83,622	572,492
Shareholders equity		
Preferred stock, no par value: Authorized 5,000,000 shares		
Common stock, no par value:		
Authorized 100,000,000 shares; issued and outstanding 36,763,407 and 28,133,560 shares at December 31, 2003 and 2002, respectively	172,452,536	122,182,607
Warrants	950,588	798,076
Deferred stock compensation	(505,708)	(1,243,786)
Accumulated deficit	(142,531,315)	(89,243,494)
Accumulated other comprehensive income	10,905	310
	<u>30,377,006</u>	<u>32,493,713</u>
Total shareholders equity	30,377,006	32,493,713
	<u>138,836,746</u>	<u>37,952,044</u>
Total liabilities and shareholders equity	\$ 138,836,746	\$ 37,952,044

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



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**ATHEROGENICS, INC.**  
**STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2003	2002	2001
<b>Revenues:</b>			
License fees	\$	\$	\$ 1,111,111
Research and development			2,398,429
Total revenues			3,509,540
<b>Operating expenses:</b>			
Research and development *	45,721,087	22,838,066	16,884,027
General and administrative *	5,504,650	4,070,189	3,979,813
Amortization of deferred stock compensation	1,365,898	1,976,872	2,652,031
Total operating expenses	52,591,635	28,885,127	23,515,871
Operating loss	(52,591,635)	(28,885,127)	(20,006,331)
Interest and other income	1,258,216	962,040	2,366,748
Interest expense	(1,954,402)	(42,420)	
Net loss	\$(53,287,821)	\$(27,965,507)	\$(17,639,583)
Net loss per share basic and diluted	\$ (1.49)	\$ (1.00)	\$ (0.68)
Weighted average shares outstanding basic and diluted	35,770,994	27,978,705	26,010,347
* Exclusive of amounts recorded as amortization of deferred stock compensation which was allocable as follows:			
Research and development	\$ 939,873	\$ 908,061	\$ 940,053
General and administrative	\$ 426,025	\$ 1,068,811	\$ 1,711,978

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

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**ATHEROGENICS, INC.**  
**STATEMENTS OF SHAREHOLDERS EQUITY**

	Common Stock		Warrants	Deferred	Accumulated	Accumulated	Total
	Shares	Amount		Stock Compensation		Deficit	
<b>Balance at January 1, 2001</b>	23,909,295	\$ 103,608,655	\$ 225,713	\$(5,930,880)	\$ (43,638,404)	\$ 6,602	\$ 54,271,686
Issuance of common stock for exercise of stock options at \$.30 to \$.38 per share	335,478	108,764					108,764
Issuance of common stock for services	5,000	29,778					29,778
Issuance of common stock, net of issuance cost of \$1,788,310	3,585,000	18,825,440					18,825,440
Deferred stock compensation for issuance of stock options and warrants related to a technology license agreement		546,200	546,000	(1,092,200)			
Amortization of deferred stock compensation		(1,395,735)		4,047,766			2,652,031
Net loss					(17,639,583)		(17,639,583)
Unrealized gain on available-for-sale securities						46,696	46,696
<b>Comprehensive loss</b>							(17,592,887)
<b>Balance at December 31, 2001</b>	27,834,773	121,723,102	771,713	(2,975,314)	(61,277,987)	53,298	58,294,812
Issuance of common stock for exercise of stock options at \$.30 to \$5.00 per share	262,654	240,524					240,524
Issuance of common stock for exercise of warrants	36,133	78,637	(78,637)				
Deferred stock compensation for re-measurement of stock options related to a consulting agreement		235,956		(235,956)			
Adjustments to market value for variable stock options and warrants issued to non-employees		16,229	105,000	(121,229)			
Amortization of deferred stock compensation		(111,841)		2,088,713			1,976,872
Net loss					(27,965,507)		(27,965,507)
Unrealized loss on available-for-sale securities						(52,988)	(52,988)

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Comprehensive loss							(28,018,495)
<b>Balance at December 31, 2002</b>	28,133,560	122,182,607	798,076	(1,243,786)	(89,243,494)	310	32,493,713
Issuance of common stock for exercise of stock options at \$.30 to \$8.25 per share	340,395	1,382,972					1,382,972
Issuance of common stock for exercise of warrants	9,452	150,400	(150,400)				
Issuance of common stock, net of issuance cost of \$3,264,905	8,280,000	48,411,649					48,411,649
Adjustments to market value for variable stock options and warrants issued to non-employees		324,908	302,912	(627,820)			
Amortization of deferred stock compensation				1,365,898			1,365,898
Net loss					(53,287,821)		(53,287,821)
Unrealized gain on available-for-sale securities						10,595	10,595
Comprehensive loss							(53,277,226)
<b>Balance at December 31, 2003</b>	36,763,407	\$ 172,452,536	\$ 950,588	\$ (505,708)	\$ (142,531,315)	\$ 10,905	\$ 30,377,006

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

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**ATHEROGENICS, INC.**  
**STATEMENTS OF CASH FLOWS**

	Year Ended December 31,		
	2003	2002	2001
<b>Operating activities</b>			
Net loss	\$ (53,287,821)	\$ (27,965,507)	\$ (17,639,583)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	839,503	746,949	491,973
Amortization of debt issuance costs	217,660		
Amortization of deferred stock compensation	1,365,898	1,976,872	2,652,031
Stock issued for services			29,778
Changes in operating assets and liabilities:			
Accounts receivable			1,138,244
Prepaid expenses	(977,011)	23,679	206,385
Notes receivable and other assets	(252,126)	420,446	(401,682)
Accounts payable	(181,108)	837,745	616,559
Accrued research and development	2,015,579	(361,929)	965,225
Accrued liabilities and compensation	1,611,006	102,021	286,093
Deferred revenues			(1,111,111)
Net cash used in operating activities	(48,648,420)	(24,219,724)	(12,766,088)
<b>Investing activities</b>			
(Purchases) sales of short-term investments	(56,976,282)	27,166,155	(2,193,080)
Purchases of equipment and leasehold improvements	(535,026)	(656,704)	(1,632,491)
Net cash (used in) provided by investing activities	(57,511,308)	26,509,451	(3,825,571)
<b>Financing activities</b>			
Proceeds from the convertible notes	96,735,095		
Proceeds from the issuance of common stock	48,411,649		18,825,440
Proceeds from the exercise of common stock options	1,382,972	240,524	108,764
Proceeds from equipment loan facility		1,258,473	
Payments on equipment loan facility and capital lease obligation	(444,068)	(338,445)	(123,565)
Net cash provided by financing activities	146,085,648	1,160,552	18,810,639
Increase in cash and cash equivalents	39,925,920	3,450,279	2,218,980
Cash and cash equivalents at beginning of year	32,132,329	28,682,050	26,463,070
Cash and cash equivalents at end of year	\$ 72,058,249	\$ 32,132,329	\$ 28,682,050
<b>Supplemental disclosures of cash flow information</b>			
Interest paid	\$ 61,844	\$ 50,689	\$ 21,536
Re-measurement adjustment for variable options and warrants issued for technology license agreements and consulting agreements	\$ 627,820	\$ 357,185	\$ 1,092,200

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

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**Notes to Financial Statements**

**1. Description of Business and Significant Accounting Policies**

*Description of Business*

AtheroGenics, Inc. ( AtheroGenics ) was incorporated on November 23, 1993 (date of inception) in the State of Georgia to focus on the discovery, development and commercialization of novel therapeutics for the treatment of chronic inflammatory diseases, such as heart disease (atherosclerosis), rheumatoid arthritis and asthma.

*Use of Estimates*

The preparation of the financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

*Cash and Cash Equivalents*

AtheroGenics considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. AtheroGenics cash equivalents consist primarily of money market accounts, commercial paper, government agency notes and corporate notes on deposit with several financial institutions and the carrying amounts reported in the balance sheets approximate their fair value.

*Short-Term Investments*

Short-term investments consist of certificates of deposit, commercial paper, government agency notes and corporate notes with original maturities greater than three months and with maturities less than one year.

Management determines the appropriate classification of debt securities at the time of purchase and reevaluates such designation as of each balance sheet date. These investments are accounted for in accordance with Statement of Financial Accounting Standard ( SFAS ) No. 115, *Accounting for Certain Investments in Debt and Equity Securities* ( SFAS 115 ). AtheroGenics has classified all investments as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in a separate component of shareholders equity. Realized gains and losses are included in investment income and are determined on a specific identification basis.

*Fair Value of Financial Instruments and Concentration of Credit Risk*

Financial instruments that subject AtheroGenics to concentration of credit risk consist primarily of cash, cash equivalents and short-term investments. These assets are maintained by reputable third-party financial institution custodians. The carrying values reported in the balance sheets for cash, cash equivalents and short-term investments approximate fair values.

*Equipment and Leasehold Improvements*

Equipment and leasehold improvements are stated at cost. Depreciation of computer and lab equipment is computed using the straight-line method over the estimated useful lives of three and five years, respectively. Amortization of leasehold improvements is recorded over the shorter of: (a) the estimated useful lives of the related assets; or (b) the lease term.

*Research and Development Accrual*

AtheroGenics research and development accrual is based on expenses that are believed to have been incurred, but have not yet been billed for. Examples of expenses for which AtheroGenics accrued based on its estimates include fees for professional services, such as those provided by certain clinical research organizations and investigators in conjunction with clinical trials, and fees owed to contract manufacturers in conjunction with the manufacture of clinical trial materials. AtheroGenics must sometimes estimate the date on which certain services commence and/or the level of services performed on or before a given date and the cost of such services. AtheroGenics makes these estimates based upon the facts and circumstances known at the time and in accordance with generally accepted accounting principles.

**Table of Contents***Revenue Recognition*

License fees, which are nonrefundable, are recognized when the related license agreements specify that no further efforts or obligations are required of AtheroGenics. AtheroGenics had committed to perform certain research and development activities as part of an exclusive license agreement; accordingly, the upfront license payment was amortized over the anticipated time period to conduct such activities. Revenues under research and development arrangements were recognized as the research and development activities were performed pursuant to the terms of the related agreements (see Note 2 License Agreement ). These revenues were billed quarterly and the related payments were not refundable.

*Research and Development and Patent Costs*

Research and development costs, including all related salaries, clinical trial expenses, facility costs and expenditures related to obtaining patents, are charged to expense when incurred.

*Stock-Based Compensation*

AtheroGenics has elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ), in accounting for its stock-based employee compensation plans, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ), as SFAS 123 requires the use of option valuation models that were not developed for use in valuing employee stock options. AtheroGenics accounts for transactions in which services are received in exchange for equity instruments based on the fair value of such services received from non-employees, in accordance with SFAS 123 and Emerging Issues Task Force ( EITF ) Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* ( SFAS 148 ), an amendment to SFAS 123, requires disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements.

The following table illustrates the effect on net loss and net loss per share if the fair value based method had been applied to all outstanding and unvested options in each period, based on the provisions of SFAS 123 and SFAS 148.

	2003	2002	2001
Net loss, as reported	\$(53,287,821)	\$(27,965,507)	\$(17,639,583)
Add: Stock-based employee compensation expense included in reported net loss	553,309	1,495,249	2,316,141
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(3,375,253)	(3,441,554)	(3,370,753)
Pro forma net loss	\$(56,109,765)	\$(29,911,812)	\$(18,694,195)
Net loss per share:			
Basic and diluted, as reported	\$ (1.49)	\$ (1.00)	\$ (0.68)
Basic and diluted, pro forma	\$ (1.57)	\$ (1.07)	\$ (0.72)

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The fair value for these options (which are granted with an exercise price equal to fair market value on the grant date) was estimated using the Black-Scholes option valuation model with the following assumptions:

	2003	2002	2001
Expected life	5 years	5 years	5 years
Risk free interest rate	4.27%	3.37%	4.51%
Volatility	80.18%	87.63%	99.79%

*Income Taxes*

The liability method is used in accounting for income taxes. Deferred income tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are anticipated to reverse.

*Comprehensive Income*

AtheroGenics computes comprehensive income in accordance with SFAS No. 130, *Reporting Comprehensive Income* ( SFAS 130 ). SFAS 130 establishes standards for the reporting and display of comprehensive income and its components in the financial statements. Comprehensive income, as defined, includes all changes in equity during a period from non-owner sources, such as unrealized gains and losses on available-for-sale securities. Comprehensive loss was \$53,277,226, \$28,018,495 and \$17,592,887 for the years ended December 31, 2003, 2002 and 2001, respectively.

*Recently Issued Accounting Standards*

In January 2003, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 46 ( FIN 46 ), *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51*. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 was effective immediately for variable interest entities obtained after January 31, 2003, and otherwise is effective for the first reporting period ending after March 15, 2004. AtheroGenics does not expect the adoption of FIN 46 to have a material impact upon its financial statements.

In May 2003, the FASB approved SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity* ( SFAS 150 ). SFAS 150 establishes standards for how to classify and measure financial instruments with characteristics of both liabilities and equity. It requires that financial instruments that fall within its scope be classified as liabilities. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003 and for pre-existing financial instruments as of July 1, 2003. AtheroGenics does not have any financial instruments that fall under the guidance of SFAS 150 and, therefore, the adoption of SFAS 150 did not have an impact on AtheroGenics financial statements.

**2. License Agreement**

In October 1999, AtheroGenics entered into an exclusive license agreement (the Agreement ), consisting of contracts with each of Schering Corporation and Schering-Plough Ltd. (collectively, Schering-Plough ). Under the Agreement, AtheroGenics granted to Schering-Plough rights to develop and commercialize AGI-1067 and specified compounds.

In November 1999, under the terms of the Agreement, AtheroGenics received a \$5,000,000 nonrefundable license fee for the exclusive worldwide license to patent rights and licensor know-how held by AtheroGenics. AtheroGenics amortized the fee over 18 months, which represents the period AtheroGenics conducted development activities pursuant to the Agreement. Schering-Plough also paid AtheroGenics \$2,398,429 for research and development activities performed during 2001 related to AGI-1067.

In October 2001, AtheroGenics reacquired all rights to AGI-1067 and related technology and terminated the license agreement.

**Table of Contents****3. Net Loss Per Share**

SFAS No. 128, *Earnings per Share*, requires presentation of both basic and diluted earnings per share. Basic earnings per share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per share is computed in the same manner as basic earnings per share except that diluted earnings per share reflects the potential dilution that would occur if outstanding options, warrants and convertible notes payable were exercised.

During all periods presented, AtheroGenics had securities outstanding which could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per share, as their effect would have been antidilutive. These outstanding securities consist of the following at the dates indicated:

	Year Ended December 31,		
	2003	2002	2001
Shares underlying convertible notes	6,518,904		
Options	4,403,179	3,895,420	3,360,660
Warrants	267,622	283,622	350,290
Total	<u>11,189,705</u>	<u>4,179,042</u>	<u>3,710,950</u>
Conversion price of shares underlying convertible notes	\$ 15.34	\$	\$
Weighted average exercise price of options	\$ 6.27	\$ 4.06	\$ 2.99
Weighted average exercise price of warrants	\$ 4.32	\$ 4.41	\$ 4.14

Because AtheroGenics reported a net loss for all periods presented, shares associated with the convertible notes, stock options and warrants are not included because they are antidilutive. Basic and diluted net loss per share amounts are the same for the periods presented.

**4. Common Stock**

On June 19, 2001, AtheroGenics completed a private placement of 3,585,000 shares of common stock that raised net proceeds of approximately \$18,800,000.

On November 9, 2001, AtheroGenics Board of Directors adopted a Shareholder Rights Plan declaring a dividend distribution of one common stock purchase right on each outstanding share of its common stock. Until the rights become exercisable, the rights will trade automatically with the common stock of AtheroGenics and separate rights certificates will not be issued. Under the rights plan, each right consists of an initial right and subsequent rights. Initial rights will be exercisable only if a person or group acquires 15% or more of AtheroGenics common stock, whether through open market or private purchases or consummation of a tender or exchange offer. Any shareholders who owned, as of November 9, 2001, in excess of 17% of AtheroGenics common stock will be permitted to acquire up to an aggregate of 20% of AtheroGenics outstanding common stock without triggering the rights plan. If, following the exercise of initial rights, a person or group again acquires 15% or more of AtheroGenics common stock, or a person or group who had previously acquired 15% or more of AtheroGenics common stock acquires an additional 10% or more of the common stock, the subsequent rights become exercisable. Each right will initially entitle shareholders to buy eight shares of common stock at an exercise price equal to 20% of the then current market value of the common stock, calculated and adjusted according to the terms of the rights plan. The number of shares that can be purchased upon exercise will increase as the number of shares held by the bidder increases.

If AtheroGenics is acquired in a merger or other business combination, each right will entitle its holder to purchase, at the right's then-current exercise price, a number of the acquiring company's shares equal in value to those obtainable if the rights were exercisable in AtheroGenics stock.



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The rights are intended to enable all shareholders to realize the long-term value of their investment in AtheroGenics. They will not prevent a takeover, but should encourage anyone seeking to acquire AtheroGenics to negotiate with the Board prior to attempting a takeover. The Board of Directors may redeem any non-exercisable rights at any time at its option at a redemption price of \$.0001 per right. The rights plan expires at the close of business on November 8, 2011.

On February 3, 2003, AtheroGenics completed a public offering of 8,280,000 shares of common stock (including the exercise of the underwriters' over-allotment option) that raised net proceeds of approximately \$48,400,000.

**Table of Contents****5. Stock Options and Warrants**

During 1995, AtheroGenics established a stock option plan (the 1995 Plan ) which, as amended, provides that options to purchase AtheroGenics common stock may be granted to employees, directors, consultants or contractors with exercise prices not less than 75% of the fair values of the shares on the dates of grant.

The 1995 Plan, as amended, authorizes the grant of options for up to 1,264,084 shares of AtheroGenics common stock, and as of December 31, 2003, AtheroGenics had reserved 267,800 shares of common stock for future issuance under the 1995 Plan. Options granted under the 1995 Plan vest over periods ranging from the date of grant to five years from that date.

During 1997, AtheroGenics established an equity ownership plan (the 1997 Plan ) whereby options to purchase AtheroGenics common stock may be granted to employees, directors, consultants or contractors with exercise prices not less than the fair value of the shares on the dates of grant. The 1997 Plan, as amended, authorizes the grant of options for up to 3,724,416 shares of AtheroGenics common stock. As of December 31, 2003, AtheroGenics had reserved 2,282,147 shares of common stock for issuance under the 1997 Plan. The 1997 Plan allows for grants of non-qualified options, incentive stock options and shares of restricted stock. Non-qualified options granted under the 1997 Plan may vest immediately for non-employees, but vest over a four-year period for employees. Incentive stock options generally vest over four years. The majority of the stock options granted under the 1997 Plan are incentive stock options.

During 2001, AtheroGenics established an equity ownership plan (the 2001 Plan ) whereby options to purchase AtheroGenics common stock may be granted to employees, directors, consultants or contractors with exercise prices not less than the fair value of the shares on the dates of grant. The 2001 Plan authorizes the grant of options for up to 2,000,000 shares of AtheroGenics common stock. As of December 31, 2003, AtheroGenics had reserved 1,946,779 shares of common stock for issuance under the 2001 Plan. The terms of the 2001 Plan are substantially similar to the terms of the 1997 Plan.

A summary of stock option activity under the 1995 Plan, the 1997 Plan and the 2001 Plan follows:

	<u>Number of Shares</u>	<u>Price Range</u>	<u>Weighted Average Price</u>
Outstanding at January 1, 2001	2,858,175	\$ .10-9.88	\$ 1.49
Granted	1,071,450	4.37 - 6.85	6.02
Exercised	(340,478)	.30 - 6.56	.41
Canceled	(228,487)	.30 - 8.25	2.31
	<hr/>		
Outstanding at December 31, 2001	3,360,660	.10 - 9.88	2.99
Granted	1,048,380	6.10 - 7.85	7.18
Exercised	(262,654)	.30 - 5.30	.92
Canceled	(250,966)	.31 - 9.88	5.97
	<hr/>		
Outstanding at December 31, 2002	3,895,420	.10 - 9.88	4.06
Granted	986,983	7.55 - 16.65	14.40
Exercised	(340,395)	.30 - 8.25	4.06
Canceled	(138,829)	.31 - 14.51	7.68
	<hr/>		
Outstanding at December 31, 2003	4,403,179	.10 - 16.65	6.27
	<hr/>		

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The following table summarizes information concerning currently outstanding and exercisable options granted under the 1995 Plan, the 1997 Plan and the 2001 Plan as of December 31, 2003.

Options Outstanding				Options Exercisable		
Exercise Price	Number Outstanding	Weighted Average Remaining Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$ .10- .38	1,426,400	5.05	\$ .31	1,426,400	\$ .31	
4.37- 6.85	1,084,024	7.65	5.89	651,165	5.87	
7.00- 8.63	953,322	8.53	7.50	342,620	7.68	
9.10-14.93	922,933	9.90	14.45	11,196	9.40	
16.52-16.65	16,500	9.80	16.56			
	<u>4,403,179</u>	7.48	6.27	<u>2,431,381</u>	2.88	

In 1999 and 2000, in connection with the grant of certain options to employees, AtheroGenics recorded non-cash deferred stock compensation of \$13,989,088, representing the difference between the exercise price and the deemed fair value of AtheroGenics' common stock on the dates these stock options were granted. Deferred stock compensation is included as a reduction of shareholders' equity and is being amortized to expense using the graded vesting method. The graded vesting method provides for vesting of each portion of the overall award over its respective vesting period, and results in higher vesting in earlier years than straight-line vesting. During 2003, 2002 and 2001, AtheroGenics recorded amortization of deferred stock compensation for these options of \$553,309, \$1,495,249 and \$2,316,141, respectively.

In June 2001, in connection with the grant of certain warrants as part of a licensing agreement with National Jewish Medical and Research Center and options granted for the addition of new members to the Scientific Advisory Board, AtheroGenics recorded non-cash deferred stock compensation of \$1,092,200. In August 2002, in connection with the modification of certain options held by an employee who changed his status to become a consultant, AtheroGenics recorded non-cash deferred stock compensation of \$235,956. The fair value of the warrants and options for purposes of these calculations was determined by using the Black-Scholes model. These amounts are included as a reduction of shareholders' equity and are being amortized over the vesting periods of the individual warrants and options, five years, using the graded vesting method, for National Jewish and one year, using the straight-line method, for the consultant. During 2003 and 2002, an additional \$627,820 and \$121,229, respectively, of non-cash deferred stock compensation was recorded due to re-measurement of the fair value of the options at each measurement date. During 2003, 2002 and 2001, AtheroGenics recorded a total of \$812,589, \$481,623 and \$335,890, respectively, of amortization of deferred stock compensation for these warrants and options. At December 31, 2003, 84,000 shares of common stock were reserved for issuance upon the exercise of these outstanding warrants.

At December 31, 2003, AtheroGenics had a total of \$505,708 remaining to be amortized over the vesting periods of all of the option grants discussed above. This amortization will approximate \$305,000 in 2004, \$154,000 in 2005 and \$47,000 in 2006. During 2002 and 2001, 13,200 shares and 165,500 shares, respectively, were forfeited and deferred stock compensation was decreased by \$111,841 and \$1,395,735, respectively.

In August 1998, AtheroGenics issued 205,002 warrants in connection with a bridge loan agreement. These warrants became exercisable on January 1, 1999 for \$3.00 per share and expire on August 19, 2008. In February 1999, in connection with an amendment to the bridge loan agreement, AtheroGenics issued an additional 200,001 warrants that became exercisable on April 13, 1999 for \$3.00 per share and expire on December 31, 2008. At December 31, 2003, AtheroGenics had 183,622 shares of common stock reserved for issuance upon the exercise of these warrants.

**Table of Contents****6. Short-Term Investments**

Short-term investments consist of debt securities classified as available-for-sale and have maturities greater than 90 days and less than 12 months from the date of acquisition. AtheroGenics has invested primarily in corporate notes and commercial paper, all of which have a minimum investment rating of A1/P1, and government agency notes. AtheroGenics had no realized gains or losses from the sale of investments for the period ended December 31, 2003. The unrealized gains were \$10,905 and \$310 for 2003 and 2002, respectively. The following table summarizes the estimated fair value of AtheroGenics' short-term investments:

	December 31,	
	2003	2002
Government agency notes	\$36,415,792	\$1,000,000
Corporate notes	20,874,579	
Commercial paper	2,194,575	1,500,309
Certificate of deposit	40,733	38,493
	<hr/>	<hr/>
Total	\$59,525,679	\$2,538,802
	<hr/>	<hr/>

All available-for-sale securities held at December 31, 2003, will mature during 2004.

**7. Equipment and Leasehold Improvements**

Equipment and leasehold improvements consists of the following:

	December 31,	
	2003	2002
Laboratory equipment	\$ 2,664,192	\$ 2,564,534
Leasehold improvements	1,563,084	1,492,540
Computer and office equipment	1,474,599	1,109,776
	<hr/>	<hr/>
	5,701,875	5,166,850
Accumulated depreciation and amortization	(3,181,085)	(2,341,583)
	<hr/>	<hr/>
	\$ 2,520,790	\$ 2,825,267
	<hr/>	<hr/>

**8. Convertible Notes Payable**

In August 2003, AtheroGenics issued \$100 million in aggregate principal amount of 4.5% convertible notes due September 1, 2008 with interest payable semi-annually in March and September. Net proceeds to AtheroGenics were approximately \$96.7 million, after deducting expenses and underwriter's discounts and commissions. AtheroGenics recorded issuance costs related to the notes of approximately \$3.3 million. These costs are recorded as other assets and are being amortized to interest expense over the five-year life of the notes.

The notes may be converted at the option of the holder into shares of AtheroGenics' common stock, prior to the close of business on September 1, 2008 at a conversion rate of 65.1890 shares per \$1,000 principal amount of notes, representing a conversion price of approximately \$15.34, subject to adjustment. Under certain circumstances, AtheroGenics may be obligated to redeem all or part of the notes prior to their maturity at a redemption price equal to 100% of their principal amount, plus accrued and unpaid interest and liquidated damages, if any, up to but excluding the maturity date.

AtheroGenics filed a shelf registration statement with the Securities and Exchange Commission that was declared effective on December 22, 2003 covering the resale of the notes and the common stock issuable upon conversion of the notes. AtheroGenics has agreed to use its

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reasonable best efforts keep the shelf registration statement effective until the earlier of: (1) the date that all of the registrable securities have been sold pursuant to the shelf registration statement or pursuant to Rule 144 under the Securities Act or any similar provision then in force; or (2) the expiration of the holding period with respect to the registrable securities under Rule 144(k) under the Securities Act of 1933, or any successor provision.

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As of December 31, 2003, AtheroGenics had reserved 6,518,900 shares of common stock for future issuance in connection with the convertible notes. In addition, as of December 31, 2003, accrued liabilities included approximately \$1,700,000 of accrued interest related to the convertible notes, which is due March 1, 2004.

**9. Bank Credit Agreements**

In March 2002, AtheroGenics entered into a revolving credit facility with Silicon Valley Bank for up to a maximum amount of \$5,000,000 to be used for working capital requirements. In December 2003, AtheroGenics canceled the line of credit, which was unused during the entire period.

In addition, in March 2002, AtheroGenics entered into an equipment loan facility with Silicon Valley Bank for up to a maximum amount of \$2,500,000 to be used to finance existing and new equipment purchases. Amounts borrowed under the equipment loan facility are repaid in 33 equal installments of principal and interest beginning on the first business day of the month following an advance. As of December 31, 2003, there was an outstanding balance of \$563,061 under the equipment loan facility and the weighted average interest rate was 7.7% per year. The borrowing period for the equipment loan facility expired in September 2003.

In connection with the revolving credit facility and the equipment loan facility, AtheroGenics has granted to Silicon Valley Bank a negative pledge on its intellectual property and on deposits with Silicon Valley Bank and its affiliates. In December 2003, AtheroGenics and Silicon Valley Bank terminated all security interests other than this negative pledge in connection with the equipment loan facility.

Maturities of long-term debt as of December 31, 2003 are as follows:

2004	\$ 479,439
2005	83,622
Thereafter	100,000,000
	\$ 100,563,061

**10. Income Taxes**

At December 31, 2003, AtheroGenics had net operating loss carryforwards and research and development credit carryforwards of \$129,470,491 and \$4,010,990, respectively, for income tax purposes, which both begin to expire in 2010. The significant components of the deferred tax assets are:

	December 31,	
	2003	2002
Net operating loss carryforwards	\$ 49,198,787	\$ 29,000,100
Deferred stock compensation	4,374,216	3,899,329
Research credits	4,010,990	2,311,134
Other	240,266	241,093
	57,824,259	35,451,656
Total deferred tax assets	57,824,259	35,451,656
Valuation allowance	(57,824,259)	(35,451,656)
	\$	\$
Net deferred tax assets	\$	\$

Because of AtheroGenics' lack of earnings history, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased \$22,372,603 and \$11,215,692 in 2003 and 2002, respectively.

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AtheroGenics' net operating loss carryforwards may be subject to certain Internal Revenue Code ( IRC ) Section 382 limitations on annual utilization in the event of changes in ownership. These limitations could significantly reduce the amount of the net operating loss carryforwards available in the future. AtheroGenics has completed an analysis of IRC Section 382 on the cumulative net operating loss carryforward. The annual limitations are not expected to prevent utilization of the net operating loss carryforward due to the significant increases in value indicated by the successive issues of our stock.

**Table of Contents****11. Leases**

On June 19, 1998, AtheroGenics entered into a 10-year operating lease for office and laboratory space through March 1, 2009. Monthly lease payments of approximately \$89,400 began March 2, 1999, the date occupancy commenced. These payments are subject to increases during each successive 12-month period based on changes in the Consumer Price Index (CPI). Future increases in monthly lease payments due to increases in the CPI are considered to be contingent rentals, and, therefore, will be charged to expense over the lease term as they become payable. AtheroGenics may extend the lease term for two successive five-year periods. AtheroGenics' other operating lease obligations are not significant.

At December 31, 2003, AtheroGenics' minimum aggregate commitments (net of sublease income) under long-term, non-cancelable operating leases are as follows:

	Gross	Sublease Income	Net
2004	\$ 1,280,975	\$ 217,181	\$ 1,063,794
2005	1,171,927	183,174	988,753
2006	1,163,258		1,163,258
2007	1,158,516		1,158,516
2008	1,156,207		1,156,207
Thereafter	192,702		192,702
	<u>\$ 6,123,585</u>	<u>\$ 400,355</u>	<u>\$ 5,723,230</u>

Rent expense under operating leases amounted to \$946,314, \$925,040 and \$835,608 in 2003, 2002 and 2001, respectively.

**12. Related Party Transactions**

On April 15, 2002, AtheroGenics made a secured loan in the amount of \$123,116 to one of its executive officers, who is also a shareholder. The loan had an interest rate of 2.88% per annum, the applicable federal rate at the time of the loan, and was due on April 15, 2005. The loan was secured by 22,500 shares of AtheroGenics' common stock. As of December 31, 2003, the loan has been repaid in full, including accrued interest.

AtheroGenics has a sublease agreement for a portion of its office and laboratory space with Inhibitex, Inc. The monthly lease payments are approximately \$16,000. The lease term ends on December 31, 2005. The President and Chief Executive Officer of AtheroGenics and the Chairman of AtheroGenics' Board of Directors are both members of the Inhibitex, Inc. Board of Directors.

AtheroGenics has a sublease agreement for a portion of its office space with ATV Management Corp. Monthly lease payments are approximately \$3,500. The lease term ends on July 31, 2005. The Chairman of the Board of Directors of AtheroGenics is the President and sole shareholder of ATV Management Corp.

**13. Employee Benefit Plan**

AtheroGenics has a defined contribution plan covering eligible employees, which is qualified under Section 401(k) of the Internal Revenue Code. Under the provisions of the plan, eligible participating employees may elect to contribute up to the maximum amount of tax deferred contribution allowed by the Internal Revenue Code. AtheroGenics may make a discretionary contribution. During 2003, AtheroGenics matched 50% of employees' contributions, up to a maximum of 6% of the employees' annual base compensation. AtheroGenics' contribution to the plan for 2003, 2002 and 2001 aggregated \$161,576, \$129,503 and \$91,852, respectively. AtheroGenics' stock is not an eligible investment under this plan.



**Table of Contents****14. Quarterly Results of Operations (Unaudited)**

The following is a summary of the unaudited quarterly results of operations:

	Year Ended December 31, 2003			
	1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter
Net revenues	\$	\$	\$	\$
Operating loss	(11,672,363)	(12,542,414)	(13,461,425)	(14,915,433)
Net loss	(11,494,701)	(12,335,978)	(13,636,617)	(15,820,525)
Net loss per share data:				
Basic and diluted	(0.35)	(0.34)	(0.37)	(0.43)

	Year Ended December 31, 2002			
	1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter
Net revenues	\$	\$	\$	\$
Operating loss	(6,868,283)	(6,841,754)	(7,132,780)	(8,042,310)
Net loss	(6,563,715)	(6,572,494)	(6,926,723)	(7,902,575)
Net loss per share data:				
Basic and diluted	(0.24)	(0.24)	(0.25)	(0.28)

Because of the method used in calculating per share data, the quarterly per share data will not necessarily add to the per share data as computed for the year.

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

None.

**Item 9A. Controls and Procedures**

*Evaluation of disclosure controls and procedures.* Our chief executive officer and chief financial officer are responsible for establishing and maintaining disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) and 15d-15(e)) for AtheroGenics. Our chief executive officer and chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures as of the end of the period covered by this quarterly report, have concluded that our disclosure controls and procedures are adequate and effective in timely alerting them to material information relating to us required to be included in our periodic SEC filings.

*Changes in internal control over financial reporting.* There were no material changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART III**

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

We have set forth information relating to the directors and executive officers and compliance with Section 16(a) of the Securities Exchange Act of 1934 (the Exchange Act ) under the captions, Nominees, Executive Officers and Directors, Board Meetings and Committees and Section 16(a) Beneficial Ownership Compliance, respectively, in our proxy statement for our 2004 annual meeting of shareholders to be held on April 28, 2004. We are incorporating this information by reference in this Form 10-K. Our definitive proxy statement will be filed with the Securities and Exchange Commission on March 29, 2004.

**Code of Ethics**

We have adopted a code of business conduct and ethics for directors, officers and employees, including our principal executive officer and principal financial officer, known as the AtheroGenics, Inc. Code of Business Conduct and Ethics. Shareholders may request a free copy from:

AtheroGenics, Inc.  
Attention: Investor Relations  
8995 Westside Parkway  
Alpharetta, Georgia 30004  
(678) 336-2500  
<http://www.investor@atherogenics.com>

**Item 11. *Executive Compensation***

We have set forth information relating to executive compensation under the captions Director Compensation, Executive Compensation, Employment Agreements and Compensation Committee Interlocks and Insider Participation in the proxy statement referred to in Item 10 above. We are incorporating this information by reference in this Form 10-K.

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

We have set forth information relating to ownership of our common stock by certain persons and to our equity compensation plans under the caption Security Ownership of Certain Beneficial Owners and Management and Equity Compensation Plan Information, respectively, in the proxy statement referred to in Item 10 above. We are incorporating this information by reference in this Form 10-K.

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

We have set forth information relating to existing or proposed relationships or transactions between us and certain of our affiliates under the caption Certain Relationships and Related Transactions in the proxy statement referred to in Item 10 above. We are incorporating this information by reference in this Form 10-K.

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

We have set forth information relating to our principal accountant fees and services under the caption Principal Accountant Fees and Services in the proxy statement referred to in Item 10 above. We are incorporating this information by reference in this Form 10-K.

**Table of Contents****PART IV****Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K**

- (a) (1) Financial Statements, filed as part of this report

Report of Independent Auditors

Balance Sheets as of December 31, 2003 and 2002

Statements of Operations for the years ended December 31, 2003, 2002 and 2001

Statements Shareholders' Equity for the years ended December 31, 2003, 2002 and 2001

Statements of Cash Flows for the years ended December 31, 2003, 2002 and 2001

Notes to Financial Statements

- (2) Financial Statement Schedules

No financial statement schedules are provided, because the information called for is not required or is shown either in the financial statements or the notes thereto.

- (3) Listing of Exhibits The response to this portion of Item 15 is submitted below as Item 15(c) of this report.

- (b) Reports on Form 8-K filed in the fourth quarter of 2003:

On October 23, 2003, we furnished a Current Report on Form 8-K under Item 12, reporting the issuance of our press release announcing our financial results for the third quarter ended September 30, 2003.

- (c) Exhibits

Exhibit No.	Description
3.01**	Form of Fourth Amended and Restated Articles of Incorporation of AtheroGenics, Inc.
3.02**	Form of Third Amended and Restated Bylaws of AtheroGenics, Inc., as amended.
4.01**	Form of Common Stock Certificate.
4.02**	Amended and Restated Master Rights Agreement dated October 31, 1995, as amended by First Amendment dated November 1, 1995; Second Amendment dated July 30, 1996; Third Amendment dated April 13, 1999; Fourth Amendment dated May 11, 1999; and Fifth Amendment dated August 30, 1999.
4.03**	Applicable provisions of Fourth Amended and Restated Articles of Incorporation and Third Amended and Restated Bylaws of AtheroGenics, Inc. (incorporated by reference to Exhibits 3.01 and 3.02).
4.04	Rights Agreement dated as of November 9, 2001 between AtheroGenics, Inc. and American Stock Transfer & Trust Company, as Rights Agent (filed as an exhibit of the same number with AtheroGenics' Form 8-K on October 9, 2001 and incorporated herein by reference).
10.02**+	Exclusive License Agreement dated July 17, 1998 between The Regents of the University of California and AtheroGenics, Inc.
10.03**+	License Agreement dated January 11, 1995 between Emory University and AtheroGenics, Inc.
10.04**+	Patent Purchase Agreement dated April 26, 1995 between AtheroGenics, Inc. and Sampath Parthasarathy, together with Services Agreement dated April 26, 1995 between AtheroGenics, Inc. and Sampath Parthasarathy.

10.05\*\*+

Sponsored Research Agreement dated October 14, 1996 between Emory University and AtheroGenics, Inc.

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Exhibit No.	Description
10.07**#	AtheroGenics, Inc. 1995 Stock Option Plan, together with form of nonqualified stock option agreement.
10.08**#	AtheroGenics, Inc. 1997 Equity Ownership Plan, as amended by Amendment No. 1 and Amendment No. 2.
10.09**	Preferred Shares Purchase Warrant dated August 24, 1998 between AtheroGenics, Inc. and certain Lenders named therein.
10.10**	Series C Convertible Preferred Stock Purchase Warrants of AtheroGenics, Inc.
10.11**	Promissory Note dated April 1, 1999 between Inhibitex, Inc. and AtheroGenics, Inc.
10.12**++	Lease Agreement dated June 19, 1998 between Cousins Properties, Inc. and AtheroGenics, Inc.
10.14#	Employment Agreement dated March 1, 2001 between AtheroGenics, Inc. and Russell M. Medford (filed as an exhibit of the same number with AtheroGenics Annual Report on Form 10-K for the year ended December 31, 2000, and incorporated herein by reference).
10.15	Amendment dated January 1, 2001 to Promissory Note dated April 1, 1999 between Inhibitex, Inc. and AtheroGenics, Inc. (filed as an exhibit of the same number with AtheroGenics Annual Report on Form 10-K for the year ended December 31, 2000, and incorporated herein by reference).
10.16	Form of Common Stock Purchase Agreement dated as of June 19, 2001 between AtheroGenics, Inc. and the Purchasers named therein (filed as an exhibit of the same number with AtheroGenics Registration Statement on Form S-1, Registration No. 333-64228, on July 23, 2001 and incorporated herein by reference).
10.17+	Exclusive License Agreement dated as of June 29, 2001 between AtheroGenics, Inc. and National Jewish Medical and Research Center (filed as an exhibit with the same number with Amendment No. 1 to AtheroGenics Registration Statement on Form S-1, Registration No. 333-64228, on June 29, 2001 and incorporated herein by reference).
10.18	AtheroGenics, Inc. 2001 Equity Ownership Plan (filed as Appendix B to the proxy statement for AtheroGenics 2001 Annual Shareholders Meeting as filed on March 22, 2001 and incorporated herein by reference).
10.20(a)	Revolving Promissory Note dated March 6, 2002 between AtheroGenics, Inc. and Silicon Valley Bank (filed as an exhibit of the same number to AtheroGenics Quarterly Report on Form 10-Q for the quarter ended March 31, 2002 and incorporated herein by reference).
10.20(b)	Equipment Term Note dated March 6, 2002 between AtheroGenics, Inc. and Silicon Valley Bank (filed as an exhibit of the same number to AtheroGenics Quarterly Report on Form 10-Q for the quarter ended March 31, 2002 and incorporated herein by reference).
10.20(c)	Loan and Security Agreement dated March 6, 2002 between AtheroGenics, Inc. and Silicon Valley Bank (filed as an exhibit of the same number to AtheroGenics Quarterly Report on Form 10-Q for the quarter ended March 31, 2002 and incorporated herein by reference).
10.20(d)	Negative Pledge Agreement dated March 6, 2002 between AtheroGenics, Inc. and Silicon Valley Bank (filed as an exhibit of the same number to AtheroGenics Quarterly Report on Form 10-Q for the quarter ended March 31, 2002 and incorporated herein by reference).
10.21#	Promissory Note and Stock Pledge Agreement dated as of April 15, 2002 between AtheroGenics, Inc. and Mark P. Colonnese (filed as Exhibit 10.21 to AtheroGenics Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 and incorporated herein by reference).
10.22#	Separation and Consulting Agreement and General Release dated as of October 3, 2002 between AtheroGenics, Inc. and Mitchell Glass, M.D. (filed as Exhibit 10.22 to AtheroGenics Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 and incorporated herein by reference).

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- 10.23 First Loan Modification dated June 20, 2003 between AtheroGenics, Inc. and Silicon Valley Bank. (filed as an exhibit of the same number to AtheroGenics Quarterly Report on Form 10-Q for the quarter ended June 30, 2003 and incorporated herein by reference).
- 10.24 Purchase Agreement dated August 19, 2003 between AtheroGenics, Inc. and the Initial Purchasers named therein (filed as an exhibit of the same number to AtheroGenics Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 and incorporated herein by reference).

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<u>Exhibit No.</u>	<u>Description</u>
10.25*	Second Loan Modification dated August 13, 2003 between AtheroGenics, Inc. and Silicon Valley Bank.
10.26*	Third Loan Modification dated December 29, 2003 between AtheroGenics, Inc. and Silicon Valley Bank.
10.27*	Negative Pledge Agreement dated December 29, 2003 between AtheroGenics, Inc. and Silicon Valley Bank.
23.01*	Consent of Ernst & Young LLP.
24.01*	Powers of Attorney.
31.1*	Certifications of Chief Executive Officer under Rule 13a-14(a).
31.2*	Certifications of Chief Financial Officer under Rule 13a-14(a).
32*	Certifications of Chief Executive Officer and Chief Financial Officer under Section 1350.
*	Filed herewith.
**	Filed as the exhibit of the same number with AtheroGenics registration statement on Form S-1, Registration No. 333-31140, declared effective by the SEC on August 8, 2000, and incorporated herein by reference.
+	Certain confidential information contained in this document has been omitted and filed separately with the Commission pursuant to a request for confidential treatment under Rule 406 of the Securities Act of 1933, as amended.
++	We agree to furnish supplementally to the Commission a copy of any omitted schedule or exhibit to this agreement upon request by the Commission.
#	Management contract or compensatory plan or arrangement.

**Table of Contents****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, on March 15, 2004.

ATHEROGENICS, INC.

By: /s/RUSSELL M. MEDFORD, M.D., PH.D.

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**Russell M. Medford, M.D., Ph.D.**  
*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.

Name	Title	Date
<b>Principal Executive Officer:</b>		
/s/RUSSELL M. MEDFORD	President and Chief Executive Officer, Director	March 15, 2004
<b>Russell M. Medford</b>		
<b>Principal Financial and Principal Accounting Officer:</b>		
/s/MARK P. COLONNESE	Senior Vice President of Finance and Administration and Chief Financial Officer	March 15, 2004
<b>Mark P. Colonnese</b>		
<b>Additional Directors:</b>		
*	Director	March 15, 2004
<b>Michael A. Henos</b>		
*	Director	March 15, 2004
<b>R. Wayne Alexander</b>		
*	Director	March 15, 2004
<b>David Bearman</b>		
*	Director	March 15, 2004
<b>Vaughn D. Bryson</b>		
*	Director	March 15, 2004
<b>T. Forcht Dagi</b>		
*	Director	March 15, 2004



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**Arthur M. Pappas**

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Director

March 15, 2004

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**William A. Scott**

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Director

March 15, 2004

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**Stephen G. Sudovar**

\*By: /s/MARK P. COLONNESE

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**Mark P. Colonnese**  
**Attorney-in-fact**