

ATHEROGENICS INC  
Form 10-K/A  
May 06, 2005

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**Form 10-K/A  
(Amendment No. 2)**

**(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, 2004**

**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**

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

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

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

The aggregate market value of shares of voting stock held by nonaffiliates of the registrant, computed by reference to the closing price of \$19.03 as reported on the Nasdaq National Market as of the last business day of AtheroGenics most recently completed second fiscal quarter (June 30, 2004), was approximately \$422,239,543. AtheroGenics has no nonvoting common equity.

The number of shares outstanding of the registrant's common stock, as of March 8, 2005: 37,668,445.

**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 2005 Annual Meeting of Shareholders are incorporated herein by reference in Part III.**

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AtheroGenics, Inc. is filing this Amendment No. 2 to its Annual Report on Form 10-K for the fiscal year ended December 31, 2004 to supplement the disclosure under Part II Item 7. Management's Discussion and Analysis of Financial Conditions and Results of Operations, as well as to correct certain typographical errors. This Amendment No. 2 includes the full text of our Annual Report on Form 10-K, including the information in Amendment No. 1 to the Annual Report on Form 10-K, filed on April 6, 2005. In addition, Item 15 includes the certifications required pursuant to Rules 13a-14(a)/15d-14(a) and 13a-14(b)/15d-14(b) of the Securities and Exchange Act of 1934, as amended (the Exchange Act), which have been re-executed and re-filed as of the date of this Amendment as Exhibits 31.5, 31.6 and 32.1, respectively.

With the exception of the foregoing, no other information in the Annual Report on Form 10-K for the fiscal year ended December 31, 2004 has been supplemented, updated or amended.

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**FORM 10-K**
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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 coronary heart disease, organ transplant rejection, rheumatoid arthritis and asthma. We have developed a proprietary vascular protectant, or v-protectant<sup>®</sup>, technology platform to discover drugs to treat these types of diseases. Based on our v-protectant<sup>®</sup> platform, we have two drug development programs in clinical trials and are pursuing a number of other preclinical programs.

AGI-1067 is our v-protectant<sup>®</sup> candidate that is most advanced in clinical development. AGI-1067 is designed to benefit patients with coronary heart disease, or CHD, which is atherosclerosis of the blood vessels of the heart. Atherosclerosis is a common disease that results from inflammation and the buildup of plaque in arterial blood vessel walls. Nearly 13 million people in the United States currently have diagnosed CHD. There are no medications available for physicians to treat directly the underlying chronic inflammation associated with CHD. 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 CHD, including those without traditional risk factors.

In November 2004, we completed a Phase IIb clinical trial called CART-2, a 465-patient study that examined the effect of 12 months of AGI-1067 therapy on atherosclerosis and post-angioplasty restenosis. Two leading cardiac intravascular ultrasound laboratories independently analyzed the final data from CART-2. The primary endpoint of the trial was a change in coronary atherosclerosis, measured as total plaque volume after a 12-month treatment period compared to baseline values. Combined results of the final analysis from the two laboratories, which were based on an evaluation of intravascular ultrasounds from approximately 230 patients in the study, indicate that AGI-1067 reduced plaque volume by an average of 2.3%, which was statistically significant. Results from the patient group receiving both placebo and standard of care indicated a plaque volume measure that was not statistically different from baseline. While the plaque regression observed in the AGI-1067 group exceeded that observed in the standard of care group numerically, the difference did not reach statistical significance, although a trend towards significance was seen in one laboratory's analysis. An important secondary endpoint from the trial, change in plaque volume in the most severely diseased subsegment, showed statistically significant regression from baseline by an average of 4.8%. The results also demonstrated a significant reduction in myeloperoxidase, an inflammatory biomarker that correlates with future cardiovascular events. Overall adverse event rates were similar in the AGI-1067 and standard of care groups, and AGI-1067 was generally well tolerated.

Based on the results of an End of Phase II meeting with the U.S. Food and Drug Administration, or FDA, we proceeded to develop a pivotal Phase III clinical trial protocol to evaluate AGI-1067 for the treatment of atherosclerosis. The Phase III protocol received a Special Protocol Assessment from the FDA in March 2003. 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.

In 2003, we initiated the 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 CHD. 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.

We originally planned to enroll in ARISE 4,000 patients who would be followed for an average of 18 months or until a minimum of 1,160 primary events, or outcome measures, had occurred. In February 2005, we announced that the FDA approved our proposed amendment to the ARISE Phase III clinical trial protocol. The changes to the ARISE protocol are intended to enhance the trial as well as to accelerate its pace without affecting the Special Protocol Assessment with the FDA. The changes approved by the FDA include our plan to increase the number of patients in the study to a target of 6,000, eliminate the minimum 12 month follow-up period for patients and decrease the minimum number of primary events to 990. With these modifications, we would expect to complete enrollment by mid-2005 and complete the ARISE trial by the end of the first quarter of 2006. We then plan to file a New Drug Application with the FDA as soon as possible after we complete the trial and analyze the results.

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We previously were developing AGIX-4207, a v-protectant<sup>®</sup> candidate for the treatment of rheumatoid arthritis. Based on our findings, however, we have discontinued clinical development of AGIX-4207 and the intravenous dosage form of AGIX-4207 for rheumatoid arthritis. We continue to have an active program aimed at investigating other v-protectants<sup>®</sup> in rheumatoid arthritis and have identified other compounds with enhanced therapeutic potential within our rheumatoid arthritis preclinical models. We are working to select another candidate to move into formal preclinical development.

We have also identified additional potential v-protectant<sup>®</sup> candidates to treat other chronic inflammatory diseases, including asthma. We are evaluating these v-protectants<sup>®</sup> to determine lead drug candidates for clinical development. We plan to develop these compounds rapidly and may seek regulatory fast track status, if available, to expedite development and commercialization. We will continue to expand upon our v-protectant<sup>®</sup> 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 continuing to enroll patients in the ARISE Phase III clinical trial for the treatment of atherosclerosis in patients with coronary heart disease.

*Extend our v-protectant<sup>®</sup> technology platform into additional therapeutic areas that address unmet medical needs.* We believe that our v-protectants<sup>®</sup> have the potential for treating a wide variety of other chronic inflammatory diseases. These indications include chronic organ transplant rejection, rheumatoid arthritis, asthma and other diseases. We completed a Phase I clinical trial with positive results for AGI-1096, a v-protectant<sup>®</sup> 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, such as AGI-1067 for atherosclerosis. 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.

## **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:

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atherosclerosis, including coronary heart disease;

organ transplant rejection;

rheumatoid arthritis; 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.

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.

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.

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

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serious side effects, and include drugs that were originally designed to treat cancer, such as methotrexate. Modern treatments with 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.

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.

**Products**

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
AGI-1096		Phase I clinical trial

	Transplant rejection	
AGI Series	Chronic asthma	Pre-IND
AGI Series	Rheumatoid arthritis	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.

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*AGI-1067*

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, or CHD, which is atherosclerosis of the blood vessels of the heart. Atherosclerosis is a common disease that results from inflammation and the buildup of plaque in arterial blood vessel walls. Nearly 13 million people in the United States currently have diagnosed CHD. There are no medications available for physicians to treat directly the underlying chronic inflammation associated with CHD. 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 CHD, including those without traditional risk factors.

We completed a 305-patient Phase II clinical trial of AGI-1067 called CART-1 (Canadian Antioxidant Restenosis Trial) in May 2001. Results from the trial showed that the study met its primary endpoint, which was improvement in the size of the luminal area, or coronary artery opening, as measured by intravascular ultrasound six months after angioplasty, with statistical significance. 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. In the trial, AGI-1067 was well tolerated, with no increase in serious adverse events versus placebo. In January 2004, we performed an analysis of CART-1 data that provided additional information on the impact of AGI-1067 on plaque burden, a measure of disease in coronary vessels. In the treatment groups in CART-1 receiving the two highest doses of AGI-1067, plaque burden decreased by 1.6% and 1.9%, a therapeutic effect that we believe is consistent with reversing coronary artery disease.

In November 2004, we completed a Phase IIb clinical trial called CART-2, a 465-patient study that examined the effect of 12 months of AGI-1067 therapy on atherosclerosis and post-angioplasty restenosis. Two leading cardiac intravascular ultrasound laboratories independently analyzed the final data from CART-2. The primary endpoint of the trial was a change in coronary atherosclerosis, measured as total plaque volume after a 12-month treatment period compared to baseline values. Combined results of the final analysis from the two laboratories, which were based on an evaluation of intravascular ultrasounds from approximately 230 patients in the study, indicate that AGI-1067 reduced plaque volume by an average of 2.3%, which was statistically significant. Results from the patient group receiving both placebo and standard of care indicated a plaque volume measure that was not statistically different from baseline. While the plaque regression observed in the AGI-1067 group exceeded that observed in the standard of care group numerically, the difference did not reach statistical significance, although a trend towards significance was seen in one laboratory's analysis. An important secondary endpoint from the trial, change in plaque volume in the most severely diseased subsegment, showed statistically significant regression from baseline by an average of 4.8%. The results also demonstrated a significant reduction in myeloperoxidase, an inflammatory biomarker that correlates with future cardiovascular events. Overall adverse event rates were similar in the AGI-1067 and standard of care groups, and AGI-1067 was generally well tolerated.

Based on the results of an End of Phase II meeting with the U.S. Food and Drug Administration, or FDA, we proceeded to develop a pivotal Phase III clinical trial protocol to evaluate AGI-1067 for the treatment of atherosclerosis. The Phase III protocol received a Special Protocol Assessment from the FDA in March 2003. 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.

In 2003, we initiated the 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 CHD. 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.

We originally planned to enroll in ARISE 4,000 patients who would be followed for an average of 18 months or until a minimum of 1,160 primary events, or outcome measures, had occurred. In February 2005, we announced that the FDA approved our proposed amendment to the ARISE Phase III clinical trial protocol. The changes to the ARISE protocol are intended to enhance the trial as well as to accelerate its pace without affecting the Special Protocol Assessment with the FDA. The changes approved by the FDA include our plan to increase the number of patients in the study to a target of 6,000, eliminate the minimum 12 month follow-up period for patients and decrease the minimum number of primary events to 990. With these modifications, we would expect to complete enrollment by mid-2005 and complete the ARISE trial by the end of the first quarter of 2006. We then plan to file a New Drug Application with the FDA as soon as possible after we complete the trial and analyze the results.

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*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.

Our second v-protectant<sup>®</sup> 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. 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 preclinical models of organ transplant rejection. In January 2004, we announced a collaboration with Fujisawa Pharmaceutical Co., Ltd. to conduct preclinical and early-stage clinical 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.

*Other V-Protectant<sup>®</sup> Candidates*

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.

We previously were developing AGIX-4207, a v-protectant<sup>®</sup> candidate for the treatment of rheumatoid arthritis. 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 were randomized into four groups and treated with one of three doses of AGI-4207 or placebo, administered orally, once a day, for 12 weeks. In October 2004, we announced the results of the OSCAR clinical trial, which evaluated the impact of various doses of AGIX-4207 versus placebo on clinical efficacy, biomarkers and safety in patients with rheumatoid arthritis. The results indicated that none of the three dosing arms of AGIX-4207 showed a statistically significant improvement in ACR 20 scores, a standard measurement of response utilized to evaluate improvement, when compared to placebo, the primary efficacy end point of the trial. Two of the pre-specified secondary endpoints, tender joint count and morning stiffness, did show statistically significant improvement when compared to placebo. Based on the aggregate findings of the study, however, we have discontinued clinical development of AGIX-4207 and the intravenous dosage form of



AGIX-4207. We continue to have an active program aimed at investigating other v-protectants<sup>®</sup> in rheumatoid arthritis and have identified other compounds with enhanced therapeutic potential within our rheumatoid arthritis preclinical models. We are working to select another candidate to move into formal preclinical development.

We have also identified additional potential v-protectant<sup>®</sup> candidates to treat other chronic inflammatory diseases, including asthma. 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. We believe that v-protectants<sup>®</sup> may reduce the inflammation associated with chronic asthma.

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We are evaluating these v-protectants<sup>®</sup> to determine lead drug candidates for clinical development. We plan to develop these v-protectants<sup>®</sup> rapidly and may seek regulatory fast track status, if available, to expedite development and commercialization. We will continue to expand upon our v-protectant<sup>®</sup> technology platform using functional genomics to identify novel therapeutic gene targets.

## **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<sup>®</sup> 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<sup>®</sup>. We believe that these v-protectants<sup>®</sup> 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<sup>®</sup>.

*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<sup>®</sup> 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<sup>®</sup>. 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 have expanded our research program 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<sup>®</sup> Technology*

We have license agreements with Emory University and The Regents of the University of California covering aspects of our v-protectant<sup>®</sup> 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

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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.

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<sup>®</sup> 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.

*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.

*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.

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### *Other V-Protectant<sup>®</sup> 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<sup>®</sup>, 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<sup>®</sup>.

### *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 made 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.

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### *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 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.

### **Manufacturing**

We have entered into arrangements with third party manufacturers for the supply of AGI-1067 bulk drug substance and for the formulated drug product for use in our ongoing and currently planned clinical trials. The suppliers of the bulk drug substance for AGI-1067 operate 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 USP, a material that is available from a number of suppliers worldwide. We have sufficient quantities to support development activities for the foreseeable future. Another third party supplier formulates AGI-1067 into the drug product under current Good Manufacturing Practice guidelines. We anticipate that these suppliers 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<sup>®</sup> product candidates to support both ongoing and planned clinical trials as well as commercial marketing of the products following regulatory approval.

### **Sales and Marketing**

We plan to collaborate with large pharmaceutical companies to commercialize product candidates that 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, but not limited to, Pfizer Inc., GlaxoSmithKline, 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.

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.

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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 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;

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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.

In addition, our research and development processes and manufacturing activities involve the controlled use of hazardous materials, chemicals and radioactive materials and produce waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposing of hazardous materials and waste products.

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 faster based on the ability to request an accelerated approval of the New Drug Application (NDA). For accelerated approval the clinical effectiveness is based on a surrogate endpoint in a smaller number of patients. In addition, the drug company may request priority review at the time of the NDA submission. If the FDA accepts the NDA submission as a priority review, the time for review is reduced from one year to six months. We plan to request fast track designation and/or priority review, as appropriate, for internal drug development programs.

## **Research and Development**

Our research and development expenses in 2004, 2003 and 2002 were \$59.2 million, \$46.7 million and \$23.7 million, respectively. We plan to increase significantly our research and development expenses as we continue to invest in our clinical programs.

## **Employees**

We currently have 106 full-time employees, including 85 in research and development. The employee group includes 29 employees with Ph.D.s, six with M.D.s and 23 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, which should not be considered part of this document.



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**Scientific Advisory Board**

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

R. Wayne Alexander, M.D., Ph.D., <i>Chairman</i>	Chairman, Department of Medicine, Emory University School of Medicine
William W. Busse, M.D.	Professor of Medicine, Director, Allergy and Clinical Immunology Department, University of Wisconsin Medical School
Victor J. Dzau, M.D.	Chancellor, Health Affairs, Duke University Medical Center
Erwin W. Gelfand, M.D.	Chairman, Department of Pediatrics, National Jewish Medical and Research Center
David G. Harrison, M.D.	Professor of Medicine, Director, Division of Cardiology, Emory University School of Medicine
Gary L. Johnson, Ph.D.	Professor and Chairman, Department of Pharmacology, University of North Carolina School of Medicine
Peter Libby, M.D.	Mallinckrodt Professor of Medicine, Harvard Medical School, Chief, Cardiovascular Division Department of Medicine, Brigham and Women's Hospital
David M. Stern, M.D.	Dean, School of Medicine, Chief Clinical Officer, Cardiovascular Division Department of Medicine, Brigham and Women's Hospital

**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 oral 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:*

**Risks Related to Our Financial Results and Need for Additional Financing**

*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 had no significant revenue to date. We have experienced operating losses since we began operations in 1994. As of December 31, 2004, we had an accumulated deficit of approximately \$212.1 million. We expect to incur additional operating losses and expect cumulative losses to increase substantially as

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our research and development, preclinical, clinical, manufacturing and marketing efforts expand. If we are unable to achieve and then maintain profitability, the market value of our common stock and our outstanding notes will decline.

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

We expect our research and development expenses to increase in connection with our ongoing activities, particularly in connection with the ARISE trial that we initiated in June 2003. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to enable us to fund our operating expenses, obligations under our financing arrangements and capital expenditure requirements for at least the next 12 months. Our future capital requirements will depend on many factors, including:

the scope and results of our research, preclinical and clinical development activities;

the timing of, and the costs involved in, obtaining regulatory approvals;

our ability to establish and maintain collaborations and the financial terms of any collaborations;

the cost of commercialization activities, including product marketing, sales and distribution;

the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs;

the costs related to purported class action lawsuits filed against us, as described under Item 3. Legal Proceedings ; and

the extent to which we acquire or invest in businesses, products and technologies.

If our future capital requirements exceed our available funds, we will need to seek additional financing. We may be unable to raise capital when needed or on attractive terms. 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 some of our products or potential markets.

## **Risks Related to Development of Product Candidates**

*We depend heavily on the success of our most advanced internal product candidate, AGI-1067 for atherosclerosis, which is in clinical development. If we are unable to commercialize this product candidate, or experience significant delays in doing so, our business will be materially harmed.*

AGI-1067 is our lead compound. Our ability to generate product revenues will depend heavily on the successful development and commercialization of this compound. The commercial success of AGI-1067 will depend on several factors, including the following:

successful completion of clinical trials;

receipt of marketing approvals from the FDA and similar foreign regulatory authorities;

establishing commercial manufacturing arrangements with third party manufacturers;

launching commercial sales of the product, either alone or in collaboration with others; and



acceptance of the product in the medical community and with third party payors.

AGI-1067 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. While the plaque regression observed in the group treated with AGI-1067 in the CART-2 trial exceeded that observed in the standard of care group numerically, the difference was not statistically significant. Moreover, the results of our Phase II clinical trials of AGI-1067 are not necessarily indicative of the results we will obtain in our Phase III clinical trial of AGI-1067, particularly because

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the primary clinical endpoints of these trials are not the same. Failure in clinical trials of AGI-1067 would have a material adverse effect on our ability to generate revenue or become profitable. If we are not successful in commercializing AGI-1067, or are significantly delayed in doing so, our business will be materially harmed.

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

Other than AGI-1067, all of our other product candidates are in early stages of development, and only one other product candidate has undergone Phase I clinical trials. Our product candidates are 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, including AGI-1067, to be commercially available until at least 2007. Our drug discovery efforts may not produce any other proprietary product candidates. Our failure to develop product candidates will limit our ability to generate additional revenue.

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

Product candidates we develop, alone or with others, may not prove safe and effective in clinical trials and may not 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 commercialize 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. Failure can occur at any stage. For example, we recently discontinued clinical development of AGI-4207 in rheumatoid arthritis following announcement of unsuccessful results of a Phase II clinical trial of that product candidate.

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. 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.

In addition, even if we receive approval for commercial sale of any of our product candidates, after 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.

## **Risks Related to Our Dependence on Third Parties for Manufacturing, Research and Development and Marketing and Distribution Activities**

*We may not be successful in establishing collaborations for AGI-1067 and any other product candidate we may seek to commercialize, which could adversely affect our ability to discover, develop and commercialize products.*

A key element of our business strategy is to collaborate with third parties, particularly leading pharmaceutical companies, to develop and commercialize some of our product candidates, including AGI-1067. We are currently seeking a collaborator for development and commercialization of AGI-1067. We also expect to seek collaborations for the development and commercialization of other product candidates in the future. The timing and terms of any collaboration for AGI-1067 will depend on the evaluation by prospective collaborators of the clinical trial results of AGI-1067 and other aspects of the drug's safety and efficacy profile. We are currently reviewing the results of our CART-2 trial of AGI-1067 with potential collaborators and cannot now predict the timing and terms of such a collaboration. If we are unable to reach agreements with suitable collaborators for AGI-1067 or any other product

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candidate, we would be forced to fund the entire development and commercialization of such product candidates, and we may not have the resources to do so. If resource constraints require us to enter into a collaboration early in the development of a product candidate, we may be forced to accept a more limited share of any revenues such products may eventually generate. We face significant competition in seeking appropriate collaborators. Moreover, these collaboration arrangements are complex and time-consuming to negotiate and document. We may not be successful in our efforts to establish collaborations or other alternative arrangements for AGI-1067 or any other product candidate.

***We expect to depend significantly on collaborations with third parties to develop and commercialize some of our product candidates. If a potential collaborator were to change its strategy or the focus of its development and commercialization efforts with respect to our relationship, the success of our product candidates and our operations could be adversely affected.***

Our collaboration with Fujisawa Pharmaceutical to develop AGI-1096 in preclinical testing and early-stage clinical trials and any other collaboration that we may establish may not be successful. The success of any collaboration arrangement will depend heavily on the efforts and activities of our collaborators. Collaborators will likely have significant discretion in determining the efforts and resources that they will apply to these collaborations. The risks that we anticipate being subject to in collaborations include:

a collaborator may develop and commercialize, either alone or with others, products and services that are similar to or competitive with the products that are the subject of the collaboration with us;

a collaborator may change the focus of its development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities from time to time, including following mergers and consolidations, which have been common in recent years in these industries;

the ability of our product candidates and products to reach their potential could be limited if our collaborators decrease or fail to increase spending relating to such products;

a collaborator may terminate a collaboration in the event of a material breach by us; and

a collaborator may fail to maintain or defend our intellectual property rights.

The termination of any collaboration that we may establish might adversely affect the development of the related product candidates and our ability to derive revenue from them. Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party or by us. For example, in 2001, Schering-Plough and we terminated a collaboration that we had established for AGI-1067, and our existing collaboration with Fujisawa Pharmaceutical for the development of AGI-1096 is scheduled to expire in March 2005. Any future terminations or expirations would adversely affect us financially and could harm our business reputation. In such event, we might be required to devote additional resources to the product or product candidate, seek a new collaborator or abandon the product or product candidate, any of which could have an adverse effect on our business.

***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 various risks that could delay our clinical trials or hinder our commercialization prospects. These risks include the following:

*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. Our present or future manufacturers may not be able to comply with the FDA's current Good Manufacturing Practices regulations and other FDA regulatory requirements or similar regulatory requirements outside the United States. 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 being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product

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candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and products.

*A failure to synthesize and manufacture our product candidates in accordance with our product specifications.* We need to maintain a very low maximal amount of one of the starting materials used in the manufacture of AGI-1067. The starting material, probucol, was prescribed by physicians as a cholesterol-lowering agent until its manufacturer withdrew the drug from the market for efficacy reasons. A failure by our third party manufacturers to maintain an acceptable level of probucol in the manufacture of AGI-1067 may result in chronic dosing of probucol, which is associated with the occurrence of a rare side effect.

*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 to supply these materials in a timely manner, could jeopardize the initiation or completion of clinical trials or could have a material adverse effect on our ability to commercialize any approved products and thereby generate revenue.

*Inability to control costs.* We may be subject 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.

*Termination or nonrenewal of an agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient to us.* Our product candidates and any products that we successfully develop may compete with product candidates and products of others for access to the third party's manufacturing facilities.

## **Risks Related to Our Intellectual Property**

***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 success will depend in large part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technologies and products. The patents and patent applications in our patent portfolio are either owned by us or licensed to us. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends substantially on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to obtain and enforce patents is uncertain and involves complex legal and factual questions for which important legal principles are unresolved.

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 obtain patents, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against our competitors or their competitive products or processes. It is possible that no patents will be issued from any pending or future patent applications owned by us or licensed to us. Others may challenge, seek to invalidate, infringe or circumvent any patents we own or license. Alternatively, we may in the future be required to initiate litigation against third parties to enforce our intellectual property rights. The cost of this litigation could be substantial and it is possible that our efforts could be unsuccessful. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Our patents also may not afford us protection against competitors with similar technology. We may not have identified all patents, published applications or published literature that affect our business either by blocking our

ability to commercialize our product candidates, by preventing the patentability of our drugs to us or our licensors or by covering the same or similar technologies that may affect our ability to market our product candidates. For example, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the United States Patent and Trademark Office for the entire time prior to issuance as a United States patent. Patent applications filed in countries outside the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we or our licensors might not have been the first to invent, or the first to file, patent applications on our drug candidates or for their use. The laws of some foreign jurisdictions do not

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protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

***If we infringe or are alleged to infringe intellectual property rights of third parties, it will adversely affect our business.***

Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or patent applications under which we do not hold licenses or other rights. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the United States Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

***If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.***

Our commercial success will also depend on our ability to develop, manufacture, use, sell and offer to sell our product candidates and proposed product candidates without breaching our agreements with our patent licensors. We are a party to a number of license agreements, including exclusive licenses to technologies from Emory University, covering aspects of our v-protectant® technology, and the National Jewish Medical and Research Center, covering aspects of our MEKK technology platform. We expect to enter into additional licenses in the future. 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 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. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payments, royalty,



insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

***If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.***

In addition to patented technology, we rely on 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

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know-how through independent discovery or otherwise. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

### **Risks Related to Regulatory Approval of Our Product Candidates**

***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 and AGI-1096, until the appropriate regulatory authorities have reviewed and approved the applications for the product candidates. The regulatory agencies may not complete their review processes in a timely manner and we may not obtain regulatory approval for any product candidate we or our collaborators develop. Satisfaction of regulatory requirements typically takes many years, if approval is obtained at all, 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. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

***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. We recently announced approval by the FDA to modify the protocol for our ARISE trial, in part to mitigate any delay in completing the trial. 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 rely heavily on independent clinical investigators, contract research organizations and other third party service providers for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates.

***Failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our products abroad.***

We intend to have our products marketed outside the United States. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We expect that a collaborator may have responsibility to obtain

regulatory approvals outside the United States with respect to some of our product candidates, and we will depend on such collaborators to obtain these approvals. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We and any future collaborators may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

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***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.

**Risks Related to Commercialization**

***The commercial success of any products that we may develop will depend on the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.***

Any products that we bring to the market may not gain market acceptance by physicians, patients, healthcare payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects;
- the efficacy and potential advantages over alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support; and
- sufficient third party coverage or reimbursement.

***If our competitors develop and market 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.***

The development and commercialization of new drugs is highly competitive. Our competitors include large pharmaceutical and more established biotechnology companies. Moreover, there are approved products on the market for many of the diseases for which we are developing drugs. In many cases, these products have well known brand names, are distributed by large pharmaceutical companies and have achieved widespread acceptance among physicians and patients. Our 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. These third parties also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for our programs or advantageous to our business.

***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 product candidates.***

We currently have no sales, marketing or distribution capabilities. 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

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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.

***If we are unable to obtain adequate reimbursement from third party payors for any products that we may develop or acceptable prices for those products, our revenues and prospects for profitability will suffer.***

Most patients will rely on Medicare and Medicaid, private health insurers and other third party payors to pay for their medical needs, including any drugs we or any collaborators may market. If third party payors do not provide adequate coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability will suffer. In December 2003, the Congress enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug and Modernization Act of 2003. While the program established by this statute may increase demand for our products, if we participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than we might otherwise obtain. Non-Medicare third party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries.

A primary trend in the United States healthcare industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization of our products.

Third party payors are challenging the prices charged for medical products and services, and many third party payors limit reimbursement for newly-approved healthcare products. In particular, third party payors may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could decrease the price we might establish for products that we may develop, which would result in lower product revenues to us.

***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. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for any product candidates or products that we may develop;

injury to our reputation;

withdrawal of clinical trial participants;

costs to defend the related litigation;

substantial monetary awards to trial participants or patients;

loss of revenue; and

the inability to commercialize any products that we may develop.

We may not be able to acquire or maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us.

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**Risks Related to Our Operations**

*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 approximately 100 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. We have entered into employment agreements with each of our executive officers. These employment agreements are terminable by the employee on short notice. Loss of the services of any of these officers or of our key scientific personnel could adversely affect progress of our research and development programs. All of our other employees are at will employees. We do not carry key person insurance on any employee.

*The outcome of informal inquiries by the SEC and NASD regarding our announcement of interim results from the CART-2 clinical trial for AGI-1067 and related trading in our common stock is uncertain.*

We have been contacted by the staff of the Securities and Exchange Commission and the NASD regarding informal inquiries they are conducting related to our September 27, 2004 announcement of interim results from the CART-2 clinical trial for AGI-1067 and trading in our common stock surrounding that announcement. The SEC staff's notice states that its inquiry should not be construed as an expression of opinion on the part of the SEC or its staff that any violations of law have occurred. The SEC and NASD staff have requested that we voluntarily provide them with documents and other information relating to that announcement. We are cooperating fully with these requests. Based on our review of the facts as to the September 27, 2004 announcement and trading in our common stock surrounding that announcement, we do not believe that we or any of our officers or directors have violated any laws related to these inquiries. However, we cannot predict the outcome of these inquiries, whether the SEC or NASD will undertake any formal investigation or proceeding relating to us or our officers or directors or when these matters might be resolved.

**Risks Related to our Common Stock and Indebtedness**

*Our stock price has been and may continue to be volatile.*

The market price of our common stock, and the market prices for securities of pharmaceutical and biotechnology companies in general, have been highly volatile and may continue to be highly volatile in the future. During the period from January 1, 2004 to March 8, 2005, the closing sale price of our common stock on the NASDAQ National Market ranged from a low of \$13.50 per share to a high of \$38.00 per share. The following factors, in addition to other risk factors described herein, may have a significant impact on the market price of our common stock:

results of clinical trials of our product candidates, particularly AGI-1067, and those of our competitors;

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

developments concerning any research and development, manufacturing, and marketing collaborations, including whether and when we achieve milestones;

announcements of technological innovations or new commercial products by our competitors or us;



developments concerning proprietary rights, including patents;

the addition or termination of research programs or funding support;

publicity regarding actual or potential results relating to medicinal products under development by our competitors or us;

manufacturing and commercialization costs for any product that receives approval for commercial sale;

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regulatory developments in the United States and other countries;

litigation;

economic and other external factors, including disasters or crises; and

period-to-period fluctuations in financial results.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. Purported securities class action lawsuits were filed against us and some of our executive officers and directors in the United States District Court for the Southern District of New York on January 5, 2005 and February 8, 2005 and in the United States District Court for the Northern District of Georgia, Atlanta division on January 7, 2005, January 10, 2005, January 11, 2005 and January 25, 2005. The allegations in these lawsuits relate to our disclosures regarding the results of the CART-2 clinical trial for AGI-1067. The results of complex legal proceedings, such as those purported class actions, are difficult to predict. Each complaint seeks unspecified damages and, therefore, we are unable to estimate the possible range of damages that we might incur should any of these lawsuits be resolved against us. An unfavorable outcome or settlement of these lawsuits could harm our financial position. In addition, similar class action lawsuits may be filed against us and our executive officers and directors in the future. Litigation can be costly, time consuming and disruptive to normal business operations. The defense of these lawsuits could also result in diversion of our management's time and attention away from business operations, which could harm our business.

***We have incurred significant additional indebtedness as a result of the sale of our 1.5% convertible notes due 2012 on January 12, 2005 and we may incur additional indebtedness in the future. Our existing indebtedness and any future indebtedness we incur exposes us to risks that could adversely affect our business, operating results and financial condition.***

As of December 31, 2004, we had \$100.0 million of total indebtedness outstanding. We incurred \$200 million of additional indebtedness when we sold our 1.5% convertible notes due 2012 on January 12, 2005. We may also incur additional long-term indebtedness or obtain additional working capital lines of credit to meet future financing needs. Our indebtedness could have significant negative consequences for our business, operating results and financial condition, including:

increasing our vulnerability to adverse economic and industry conditions;

limiting our ability to obtain additional financing;

requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, thereby reducing the amount of our cash flow available for other purposes;

limiting our flexibility in planning for, or reacting to, changes in our business; and

placing us at a possible competitive disadvantage with less leveraged competitors and competitors that may have better access to capital resources.

If we do not achieve a significant increase in revenues, we could have difficulty making required payments on our outstanding convertible notes, our other existing indebtedness and any indebtedness that we may incur in the future. During each of the last five years, we had no earnings to cover our fixed charges. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments, or if we fail to comply with the various requirements of our convertible notes, our other existing indebtedness or any indebtedness which we may incur in the future, we would be in default, which would permit the holders of the notes and such other indebtedness to

accelerate the maturity of the notes and such other indebtedness and could cause defaults under the notes and such other indebtedness. Any default under our convertible notes, our other existing indebtedness or any indebtedness which we may incur in the future could have a material adverse effect on our business, operating results and financial condition.

***Conversion of our 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 the 1.5% convertible notes due 2012 or the 4.5% convertible notes due 2008 will dilute the ownership interests of existing shareholders. Any sales in the public market of the common stock issuable upon such conversion could

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adversely affect prevailing market prices of our common stock. In addition, the existence of the notes may encourage short selling by market participants because the conversion of the notes could depress the price of our common stock.

*Our shareholder rights plan and anti-takeover provisions in our charter documents may make an acquisition of us, which may benefit our shareholders, more difficult.*

Our shareholder rights plan and provisions of our articles of incorporation and bylaws could make it more difficult for a third party to acquire us. These documents include provisions that:

allow our shareholders the right to acquire common stock from us at discounted prices in the event a person acquires 15% or more of our common stock or announces an attempt to do so without our board of directors' prior consent;

authorize the issuance of blank check preferred stock by our board of directors without shareholder approval, which would increase the number of outstanding shares and could thwart a takeover attempt;

limit who may call a special meeting of shareholders;

require shareholder action without a meeting by unanimous written consent;

establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at shareholder meetings;

establish a staggered board of directors whose members can only be dismissed for cause;

adopt the fair price requirements and rules regarding business combinations with interested shareholders set forth in Article 11, Parts 2 and 3 of the Georgia Business Corporation Code; and

require approval by the holders of at least 75% of the outstanding common stock to amend any of the foregoing provisions.

### **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 \$4.9 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, as amended, expires in 2007, and our remaining aggregate commitment under this long-term, non-cancelable lease is approximately \$374,000. We have the option to renew this lease under mutually agreeable terms.

### **Item 3. *Legal Proceedings***

Purported securities class action lawsuits were filed against us and some of our executive officers and directors in the United States District Court for the Southern District of New York on January 5, 2005 and February 8, 2005 and in the United States District Court for the Northern District of Georgia, Atlanta division on January 7, 2005, January 10, 2005, January 11, 2005 and January 25, 2005. Separate motions to consolidate these lawsuits were filed by plaintiffs

in both the Southern District of New York and the Northern District of Georgia on March 7, 2005. In addition, two plaintiffs simultaneously moved for appointment as lead plaintiffs in both districts on March 7, 2005. The allegations in these lawsuits relate to our disclosures regarding the results of the CART-2 clinical trial for AGI-1067. The results of complex legal proceedings, such as those purported class actions, are difficult to predict. Each complaint seeks unspecified damages and, therefore, we are unable to estimate the possible range of damages that we might incur should any of these lawsuits be resolved against us.

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

None.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities****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.

	<b>Common Stock</b>	
	<b>High</b>	<b>Low</b>
<b>Year ended December 31, 2004</b>		
First quarter	\$ 23.00	\$ 14.60
Second quarter	25.91	18.41
Third quarter	38.00	13.50
Fourth quarter	36.73	23.24
<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

As of March 1, 2005, there were approximately 6,500 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.

	<b>Year Ended December 31,</b>				
	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>
<b>Statement of Operations Data:</b>					
Revenues:					
License fees	\$	\$	\$	\$ 1,111,111	\$ 3,333,333
Research and development				2,398,429	4,826,370
Total revenues				3,509,540	8,159,703
Operating expenses:					
Research and development	59,235,833	46,660,960	23,746,127	17,824,080	14,672,720
General and administrative	6,607,506	5,930,675	5,139,000	5,691,791	9,151,355
Total operating expenses	65,843,339	52,591,635	28,885,127	23,515,871	23,824,075
Operating loss	(65,843,339)	(52,591,635)	(28,885,127)	(20,006,331)	(15,664,372)
Interest and other income	1,447,001	1,258,216	962,040	2,366,748	1,714,850
Interest expense	(5,192,894)	(1,954,402)	(42,420)		
Net loss	\$ (69,589,232)	\$ (53,287,821)	\$ (27,965,507)	\$ (17,639,583)	\$ (13,949,522)
Basic and diluted net loss per share	\$ (1.88)	\$ (1.49)	\$ (1.00)	\$ (0.68)	\$ (1.30)
Shares used in computing basic and diluted net loss per share	37,070,235	35,770,994	27,978,705	26,010,347	10,747,773

The following table contains a summary of our balance sheet data as of December 31:

	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$ 66,924,015	\$ 131,583,928	\$ 34,671,131	\$ 58,439,995	\$ 53,981,239
Working capital	59,719,811	124,848,687	30,009,013	55,056,263	52,422,951
Total assets	74,462,327	138,836,746	37,952,044	62,255,278	57,598,951
Long-term obligations	100,000,000	100,083,622	572,492		84,907
Accumulated deficit	(212,120,547)	(142,531,315)	(89,243,494)	(61,277,987)	(43,638,404)
Total shareholders (deficit) equity	(35,942,382)	30,377,006	32,493,713	58,294,812	54,271,686





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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.*

*This annual report contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to certain factors, risks and uncertainties that may cause actual results, events and performances to differ materially from those referred to in such statements. These risks include statements which address operating performance, events or developments that we expect or anticipate will occur in the future, such as projections about our future results of operations or financial condition, research, development and commercialization of our product candidates, anticipated trends in our business, and other risks that could cause actual results to differ materially. You should carefully consider these risks, which are discussed in this annual report, including, without limitation, in this section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations, and in AtheroGenics' Securities and Exchange Commission filings.*

#### **Overview**

AtheroGenics is a research-based pharmaceutical company focused on the discovery, development and commercialization of novel drugs for the treatment of chronic inflammatory diseases, including coronary heart disease, organ transplant rejection, rheumatoid arthritis and asthma. We have developed a proprietary vascular protectant, or v-protectant<sup>®</sup>, technology platform to discover drugs to treat these types of diseases. Based on our v-protectant<sup>®</sup> platform, we have two drug development programs in clinical trials and are pursuing a number of other preclinical programs.

AGI-1067 is our v-protectant<sup>®</sup> that is most advanced in clinical development. AGI-1067 is designed to benefit patients with coronary heart disease, or CHD, which is atherosclerosis of the blood vessels of the heart. We are currently evaluating AGI-1067 in the Phase III clinical trial called ARISE (Aggressive Reduction of Inflammation Stops Events) as an oral therapy for the treatment of atherosclerosis.

AGI-1096, our second candidate, 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 are working with Fujisawa Pharmaceutical Co., Ltd. to further develop AGI-1096 in preclinical and early-stage clinical trials.

We previously were developing AGIX-4207, a v-protectant<sup>®</sup> candidate for the treatment of rheumatoid arthritis. Based on our findings, however, we have discontinued clinical development of AGIX-4207 and the intravenous dosage form of AGIX-4207 for rheumatoid arthritis. We continue to have an active program aimed at investigating other v-protectants<sup>®</sup> in rheumatoid arthritis and have identified other compounds with enhanced therapeutic potential within our rheumatoid arthritis preclinical models. We are working to select another candidate to move into formal preclinical development.

We have also identified additional potential v-protectant<sup>®</sup> candidates to treat other chronic inflammatory diseases, including asthma. We are evaluating these v-protectants<sup>®</sup> to determine lead drug candidates for clinical development. We plan to develop these compounds rapidly and may seek regulatory fast track status, if available, to expedite development and commercialization. We will continue to expand upon our v-protectant<sup>®</sup> 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.

The following table provides information regarding our research and development expenses for our major product candidates:

	Year ended December 31,		
	2004	2003	2002
Direct external costs:			
AGI-1067	\$ 36,181,651	\$ 22,395,195	\$ 6,828,312
AGIX-4207	3,236,505	3,737,038	1,873,141
AGI-1096	19,041	32,242	662,733
Unallocated costs and other programs	19,798,636	20,496,485	14,381,941
Total research and development	\$ 59,235,833	\$ 46,660,960	\$ 23,746,127

From inception, we have devoted the large majority of our research and development efforts and financial resources to support development of the AGI-1067 product candidate. Spending for the AGI-1096 program in 2004 and 2003 was funded by our collaborative development partner, Fujisawa Pharmaceutical Co., Ltd. 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.

The nature, timing and costs of the efforts to complete the successful development of any of our product candidates are highly uncertain and subject to numerous risks, and therefore cannot be accurately estimated. These risks include the rate of progress and costs of our clinical trials, clinical trial results, cost and timing of regulatory approval and establishing commercial manufacturing supplies. These risks and uncertainties, and their effect on our operations and financial position, are more fully described above in our risk factors under the headings *Risks Related to Development of Our Product Candidates* and *Risks Related to Regulatory Approval of Our Product Candidates*.

We have incurred significant losses since we began operations and, as of December 31, 2004, had an accumulated deficit of \$212.1 million. We cannot assure you whether or when we will become profitable. We expect to continue to incur substantial 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.

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### **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 U.S. 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 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 make these estimates based upon progress of activities related to contractual obligations and also information received from vendors.

#### *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 December 2004, the FASB issued SFAS No. 123(R), *Share-Based Payment* ( SFAS 123(R) ), which revises SFAS 123 and supersedes APB 25. SFAS 123(R) requires that companies recognize compensation expense associated

with stock option grants and other equity instruments to employees in the financial statements and is effective as of the first reporting period that begins after June 15, 2005. SFAS 123(R) applies to all grants after the effective date and to the unvested portion of stock options outstanding as of the effective date. Under SFAS 123(R), we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The permitted transition methods are either a modified prospective method or a modified retrospective method. The modified prospective method requires that compensation expense be recorded for all unvested options at the beginning of the first quarter of adoption of SFAS 123(R), while the modified retrospective method requires that compensation expense be recorded for all unvested options beginning with the first period presented. Under the modified retrospective method, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The pro forma disclosures previously permitted under SFAS 123 will no longer be an alternative to financial

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statement recognition. We have not yet determined the method of adoption or the effect of adopting SFAS 123(R).

## **Results of Operations**

### **Comparison of Years Ended December 31, 2004 and 2003**

#### *Revenues*

There were no revenues during 2004 or 2003. 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 were \$59.2 million in 2004, compared to \$46.7 million in 2003. The increase of \$12.6 million, or 27%, is primarily due to increased expenditures for the AGI-1067 ARISE Phase III clinical trial, including manufacturing activities for clinical drug supply, study monitoring, payments to clinical investigators, and salary and personnel related expenses.

We expect that research and development expenses will continue to increase in 2005. This increase will be primarily related to activities surrounding the AGI-1067 ARISE Phase III clinical trial and precommercialization development activities.

*General and Administrative.* General and administrative expenses were \$6.6 million in 2004, compared to \$5.9 million in 2003. The increase of \$676,831, or 11%, is primarily due to a full year's impact of the increase in directors and officers' insurance premiums in 2004 compared to a partial year's impact of the increase in premiums in 2003, an increase in professional fees in connection with compliance with the Sarbanes-Oxley Act of 2002 and consulting fees. Also contributing to the increase were business development expenses related to partnering activities, along with salary and personnel expenses.

#### *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 \$1.4 million in 2004, compared to \$1.3 million in 2003. The slight increase is due to the increase in the weighted average cash and short-term investment balances along with an increase in interest rates.

#### *Interest Expense*

Interest expense was \$5.2 million in 2004 compared to \$2.0 million in 2003. The increase in interest expense is due to a full year of interest expense resulting from our \$100 million long-term convertible debt, issued in August 2003, compared to a partial year in 2003. We anticipate that interest expense will increase in 2005 due to our recent issuance of \$200 million in aggregate principal amount of 1.5% convertible notes.

#### *Income Taxes*

As of December 31, 2004, we had net operating loss carryforwards and research and development credit carryforwards of \$205.9 million and \$6.4 million, respectively, available to offset future taxable income. The net operating loss carryforwards and the research and development credit carryforwards will expire between 2010 and 2025. Because of our lack of earnings history, the resulting deferred tax assets have been fully offset by a valuation allowance. The utilization of the carryforwards is dependent upon the timing and extent of our future profitability. The

annual limitations combined with the expiration dates of the carryforwards may prevent the utilization of all of the net operating loss and research and development credit carryforwards if we do not attain sufficient profitability by the expiration dates of the carryforwards.

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

#### *Revenues*

There were no revenues during 2003 or 2002.

#### *Expenses*

*Research and Development.* Research and development expenses were \$46.7 million in 2003, compared to \$23.7 million in 2002. The increase of \$22.9 million, or 96%, was 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 were the ongoing patient related costs for the AGI-1067 CART-2 Phase IIb clinical trial.

*General and Administrative.* General and administrative expenses were \$5.9 million in 2003, compared to \$5.1 million in 2002. The increase of \$791,675, or 15%, was primarily due to an increase in directors and officers insurance premiums, consulting fees and business development expenses related to partnering activities, partially offset by a lower amount of deferred stock compensation expense.

#### *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 \$129.4 million and \$4.0 million, respectively, available to offset future taxable income.

### **Liquidity and Capital Resources**

Since inception, we have financed our operations primarily through sales of equity securities and convertible notes. At December 31, 2004, we had cash, cash equivalents and short-term investments of \$66.9 million, compared with \$131.6 million and \$34.7 million at December 31, 2003 and 2002, respectively. Working capital at December 31, 2004 was \$59.7 million, compared to \$124.8 million and \$30.0 million at December 31, 2003 and 2002, respectively. The decrease in cash, cash equivalents, short-term investments and working capital for the year ended December 31, 2004 is primarily due to the use of funds for operating purposes. 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.

Net cash used in operating activities was \$66.6 million in 2004 compared to \$48.6 million in 2003 and \$24.2 million in 2002. The increase in the use of cash in operating activities in 2004 is principally due to funding a net loss of \$69.6 million. The increase in cash needed to fund the net loss is primarily attributable to expenditures for our ARISE Phase III clinical trial for AGI-1067, our CART-2 Phase IIb clinical trial for AGI-1067, and our OSCAR Phase II clinical trial for AGIX-4207, as well as other ongoing product development activities. For 2005 and 2006, expenditures for the ARISE clinical trial are estimated to be approximately \$57.0 million. We expect to complete ARISE enrollment by mid-2005 and complete the ARISE trial by the end of the first quarter of 2006. We then plan to file a New Drug Application with the U.S. Food and Drug Administration as soon as possible after we complete the trial and analyze the results. Expenditures for CART-2 and OSCAR are essentially completed. We anticipate net cash usage in 2005 for ARISE and our other on going preclinical and clinical programs, as well as our other operating activities, to be in a range of \$85.0 million to \$89.0 million.



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Net cash provided by investing activities was \$27.1 million in 2004 compared to net cash used in investing activities of \$68.1 million in 2003 and \$18.1 million provided by investing activities in 2002. Net cash provided by investing activities consisted primarily of net sales of available-for-sale securities, with the proceeds reinvested in interest-bearing cash equivalents. Net cash used in investing activities consisted primarily of net purchases of available-for-sale securities.

Net cash provided by financing activities was \$2.3 million in 2004 compared to \$146.1 million in 2003 and \$1.2 million in 2002. Net cash provided by financing activities in 2004 consisted primarily of the proceeds received upon exercise of common stock options. Net cash provided by financing activities in 2003 consisted 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 the exercise of common stock options.

In March 2002, we entered into an equipment loan facility, as modified in June 2003, with Silicon Valley 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 equipment loan facility, as modified, expired on September 30, 2003. At December 31, 2004, there was an outstanding balance of approximately \$83,622 on the equipment loan facility and the weighted average interest rate was 7.5% per year.

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. As of December 31, 2004, we have recorded \$1.5 million of accrued interest expense related to the notes, which is due March 1, 2005.

On January 12, 2005, we issued \$200 million in aggregate principal amount of 1.5% convertible notes due 2012 through a Rule 144A private placement to qualified institutional buyers. These notes are convertible into shares of our common stock at a conversion rate of 38.5802 shares per \$1,000 principal amount of notes, or approximately \$25.92 per share. Interest on the 1.5% convertible notes is payable semi-annually in arrears on February 1 and August 1. Net proceeds were approximately \$193.5 million. We are using the net proceeds from the sale of the notes to fund the ongoing costs of the ARISE Phase III clinical trial for AGI-1067 and other 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.

The following table summarizes our long-term contractual obligations as of December 31, 2004:

Contractual Obligations	Total	Payments Due by Period			Thereafter
		2005	2006-2007	2008-2009	
Operating leases, net of sublease income	\$ 5,140,305	\$ 1,115,388	\$ 2,652,292	\$ 1,372,625	\$
Long-term debt	100,083,622	83,622		100,000,000	
Total contractual obligations	\$ 105,223,927	\$ 1,199,010	\$ 2,652,292	\$ 101,372,625	\$

Based upon the current status of our product development and commercialization plans, we believe that our existing cash and cash equivalents, along with the funds received from the 1.5% convertible notes issued in January 2005, 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 scope and results of our research, preclinical and clinical development activities;

the timing of, and the costs involved in, obtaining regulatory approvals;

our ability to establish and maintain collaborations and the financial terms of any collaborations;

the cost of commercialization activities, including product marketing, sales and distribution;

the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs;

the costs related to purported class action lawsuits filed against us; and

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the extent to which we acquire or invest in businesses, products and technologies.

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. We cannot estimate the timing of material net cash inflows from our product candidates, since they are dependent upon regulatory approvals and subsequent market acceptance.

**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, 2004.

	<b>2005</b>	<b>2006-2007</b>	<b>2008-2009</b>	<b>Total</b>	<b>Value as of December 31, 2004</b>
Long-term debt-fixed rate					
Maturity	\$ 83,622	\$	\$ 100,000,000	\$ 100,083,622	\$ 177,083,622
Average interest rate	7.5%		4.5%		

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

**ATHEROGENICS, INC.  
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**MANAGEMENT'S ANNUAL REPORT ON  
INTERNAL CONTROL OVER FINANCIAL REPORTING**

Management of AtheroGenics, Inc. is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. AtheroGenics' internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. AtheroGenics' internal control over financial reporting includes those policies and procedures that:

pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of AtheroGenics;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of AtheroGenics are being made only in accordance with authorizations of management and directors of AtheroGenics; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of AtheroGenics' assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of AtheroGenics' internal control over financial reporting as of December 31, 2004. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

Based on our assessment and those criteria, management believes that AtheroGenics maintained effective internal control over financial reporting as of December 31, 2004.

AtheroGenics' independent registered public accounting firm has issued an attestation report on management's assessment of AtheroGenics' internal control over financial reporting which is included herein.

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL**

The Board of Directors and Shareholders of AtheroGenics, Inc.

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting, that AtheroGenics, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). AtheroGenics, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that AtheroGenics, Inc. maintained effective internal control over financial reporting as of December 31, 2004 is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, AtheroGenics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004 based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of AtheroGenics, Inc. as of December 31, 2004 and 2003, and the related statements of operations, shareholders' (deficit) equity and cash flows for each of the three years in the period ended December 31, 2004 and our report dated March 16, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Atlanta, Georgia  
March 16, 2005

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON FINANCIAL STATEMENTS**

The Board of Directors and Shareholders  
AtheroGenics, Inc.

We have audited the accompanying balance sheets of AtheroGenics, Inc. as of December 31, 2004 and 2003, and the related statements of operations, shareholders' (deficit) equity and cash flows for each of the three years in the period ended December 31, 2004. 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 of the Public Company Accounting Oversight Board (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, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of AtheroGenics, Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Atlanta, Georgia  
March 16, 2005



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BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 15,888,919	\$ 53,058,249
Short-term investments	51,035,096	78,525,679
Prepaid expenses	2,634,297	1,144,006
Notes receivable and other current assets	566,208	496,871
<b>Total current assets</b>	<b>70,124,520</b>	<b>133,224,805</b>
Equipment and leasehold improvements, net of accumulated depreciation and amortization	1,940,011	2,520,790
Other assets	2,397,796	3,091,151
<b>Total assets</b>	<b>\$ 74,462,327</b>	<b>\$ 138,836,746</b>
<b>Liabilities and Shareholders (Deficit) Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,838,053	\$ 1,778,187
Accrued research and development	4,083,894	2,961,085
Accrued liabilities	2,159,893	2,118,500
Accrued compensation	1,239,247	1,038,907
Current portion of equipment loan facility	83,622	479,439
<b>Total current liabilities</b>	<b>10,404,709</b>	<b>8,376,118</b>
Convertible notes payable	100,000,000	100,000,000
Equipment loan facility, net of current portion		83,622
Shareholders (deficit) equity Preferred stock, no par value:		
Authorized 5,000,000 shares		
Common stock, no par value:		
Authorized 100,000,000 shares; issued and outstanding 37,368,658 and 36,763,407 shares at December 31, 2004 and 2003, respectively	175,713,265	172,452,536
Warrants	828,804	950,588
Deferred stock compensation	(324,607)	(505,708)
Accumulated deficit	(212,120,547)	(142,531,315)
Accumulated other comprehensive (loss) income	(39,297)	10,905
<b>Total shareholders (deficit) equity</b>	<b>(35,942,382)</b>	<b>30,377,006</b>
<b>Total liabilities and shareholders (deficit) equity</b>	<b>\$ 74,462,327</b>	<b>\$ 138,836,746</b>

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



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**ATHEROGENICS, INC.  
STATEMENTS OF OPERATIONS**

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Revenues	\$	\$	\$
Operating expenses:			
Research and development	59,235,833	46,660,960	23,746,127
General and administrative	6,607,506	5,930,675	5,139,000
Total operating expenses	65,843,339	52,591,635	28,885,127
Operating loss	(65,843,339)	(52,591,635)	(28,885,127)
Interest and other income	1,447,001	1,258,216	962,040
Interest expense	(5,192,894)	(1,954,402)	(42,420)
Net loss	\$ (69,589,232)	\$ (53,287,821)	\$ (27,965,507)
Net loss per share basic and diluted	\$ (1.88)	\$ (1.49)	\$ (1.00)
Weighted average shares outstanding basic and diluted	37,070,235	35,770,994	27,978,705

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

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**ATHEROGENICS, INC.**  
**STATEMENTS OF SHAREHOLDERS (DEFICIT) EQUITY**

	Common Stock		Warrants	Deferred	Accumulated	Accumulated	Total
	Shares	Amount		Stock		Comprehensive	
				Compensation	Deficit	(Loss) Income	(Deficit) Equity
<b>Balance at January 1, 2002</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)
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	340,395	1,382,972					1,382,972

exercise of stock options at \$.30 to \$8.25 per share							
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
Issuance of common stock for exercise of stock options at \$.30 to \$16.52 per share	495,265	2,783,894					2,783,894
Issuance of common stock for exercise of warrants	109,986	289,540	(289,540)				
Adjustments to market value for variable stock options and warrants issued to non-employees		145,663	167,756	(313,419)			
Amortization of deferred stock compensation		41,632		494,520			536,152
Net loss					(69,589,232)		(69,589,232)

Unrealized loss on available-for-sale securities						(50,202)	(50,202)
Comprehensive loss							(69,639,434)
<b>Balance at December 31, 2004</b>	37,368,658	\$ 175,713,265	\$ 828,804	\$ (324,607)	\$ (212,120,547)	\$ (39,297)	\$ (35,942,382)

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

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

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
<b>Operating activities</b>			
Net loss	\$ (69,589,232)	\$ (53,287,821)	\$ (27,965,507)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	883,312	839,503	746,949
Amortization of debt issuance costs	652,981	217,660	
Amortization of deferred stock compensation	536,152	1,365,898	1,976,872
Changes in operating assets and liabilities:			
Prepaid expenses	(1,490,291)	(977,011)	23,679
Notes receivable and other assets	(28,963)	(252,126)	420,446
Accounts payable	1,059,866	(181,108)	837,745
Accrued research and development	1,122,809	2,015,579	(361,929)
Accrued liabilities and compensation	241,733	1,611,006	102,021
Net cash used in operating activities	(66,611,633)	(48,648,420)	(24,219,724)
<b>Investing activities</b>			
Sales and maturities of short-term investments	103,984,437	61,337,482	37,336,165
Purchases of short-term investments	(76,544,056)	(128,913,764)	(18,570,010)
Purchases of equipment and leasehold improvements	(302,533)	(535,026)	(656,704)
Net cash provided by (used in) investing activities	27,137,848	(68,111,308)	18,109,451
<b>Financing activities</b>			
Proceeds from the exercise of common stock options	2,783,894	1,382,972	240,524
Proceeds from the convertible notes		96,735,095	
Proceeds from the issuance of common stock		48,411,649	
Proceeds from equipment loan facility			1,258,473
Payments on equipment loan facility and capital lease obligation	(479,439)	(444,068)	(338,445)
Net cash provided by financing activities	2,304,455	146,085,648	1,160,552
(Decrease) increase in cash and cash equivalents	(37,169,330)	29,325,920	(4,949,721)
Cash and cash equivalents at beginning of year	53,085,249	23,732,329	28,682,050
Cash and cash equivalents at end of year	\$ 15,888,919	\$ 53,058,249	\$ 23,732,329
<b>Supplemental disclosures of cash flow information</b>			
Interest paid	\$ 4,676,472	\$ 61,844	\$ 50,689
Re-measurement adjustment for variable options and warrants issued for technology license agreements and consulting agreements	\$ 313,419	\$ 627,820	\$ 357,185

*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 U.S. 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.

*Reclassifications*

In order to present auction rate securities with short-term interest auction features as short-term investments in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 95, *Statement of Cash Flows* and SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* ( SFAS 115 ) for the fiscal year ended December 31, 2003 and 2002, \$10,600,000 and \$8,400,000, respectively, was reclassified from cash and cash equivalents to short-term investments. This reclassification was to properly state cash and cash equivalents and had no effect on previously reported net loss or shareholders (deficit) equity. The effect of the reclassification on cash flow was to decrease cash provided by investing activities by \$10,600,000 and \$8,400,000 for the years ended December 31, 2003 and 2002, respectively.

*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 government agency notes, corporate notes, commercial paper, auction rate securities and certificates of deposit with original maturities when purchased greater than three months.

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 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 (deficit) 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.

**Table of Contents***Research and Development Accrual*

As part of the process of preparing its financial statements, AtheroGenics is required to estimate expenses that it believes it has incurred, but has not yet been billed for. This process involves identifying services and activities that have been performed by third-party vendors on its 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 its financial statements. Examples of expenses for which AtheroGenics accrues 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 makes these estimates based upon progress of activities related to contractual obligations and also information received from vendors.

*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.

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Net loss, as reported	\$ (69,589,232)	\$ (53,287,821)	\$ (27,965,507)
Add: Stock-based employee compensation expense included in reported net loss	57,511	553,309	1,495,249
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(6,125,770)	(3,375,253)	(3,441,554)
Pro forma net loss	\$ (75,657,491)	\$ (56,109,765)	\$ (29,911,812)
Net loss per share:			
Basic and diluted, as reported	\$ (1.88)	\$ (1.49)	\$ (1.00)
Basic and diluted, pro forma	\$ (2.04)	\$ (1.57)	\$ (1.07)



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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:

	2004	2003	2002
Expected life	5 years	5 years	5 years
Risk free interest rate	4.24%	4.27%	3.37%
Volatility	78.77%	80.18%	87.63%
Weighted average fair value of grants	\$ 15.27	\$ 9.64	\$ 5.13

*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 \$69,639,434, \$53,277,226 and \$28,018,495 for the years ended December 31, 2004, 2003 and 2002, respectively.

*Recently Issued Accounting Standards*

In December 2004, the FASB issued SFAS No. 123(R), *Share-Based Payment* ( SFAS 123(R) ), which revises SFAS 123 and supersedes APB 25. SFAS 123(R) requires that companies recognize compensation expense associated with stock option grants and other equity instruments to employees in the financial statements and is effective as of the first reporting period that begins after June 15, 2005. SFAS 123(R) applies to all grants after the effective date and to the unvested portion of stock options outstanding as of the effective date. Under SFAS 123(R), AtheroGenics must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The permitted transition methods are either a modified prospective method or a modified retrospective method. The modified prospective method requires that compensation expense be recorded for all unvested options at the beginning of the first quarter of adoption of SFAS 123(R), while the modified retrospective method requires that compensation expense be recorded for all unvested options beginning with the first period presented. Under the modified retrospective method, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The pro forma disclosures previously permitted under SFAS 123 will no longer be an alternative to financial statement recognition. AtheroGenics has not yet determined the method of adoption or the effect of adopting SFAS 123(R).

**2. Short-Term Investments**

Short-term investments consist of debt securities classified as available-for-sale and have maturities greater than 90 days 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 years ended December 31, 2004 and 2003. The cumulative unrealized (loss) gains were \$(39,297) and \$10,905 at December 31, 2004 and 2003, respectively. The following table

summarizes the estimated fair value of AtheroGenics short-term investments:

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Government agency notes	\$ 19,803,045	\$ 36,415,792
Corporate notes	10,751,955	17,824,579
Commercial paper	9,939,363	2,194,575
Auction rate securities	10,500,000	22,050,000
Certificate of deposit	40,733	40,733
<b>Total</b>	<b>\$ 51,035,096</b>	<b>\$ 78,525,679</b>

All available-for-sale securities held at December 31, 2004 will mature during 2005.

**Table of Contents****3. Equipment and Leasehold Improvements**

Equipment and leasehold improvements consist of the following:

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Laboratory equipment	\$ 2,538,760	\$ 2,664,192
Leasehold improvements	1,563,084	1,563,084
Computer and office equipment	1,479,392	1,474,599
	5,581,236	5,701,875
Accumulated depreciation and amortization	(3,641,225)	(3,181,085)
	\$ 1,940,011	\$ 2,520,790

**4. Convertible Notes Payable**

In August 2003, AtheroGenics issued \$100,000,000 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 \$96,700,000, after deducting expenses and underwriter's discounts and commissions. AtheroGenics recorded issuance costs related to the notes of approximately \$3,300,000. 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.

On January 12, 2005, AtheroGenics issued \$200,000,000 in aggregate principal amount of 1.5% convertible notes due February 1, 2012 with interest payable semi-annually in February and August. Net proceeds to AtheroGenics were approximately \$193,500,000, after deducting expenses and underwriter's discounts and commissions. The 1.5% convertible notes are convertible into shares of common stock, at the option of the holder, at a conversion rate of 38.5802 shares per \$1,000 principal amount of notes, which represents a conversion price of approximately \$25.92, subject to adjustment.

AtheroGenics has reserved a total of 14,234,953 shares of common stock for future issuance in connection with the 4.5% convertible notes and the 1.5% convertible notes. In addition, as of December 31, 2004, accrued liabilities included approximately \$1,500,000 of accrued interest related to the 4.5% convertible notes, which is due March 1, 2005.

**5. Bank Credit Agreements**

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, 2004, there was an outstanding balance of \$83,622 under the equipment loan facility and the weighted average interest rate was 7.5% per year. The borrowing period for the equipment loan facility expired in September 2003.

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



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Maturities of long-term debt as of December 31, 2004 are as follows:

2005	\$ 83,622
2008	100,000,000
	\$ 100,083,622

**6. 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:

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Shares underlying convertible notes	6,518,904	6,518,904	
Options	4,955,801	4,403,179	3,895,420
Warrants	142,310	267,622	283,622
<b>Total</b>	<b>11,617,015</b>	<b>11,189,705</b>	<b>4,179,042</b>
Conversion price of shares underlying convertible notes	\$ 15.34	\$ 15.34	\$
Weighted average exercise price of options	\$ 10.20	\$ 6.27	\$ 4.06
Weighted average exercise price of warrants	\$ 4.78	\$ 4.32	\$ 4.41

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

**7. Common Stock**

In November 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 common stock.

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 of Directors 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.

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In February 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.

**8. 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, 2004, AtheroGenics had reserved 227,800 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, 2004, AtheroGenics had reserved 1,897,433 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, 2004, AtheroGenics had reserved 1,874,585 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.

Effective April 28, 2004, AtheroGenics established an equity ownership plan (the 2004 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 2004 Plan authorizes the grant of options for up to 4,500,000 shares of AtheroGenics' common stock. As of December 31, 2004, AtheroGenics had reserved 4,500,000 shares of common stock for issuance under the 2004 Plan. The terms of the 2004 Plan are substantially similar to the terms of the 2001 Plan and the 1997 Plan.

A summary of stock option activity under the 1995 Plan, the 1997 Plan, the 2001 Plan and the 2004 Plan follows:

	<b>Number of Shares</b>	<b>Price Range</b>	<b>Weighted Average Price</b>
Outstanding at January 1, 2002	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

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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
Outstanding at December 31, 2003	4,403,179	.10 - 16.65	6.27
Granted	1,166,125	14.38 - 32.95	23.16
Exercised	(496,908)	.30 - 16.52	5.72
Canceled	(116,595)	4.53 - 14.93	10.23
Outstanding at December 31, 2004	4,955,801	\$ .10-\$32.95	\$ 10.20

The following table summarizes information concerning currently outstanding and exercisable options granted under the 1995 Plan, the 1997 Plan, the 2001 Plan and the 2004 Plan as of December 31, 2004.

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Exercise Price	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$.10-.38	1,353,015	4.11	\$ .31	1,353,015	\$ .31
4.37-7.41	1,425,865	7.23	6.51	924,087	6.30
7.55-14.93	1,008,796	8.62	13.66	358,563	12.18
16.52-23.56	1,034,125	9.85	22.83	4,795	16.57
25.30-32.95	134,000	9.37	25.86	80,000	25.30
.10-32.95	4,955,801	7.27	10.20	2,720,460	4.67

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 (deficit) 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 2004, 2003 and 2002, AtheroGenics recorded amortization of deferred stock compensation for these options of \$57,511, \$553,309 and \$1,495,249, 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. In December 2004, 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 \$18,685. 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 (deficit) equity and are being amortized over the vesting periods of the individual warrants and options. The amortization period is five years, using the graded vesting method, for National Jewish and one year, using the straight-line method, for the consultants. During 2004, 2003 and 2002, an additional \$313,419, \$627,820 and \$357,185, respectively, of non-cash deferred stock compensation was recorded due to re-measurement of the fair value of the options and warrants at each measurement date. During 2004, 2003 and 2002, AtheroGenics recorded a total of \$478,641, \$812,589 and \$481,623, respectively, of amortization of deferred stock compensation for these options and warrants. At December 31, 2004, 68,000 shares of common stock were reserved for issuance upon the exercise of these outstanding warrants.

At December 31, 2004, AtheroGenics had a total of \$324,607 remaining to be amortized over the vesting periods of all of the option and warrant grants discussed above. This amortization will approximate \$252,000 in 2005 and \$73,000 in 2006. During 2002, 13,200 shares were forfeited and deferred stock compensation was decreased by \$111,841.

**9. Employee Benefit Plan**

AtheroGenics has a defined contribution plan covering eligible employees, which is qualified under Section 401(k) of the Internal Revenue Code ( IRC ). 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 IRC. AtheroGenics may make a discretionary contribution. During 2004, AtheroGenics matched 50% of employees' contributions, up to a maximum of 6% of the employees' annual base compensation. AtheroGenics' contribution to the plan for 2004, 2003 and 2002 aggregated \$204,094, \$161,576 and \$129,503, respectively. AtheroGenics' stock is not an eligible investment under this plan.

**Table of Contents****10. Income Taxes**

At December 31, 2004, AtheroGenics had net operating loss carryforwards and research and development credit carryforwards of \$205,886,593 and \$6,366,269, respectively, for income tax purposes, which both begin to expire in 2010. The significant components of the deferred tax assets are:

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Net operating loss carryforwards	\$ 78,154,551	\$ 49,198,787
Deferred stock compensation	3,075,991	4,374,216
Research credits	6,366,269	4,010,990
Other	194,803	240,266
<b>Total deferred tax assets</b>	<b>87,791,614</b>	<b>57,824,259</b>
Valuation allowance	(87,791,614)	(57,824,259)
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

Because of AtheroGenics' lack of earnings history, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased \$29,967,355 and \$22,372,603 in 2004 and 2003, respectively, due to the change in net cumulative tax differences and the excess tax benefit from disqualifying dispositions of incentive stock options.

AtheroGenics' net operating loss carryforwards and research and development credit carryforwards may be subject to certain IRC Section 382 and Section 383 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. The utilization of the carryforwards is dependent upon the timing and extent of our future profitability. The annual limitations combined with the expiration dates of the carryforwards may prevent the utilization of all of the net operating loss and research and development credit carryforwards if we do not attain sufficient profitability by the expiration dates of the carryforwards.

**11. Commitments and Contingencies**

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, 2004, AtheroGenics' minimum aggregate commitments (net of sublease income) under long-term, non-cancelable operating leases are as follows:

<b>Gross</b>	<b>Sublease Income</b>	<b>Net</b>
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2005	\$ 1,315,874	\$ 200,486	\$ 1,115,388
2006	1,334,435		1,334,435
2007	1,317,857		1,317,857
2008	1,176,536		1,176,536
2009	196,089		196,089
Thereafter			
	\$ 5,340,791	\$ 200,486	\$ 5,140,305

Net rent expense under operating leases amounted to \$1,050,333, \$1,026,495 and \$984,043 in 2004, 2003 and 2002, respectively.



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In July 2004, AtheroGenics signed a term sheet with a contract manufacturer under which it purchased a portion of its clinical supply requirements. The term sheet includes contingent future payments and royalties. The potential financial obligations are not considered to be material.

**12. Related Party Transactions**

AtheroGenics has a sublease agreement for a portion of its office and laboratory space with Inhibitex, Inc. The monthly lease payments are approximately \$16,700. 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 had a sublease agreement for a portion of its office space with ATV Management Corp. Monthly lease payments were approximately \$3,500. The lease term ended in December 2004. The Chairman of the Board of Directors of AtheroGenics is the President and sole shareholder of ATV Management Corp.

**13. Subsequent Events**

Purported securities class action lawsuits were filed against AtheroGenics and some of its executive officers and directors in the United States District Court for the Southern District of New York on January 5, 2005 and February 8, 2005 and in the United States District Court for the Northern District of Georgia, Atlanta division on January 7, 2005, January 10, 2005, January 11, 2005 and January 25, 2005. Separate motions to consolidate these lawsuits were filed by plaintiffs in both the Southern District of New York and the Northern District of Georgia on March 7, 2005. In addition, two plaintiffs simultaneously moved for appointment as lead plaintiffs in both districts on March 7, 2005. The allegations in these lawsuits relate to AtheroGenics disclosures regarding the results of the CART-2 clinical trial for AGI-1067. The results of complex legal proceedings, such as those purported class actions, are difficult to predict. Each complaint seeks unspecified damages and, therefore, AtheroGenics is unable to estimate the possible range of damages that it might incur should any of these lawsuits be resolved against them. AtheroGenics intends to defend the litigation vigorously.

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

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

	<b>Year Ended December 31, 2004</b>			
	<b>1<sup>st</sup> Quarter</b>	<b>2<sup>nd</sup> Quarter</b>	<b>3<sup>rd</sup> Quarter</b>	<b>4<sup>th</sup> Quarter</b>
Net revenues	\$	\$	\$	\$
Operating loss	(15,680,847)	(15,597,955)	(18,046,883)	(16,517,654)
Net loss	(16,602,700)	(16,525,159)	(19,003,116)	(17,458,257)
Net loss per share data:				
Basic and diluted	(0.45)	(0.45)	(0.51)	(0.47)
	<b>Year Ended December 31, 2003</b>			
	<b>1<sup>st</sup> Quarter</b>	<b>2<sup>nd</sup> Quarter</b>	<b>3<sup>rd</sup> Quarter</b>	<b>4<sup>th</sup> Quarter</b>
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)

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***

*Management's annual report on internal control over financial reporting.* Section 404 of the Sarbanes-Oxley Act of 2002 requires management to include in this Annual Report on Form 10-K a report on management's assessment of the effectiveness of our internal control over financial reporting, as well as an attestation report from our independent registered public accounting firm on management's assessment of the effectiveness of our internal control over financial reporting. Management's annual report on internal control over financial reporting and the related attestation report from our independent registered public accounting firm are located herein and are incorporated herein by reference.

*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

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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.

**Item 9B. Other Information**

On December 22, 2004, AtheroGenics' board of directors, based on the recommendation of the compensation committee, granted our executive officers options to acquire shares of our common stock under the AtheroGenics, Inc. 2004 Equity Ownership Plan. The option grants are effective as of December 31, 2004 and have an exercise price equal to the fair market value on that date of \$23.56 per share. The options vest at a rate of 25 percent on the anniversary of the date of grant, and following that date, the remaining options vest at a rate of approximately two percent per month over the next 36 months. The option grants expire December 31, 2014. The following is a summary of the option grants:

Name	Title	Number of Shares
Russell M. Medford, M.D., Ph.D.	Chief Executive Officer and President	140,000
Mark P. Colonnese	Senior Vice President of Finance and Administration and Chief Financial Officer	60,000
Robert A. D. Scott, M.D.	Senior Vice President of Clinical Development and Regulatory Affairs and Chief Medical Officer	60,000
Martin A. Wasserman, Ph.D.	Senior Vice President of Discovery Research and Chief Scientific Officer	54,000
W. Charles Montgomery, Ph.D.	Vice President of Business Development	50,000

The form of option agreement for these grants is attached as Exhibit 10.33 to this report.

**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 under the captions Nominees, Executive Officers and Directors, Board Meetings and Committees and Section 16(a) Beneficial Ownership Reporting Compliance, respectively, in our proxy statement for our 2005 annual meeting of shareholders to be held on April 27, 2005. 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 no later than 120 days after December 31, 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.

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

We have set forth information relating to ownership of our common stock by certain persons and to our equity compensation plans under the captions 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.

**PART IV**

**Item 15. *Exhibits and Financial Statement Schedules***

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

Report of Independent Registered Public Accounting Firm

Balance Sheets as of December 31, 2004 and 2003

Statements of Operations for the years ended December 31, 2004, 2003 and 2002

Statements Shareholders (Deficit) Equity for the years ended December 31, 2004, 2003 and 2002

Statements of Cash Flows for the years ended December 31, 2004, 2003 and 2002

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

<b>Exhibit No.</b>	<b>Description</b>
3.01	

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- Fourth Amended and Restated Articles of Incorporation of AtheroGenics, Inc. (filed as Exhibit 3.01 to Amendment No. 1 to AtheroGenics Annual Report on Form 10-K for the year ended December 31, 2004 on April 6, 2005 and incorporated herein by reference).
- 3.02 Third Amended and Restated Bylaws of AtheroGenics, Inc., as amended (filed as an exhibit of the same number with AtheroGenics Annual Report on Form 10-K for the year ended December 31, 2001 and incorporated herein by reference).
- 4.01 Form of Common Stock Certificate (filed as Exhibit 4.01 to Amendment No. 4 to AtheroGenics Registration Statement on Form S-1, Registration No. 333-31140, on August 4, 2000 and incorporated herein by reference).
- 4.02 Rights Agreement dated as of November 9, 2001 between AtheroGenics, Inc. and American Stock Transfer & Trust Company, as Rights Agent (filed as Exhibit 4.4 of AtheroGenics Form 8-K on November 19, 2001 and incorporated herein by reference).
- 4.03 Indenture dated August 19, 2003 between AtheroGenics, Inc. and The Bank of New York Trust Company of Florida N.A., as Trustee (filed as Exhibit 4.1 to AtheroGenics Registration Statement on Form S-3, Registration No. 333-110160, on October 31, 2003, and incorporated herein by reference).

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<b>Exhibit No.</b>	<b>Description</b>
4.04	Global 4 <sup>1</sup> / <sub>2</sub> % Convertible Note Due 2008 (filed as Exhibit 4.04 to Amendment No. 1 to AtheroGenics Annual Report on Form 10-K for the year ended December 31, 2004 on April 6, 2005 and incorporated herein by reference).
10.01	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 (filed as Exhibit 4.02 to AtheroGenics Registration Statement on Form S-1, Registration No. 333-31140, on February 25, 2000 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. (filed as Exhibit 10.02 to Amendment No. 4 to AtheroGenics Registration Statement on Form S-1, Registration No. 333-31140, on August 4, 2000 and incorporated herein by reference).
10.03+	License Agreement dated January 11, 1995 between Emory University and AtheroGenics, Inc. (filed as Exhibit 10.03 to Amendment No. 2 to AtheroGenics Registration Statement on Form S-1, Registration No. 333-31140, on July 13, 2000 and incorporated herein by reference).
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 (filed as Exhibit 10.04 to Amendment No. 2 to AtheroGenics Registration Statement on Form S-1, Registration No. 333-31140, on July 13, 2000 and incorporated herein by reference).
10.05+	Sponsored Research Agreement dated October 14, 1996 between Emory University and AtheroGenics, Inc. (filed as Exhibit 10.05 to Amendment No. 2 to AtheroGenics Registration Statement on Form S-1, Registration No. 333-31140, on July 13, 2000 and incorporated herein by reference).
10.06#	AtheroGenics, Inc. 1995 Stock Option Plan, together with form of nonqualified stock option agreement (filed as Exhibit 10.07 to AtheroGenics Registration Statement on Form S-1, Registration No. 333-31140, on February 25, 2000 and incorporated herein by reference).
10.07#	AtheroGenics, Inc. 1997 Equity Ownership Plan, as amended by Amendment No. 1 and Amendment No. 2 (filed as Exhibit 10.08 to Amendment No. 2 to AtheroGenics Registration Statement on Form S-1, Registration No. 333-31140, on July 13, 2000 and incorporated herein by reference).
10.08	Preferred Shares Purchase Warrant dated August 24, 1998 between AtheroGenics, Inc. and certain Lenders named therein (filed as Exhibit 10.09 to AtheroGenics Registration Statement on

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- Form S-1, Registration No. 333-31140, on February 25, 2000 and incorporated herein by reference).
- 10.09 Series C Convertible Preferred Stock Purchase Warrants of AtheroGenics, Inc. (filed as Exhibit 10.10 to AtheroGenics Registration Statement on Form S-1, Registration No. 333-31140, on February 25, 2000 and incorporated herein by reference).
- 10.10 Promissory Note dated April 1, 1999 between Inhibitex, Inc. and AtheroGenics, Inc. (filed as Exhibit 10.11 to AtheroGenics Registration Statement on Form S-1, Registration No. 333-31140, on February 25, 2000 and incorporated herein by reference).
- 10.11++ Lease Agreement dated June 19, 1998 between Cousins Properties, Inc. and AtheroGenics, Inc. (filed as Exhibit 10.12 to AtheroGenics Registration Statement on Form S-1, Registration No. 333-31140, on February 25, 2000 and incorporated herein by reference).
- 10.12# Employment Agreement dated March 1, 2001 between AtheroGenics, Inc. and Russell M. Medford (filed as Exhibit 10.14 to AtheroGenics Annual Report on Form 10-K for the year ended December 31, 2000, and incorporated herein by reference).
- 10.13 Amendment dated January 1, 2001 to Promissory Note dated April 1, 1999 between Inhibitex, Inc. and AtheroGenics, Inc. (filed as Exhibit 10.15 to AtheroGenics Annual Report on Form 10-K for the year ended December 31, 2000, and incorporated herein by reference).
- 10.14+ Exclusive License Agreement dated as of June 29, 2001 between AtheroGenics, Inc. and National Jewish Medical and Research Center (filed as Exhibit 10.17 to Amendment No. 1 to AtheroGenics Registration Statement on Form S-1, Registration No. 333-64228, on July 23, 2001 and incorporated herein by reference).
- 10.15# AtheroGenics, Inc. 2001 Equity Ownership Plan (filed as Appendix B to the proxy statement on Schedule 14A for AtheroGenics 2001 Annual Shareholders Meeting as filed on March 22, 2001 and incorporated herein by reference).
- 10.16 Equipment Term Note dated March 6, 2002 between AtheroGenics, Inc. and Silicon Valley Bank (filed as Exhibit 10.20(b) to AtheroGenics Quarterly Report on Form 10-Q for the quarter ended March 31, 2002 and incorporated herein by reference).
- 10.17 Loan and Security Agreement dated March 6, 2002 between AtheroGenics, Inc. and Silicon Valley Bank (filed as Exhibit 10.20(c) to AtheroGenics Quarterly Report on Form 10-Q for the quarter ended March 31, 2002 and incorporated herein by reference).
- 10.18# 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).
- 10.19#



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).

10.20 First Loan Modification dated June 20, 2003 between AtheroGenics, Inc. and Silicon Valley Bank. (filed as Exhibit 10.23 to AtheroGenics Quarterly Report on Form 10-Q for the quarter ended June 30, 2003 and incorporated herein by reference).

10.21 Purchase Agreement dated August 19, 2003 between AtheroGenics, Inc. and the Initial Purchasers named therein (filed as Exhibit 10.24 to AtheroGenics Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 and incorporated herein by reference).

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<b>Exhibit No.</b>	<b>Description</b>
10.22	Registration Rights Agreement dated as of August 19, 2003 among AtheroGenics, Inc., as Issuer, and Morgan Stanley & Co., Incorporated, Lehman Brothers, Inc., and Adams, Harkness & Hill, Inc., as Initial Purchasers (filed as Exhibit 4.2 to AtheroGenics Registration Statement on Form S-3, Registration No. 333-110160, on October 31, 2003, and incorporated herein by reference).
10.23	Second Loan Modification dated August 13, 2003 between AtheroGenics, Inc. and Silicon Valley Bank (filed as Exhibit 10.25 to AtheroGenics Annual Report on Form 10-K for the year ended December 31, 2003 and incorporated herein by reference).
10.24	Third Loan Modification dated December 29, 2003 between AtheroGenics, Inc. and Silicon Valley Bank (filed as Exhibit 10.26 to AtheroGenics Annual Report on Form 10-K for the year ended December 31, 2003 and incorporated herein by reference).
10.25	Negative Pledge Agreement dated December 29, 2003 between AtheroGenics, Inc. and Silicon Valley Bank (filed as Exhibit 10.27 to AtheroGenics Annual Report on Form 10-K for the year ended December 31, 2003 and incorporated herein by reference).
10.26#	Employment Agreement dated December 22, 2004 between AtheroGenics, Inc. and Mark P. Colonnese (filed as Exhibit 10.28 to AtheroGenics Form 8-K on December 22, 2004 and incorporated herein by reference).
10.27#	Employment Agreement dated December 22, 2004 between AtheroGenics, Inc. and Martin A. Wasserman (filed as Exhibit 10.29 to AtheroGenics Form 8-K on December 22, 2004 and incorporated herein by reference).
10.28#	Employment Agreement dated December 22, 2004 between AtheroGenics, Inc. and Robert A. D. Scott (filed as Exhibit 10.30 to AtheroGenics Form 8-K on December 22, 2004 and incorporated herein by reference).
10.29#	Employment Agreement dated December 22, 2004 between AtheroGenics, Inc. and W. Charles Montgomery (filed as Exhibit 10.31 to AtheroGenics Form 8-K on December 22, 2004 and incorporated herein by reference).
10.30#	AtheroGenics, Inc. 2004 Equity Ownership Plan (filed as Appendix B to the proxy statement on Schedule 14A for AtheroGenics 2004 Annual Shareholders Meeting as filed on March 26, 2004 and incorporated herein by reference).
10.31#	AtheroGenics, Inc. 2004 Equity Ownership Plan form of incentive equity ownership agreement and form of directors nonqualified equity ownership agreement (filed as Exhibit 10.33 to AtheroGenics Annual Report on Form 10-K for the year ended December 31, 2004 on March 16, 2005 and incorporated herein

	by reference).
10.32#	Summary of non-employee director compensation (filed as the first paragraph under the caption Director Compensation in the proxy statement on Schedule 14A for AtheroGenics 2005 Annual Meeting of Shareholders as filed with the SEC on March 28, 2005 and incorporated herein by reference).
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).
31.3**	Certifications of Chief Executive Officer under Rule 13a-14(a).
31.4**	Certifications of Chief Financial Officer under Rule 13a-14(a).
31.5*	Certifications of Chief Executive Officer under Rule 13a-14(a).
31.6*	Certifications of Chief Financial Officer under Rule 13a-14(a).
32***	Certifications of Chief Executive Officer and Chief Financial Officer under Section 1350.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer under Section 1350.

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\* Filed herewith.

\*\* Filed as the exhibit of the same number with Amendment No. 1 to AtheroGenics Annual Report on Form 10-K for the year ended December 31, 2004 on April 6, 2005 and incorporated herein by reference.

\*\*\* Filed as the exhibit of the same number with AtheroGenics Annual Report on Form 10-K for the year ended December 31, 2004 on March 16, 2005 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 May 6, 2005.

ATHEROGENICS, INC.

By: /s/ RUSSELL M. MEDFORD  
**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 ----- <b>Russell M. Medford</b>	President and Chief Executive Officer, Director	May 6, 2005
<b>Principal Financial and Principal Accounting Officer:</b>		
/s/ MARK P. COLONNESE ----- <b>Mark P. Colonnese</b>	Senior Vice President of Finance and Administration and Chief Financial Officer	May 6, 2005
<b>Additional Directors:</b>		
* ----- <b>Michael A. Henos</b>	Director	May 6, 2005
* ----- <b>R. Wayne Alexander</b>	Director	May 6, 2005
* ----- <b>David Bearman</b>	Director	May 6, 2005
* ----- <b>Vaughn D. Bryson</b>	Director	May 6, 2005
*	Director	May 6, 2005

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**T. Forcht Dagi**

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Director

May 6, 2005

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**Arthur M. Pappas**

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Director

May 6, 2005

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**William A. Scott**

\*

Director

May 6, 2005

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**Stephen G. Sudovar**

\*By: /s/ MARK P. COLONNESE

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