

ATHEROGENICS INC  
Form 10-Q  
November 02, 2005

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

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2005

Commission File No. 0-31261

**ATHEROGENICS, INC.**

(Exact name of registrant as specified in its charter)

**Georgia**                      **58-2108232**  
(State of incorporation)      (I.R.S. Employer  
Identification Number)

**8995 Westside Parkway, Alpharetta, Georgia 30004**  
(Address of registrant's principal executive offices, including zip code)

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(Registrant's telephone number, including area code): **(678) 336-2500**

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 whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes [  ] No [  ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [  ] No [  ]

As of October 28, 2005 there were 37,972,109 shares of the registrant's common stock outstanding.

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**FORM 10-Q**  
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**PART I. - FINANCIAL INFORMATION****Item 1. Financial Statements**

**ATHEROGENICS, INC.**  
**CONDENSED BALANCE SHEETS**  
**(Unaudited)**

**September      December**  
**30,                      31,**  
**2005                    2004**

**ASSETS**

Current assets:		
Cash and cash equivalents	\$	\$ 15,888,919
	100,263,078	
Short-term investments	96,463,799	51,035,096
Prepaid expenses	2,788,049	2,634,297
Notes receivable and other current assets	1,375,210	566,208
Total current assets	200,890,136	70,124,520
Equipment and leasehold improvements, net of		
accumulated depreciation and amortization	4,235,335	1,940,011
Debt issuance costs and other assets	7,739,838	2,397,796
Total assets	\$	\$ 74,462,327
	212,865,309	

**LIABILITIES AND SHAREHOLDERS'**  
**DEFICIT**

Current liabilities:		
Accounts payable	\$ 3,686,801	\$ 2,838,053
Accrued research and development	4,204,011	4,083,894
Accrued and other liabilities	1,573,417	2,243,515
Accrued compensation	1,002,575	1,239,247
Total current liabilities	10,466,804	10,404,709

Convertible notes payable and equipment loan,		
net of current portion	300,062,393	100,000,000

Shareholders' deficit:		
Preferred stock, no par value: Authorized - 5,000,000 shares	—	—
Common stock, no par value: Authorized - 100,000,000 shares; issued and outstanding - 37,971,936 and 37,368,658 shares	178,041,856	175,713,265

at September 30, 2005 and December 31, 2004, respectively		
Warrants	606,755	828,804
Deferred stock compensation	(89,544)	(324,607)
Accumulated deficit	(276,014,834)	(212,120,547)
Accumulated other comprehensive loss	(208,121)	(39,297)
Total shareholders' deficit	(97,663,888)	(35,942,382)
Total liabilities and shareholders' deficit	\$	\$ 74,462,327
	212,865,309	

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

**ATHEROGENICS, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Revenues	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	20,459,188	16,636,708	55,995,126	44,483,900
General and administrative	2,082,075	1,410,175	6,134,624	4,841,784
Total operating expenses	22,541,263	18,046,883	62,129,750	49,325,684
Operating loss	(22,541,263)	(18,046,883)	(62,129,750)	(49,325,684)
Interest and other income	1,755,508	343,795	4,881,021	1,089,877
Interest expense	(2,271,597)	(1,300,028)	(6,645,558)	(3,895,169)
Net loss	\$ (23,057,352)	\$ (19,003,116)	\$ (63,894,287)	\$ (52,130,976)
Net loss per share -				
basic and diluted	\$ (0.61)	\$ (0.51)	\$ (1.69)	\$ (1.41)
Weighted average shares				
outstanding - basic and diluted	37,852,507	37,047,826	37,701,715	36,976,911

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

**ATHEROGENICS, INC.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
**(Unaudited)**

**Nine months ended**  
**September 30,**  
**2005**                      **2004**

<b>Operating activities</b>		
Net loss	\$	\$
	(63,894,287	(52,130,976
Adjustments to reconcile net loss to net cash used		
in operating activities:		
Depreciation and amortization	721,730	1,077,359
Amortization of debt issuance costs	1,108,784	489,736
Changes in operating assets and liabilities:		
Notes receivable and other assets	(826,805)	49,063
Prepaid expenses	(153,752)	(550,044)
Accounts payable	145,714	1,788,288
Accrued research and development	120,117	2,411,702
Accrued compensation and other	(752,655)	(586,587)
liabilities		
Net cash used in operating activities	(63,531,154)	(47,451,459)
<b>Investing activities</b>		
Purchases of short-term investments	(151,889,430)	(65,073,344)
Sales and maturities of short-term investments	106,291,903	84,983,396
Purchases of equipment and leasehold improvements	(2,183,853)	(240,426)
Net cash (used in) provided by investing activities	(47,781,380)	19,669,626
<b>Financing activities</b>		
Proceeds from the issuance of 1.5% convertible notes	193,566,977	—
Proceeds from the exercise of common stock options	2,211,438	2,587,126
Payments on equipment loan facility	(91,722)	(356,113)
Net cash provided by financing activities	195,686,693	2,231,013
Increase (decrease) in cash and cash equivalents	84,374,159	(25,550,820)
Cash and cash equivalents at beginning of period	15,888,919	53,058,249
Cash and cash equivalents at end of period	\$	\$
	100,263,078	27,507,429

**Supplemental disclosures**

Interest paid	\$	\$
	6,161,775	4,673,321

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

**ATHEROGENICS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**(Unaudited)**

**1. Organization and Nature of Operations**

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

**2. Basis of Presentation**

The accompanying unaudited condensed financial statements reflect all adjustments (consisting solely of normal recurring adjustments) which management considers necessary for a fair presentation of the financial position, results of operations and cash flows of AtheroGenics for the interim periods presented. Certain footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted from the interim financial statements as permitted by the rules and regulations of the Securities and Exchange Commission (the “SEC”). Interim results are not necessarily indicative of results for the full year.

The interim results should be read in conjunction with the financial statements and notes thereto included in AtheroGenics' Annual Report on Form 10-K for the year ended December 31, 2004, as amended by Amendment No. 1 filed on April 6, 2005 and Amendment No. 2 filed on May 6, 2005 (the “Form 10-K”). Shareholders are encouraged to review the Form 10-K for a broader discussion of the opportunities and risks inherent in AtheroGenics' business. Copies of the Form 10-K are available on request.

**3. Recently Issued Accounting Standards**

In December 2004, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards (“SFAS”) No. 123(R), *Share-Based Payment* (“SFAS 123(R)”), which revises SFAS No. 123, *Accounting for Stock-Based Compensation* (“SFAS 123”), and supersedes Accounting Principles Board (“APB”) Opinion No. 25, *Accounting for Stock Issued to Employees* (“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 January 1, 2006. 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. The pro forma disclosures previously permitted under SFAS 123 will no longer be an alternative to financial statement recognition. In March 2005, the SEC issued Staff Accounting Bulletin No. 107 which provides interpretive guidance to assist issuers in their initial implementation of FAS 123R. AtheroGenics is evaluating 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. AtheroGenics expects to adopt SFAS 123(R) on January 1, 2006 and expects that the adoption will have a material impact on its results of operations and net loss per share.

**4. 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 were exercised. Because AtheroGenics reported a net loss for all periods presented, shares



associated with stock options, warrants and convertible notes are not included because their effect would be antidilutive. Basic and diluted net loss per share amounts are the same for the periods presented.

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## 5. Stock-Based Compensation

AtheroGenics has elected to follow APB 25 in accounting for its stock-based employee compensation plans, rather than the alternative fair value accounting method provided for under 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 the fair value of stock-based employee compensation on reported net income (loss) and earnings (loss) per share in annual and interim financial statements.

The following table illustrates the effect on net loss and net loss per share as 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.

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2005	2004	2005	2004
Net loss, as reported	\$ (23,057,352)	\$ (19,003,116)	\$ (63,894,287)	\$ (52,130,976)
Add: Stock-based employee compensation expense included in reported net loss	—	25,526	—	50,933
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(2,182,600)	(1,713,838)	(6,841,315)	(4,433,463)
Pro forma net loss	\$ (25,239,952)	\$ (20,691,428)	\$ (70,735,602)	\$ (56,513,506)
Net loss per share:				
Basic and diluted, as reported	\$ (0.61)	\$ (0.51)	\$ (1.69)	\$ (1.41)
Basic and diluted, pro forma	\$ (0.67)	\$ (0.56)	\$ (1.88)	\$ (1.53)

## 6. Convertible Notes Payable

In August 2003, AtheroGenics issued \$100.0 million in aggregate principal amount of 4.5% convertible notes due September 1, 2008 with interest payable semi-annually in March and September. Net proceeds to AtheroGenics were approximately \$96.7 million, after deducting expenses and underwriter’s discounts and commissions. The issuance costs related to the notes are recorded as debt issuance costs and other assets and are being amortized to interest expense over the five-year life of the notes.

The 4.5% convertible 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 per share, subject to adjustment. Under certain circumstances, AtheroGenics may be obligated to redeem all or part of the 4.5% convertible 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. As of September 30, 2005, accrued and other liabilities included approximately \$375,000 of accrued interest related to the 4.5% convertible notes.

On January 12, 2005, AtheroGenics issued \$200.0 million 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 \$193.6 million, after deducting expenses and underwriter's discounts and

commissions. The issuance costs related to the notes are recorded as debt issuance costs and other assets and are being amortized to interest expense over the seven-year life of the notes.

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 per share, subject to adjustment. Under certain circumstances, AtheroGenics may be obligated to redeem all or part of the 1.5% convertible 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. In addition, under certain circumstances, AtheroGenics may adjust the conversion rate. As of September 30, 2005, accrued and other liabilities included approximately \$500,000 of accrued interest related to the 1.5% convertible notes.

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.

## **7. Bank Credit Agreements**

In March 2002, AtheroGenics entered into an equipment loan facility with Silicon Valley Bank for up to a maximum amount of \$2.5 million to be used to finance existing and new equipment purchases. As of March 31, 2005, the equipment loan facility had been paid in full. In connection with the equipment loan facility, AtheroGenics had granted to Silicon Valley Bank a negative pledge on its intellectual property. This negative pledge was terminated with repayment in full of the equipment loan facility.

## **8. Reclassifications**

In order to present auction rate securities with short-term interest auction features as short-term investments in accordance with SFAS No. 95, *Statement of Cash Flows* and SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, for the nine months ended September 30, 2004, \$6.9 million 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. The effect of the reclassification on cash flows was to increase cash used in investing activities by \$6.9 million for the nine months ended September 30, 2004.

## **9. Commitments and Contingencies**

Except as set forth below, AtheroGenics' commitments and contingencies have not changed significantly from those previously discussed in its Form 10-K.

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 (the "SDNY Actions") 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 "NDGA Actions"). Plaintiffs filed separate motions to consolidate these lawsuits in both the Southern District of New York and the Northern District of Georgia on March 7, 2005. In addition, three class members simultaneously moved for appointment as lead plaintiffs in both districts on March 7, 2005. On April 18, 2005, the Honorable Richard J. Holowell ordered the SDNY Actions consolidated under the caption "*In re Atherogenics Securities Litigation*" (the "SDNY Action") and appointed lead plaintiff and co-lead counsel. On July 5, 2005, AtheroGenics filed a motion to transfer the SDNY Action to the Northern District of Georgia. On July 14, 2005, the plaintiffs voluntarily dismissed the NDGA Actions. The SDNY Action and the defendants' motion to transfer that action to Georgia are still pending. The allegations in these lawsuits relate to AtheroGenics' disclosures regarding the results of the CART-2 clinical trial for AGI-1067. The complaint seeks unspecified damages on behalf of a purported class of purchasers of

AtheroGenics' securities during the period after these disclosures were made in September 2004 to December 31, 2004. AtheroGenics believes that it has meritorious defenses to the plaintiffs' allegations and intends to defend this matter vigorously.

In March 2005, AtheroGenics committed to purchase approximately \$3.5 million of commercial manufacturing equipment for AGI-1067, to be delivered in 2006. As of September 30, 2005, AtheroGenics has recorded \$1.9 million related to the purchase of this equipment.

## 10. Subsequent Events

Effective October 27, 2005, AtheroGenics entered into a commercial supply agreement with a multinational pharmaceutical chemical manufacturing company for the manufacture of the bulk active ingredient of AGI-1067. The agreement sets forth minimum annual purchase requirements, which can reach an aggregate of \$19 million over the initial seven-year term of the agreement, if marketing approval of AGI-1067 is received from the U. S. Food and Drug Administration ("FDA"). In the event AGI-1067 does not receive FDA approval, the agreement can be renegotiated or terminated with the payment of a termination fee of up to \$750,000.

### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The following should be read with the financial statements and related footnotes and Management's Discussion and Analysis of Financial Condition and Results of Operations included in AtheroGenics' Annual Report on Form 10-K for the fiscal year ended December 31, 2004, as amended by Amendment No. 1 filed on April 6, 2005 and Amendment No. 2 filed on May 6, 2005 (the "Annual Report on Form 10-K"). The results discussed below are not necessarily indicative of the results to be expected in any future periods. The following discussion contains forward-looking statements that are subject to risks and uncertainties which could cause actual results to differ from the statements made. These risks are set forth in more detail in our Annual Report on Form 10-K.*

## 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> 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.

In 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 FDA, we developed 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 2003. A Special Protocol Assessment is written confirmation from the FDA

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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 were 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 included 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 approximately 990. We have completed patient enrollment with a total of 6,127 patients in the study. We expect to complete the ARISE trial by approximately the end of the first quarter of 2006, although the actual end of the trial will be determined by the accumulation of the requisite number of primary events. We plan to file a New Drug Application with the FDA as soon as possible after we complete the trial and analyze the results.

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 2004, we announced a collaboration with Astellas Pharma Inc. (formerly Fujisawa Pharmaceutical Co., Ltd.) to conduct preclinical and early-stage clinical trials, with Astellas funding all development costs during the term of the initial agreement. Astellas will also receive an option to negotiate for late stage development and commercial right to AGI-1096. In September 2005, the collaboration with Astellas expired, and we are in active discussions with Astellas regarding an extension of the collaboration agreement.

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 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. 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:

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	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Direct external costs:				
AGI-1067	\$ 12,981,694	\$ 8,822,736	\$ 40,975,276	\$ 24,854,714
AGIX-4207*	86,286	291,183	114,245	3,127,992
AGI-1096	—	(32,536)	—	12,325
Unallocated costs and other programs	7,391,208	7,555,325	14,905,605	16,488,869
Total research and development	\$ 20,459,188	\$ 16,636,708	\$ 55,995,126	\$ 44,483,900

\* In 2004, we discontinued clinical development of AGIX-4207.

From inception, we have devoted the large majority of our research and development efforts and financial resources to support the development of the AGI-1067 product candidate. Spending for the AGI-1096 program in both periods presented was funded by our collaborative development partner, Astellas.

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 in the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2004, under the headings Risks Related to Development of Our Product Candidates and Risks Related to Regulatory Approval of Our Product Candidates.

We have not received any commercial revenues from product sales. We expect to incur significant losses in most years prior to deriving any product revenue as we continue to increase research and development costs. We have incurred significant losses since we began operations in 1994 and as of September 30, 2005, we had an accumulated deficit of \$276.0 million. We cannot assure you that we will become profitable. We expect that losses will fluctuate from quarter to quarter and that these fluctuations may be substantial. Our ability to achieve profitability depends upon a variety of factors, including our ability, alone or with others, to complete the successful development of our product candidates, to obtain required regulatory clearances, and to manufacture and market our future products.

## CRITICAL ACCOUNTING POLICIES

AtheroGenics considers certain accounting policies related to use of estimates, research and development accruals and stock-based compensation to be critical policies. There have been no material changes in the critical accounting policies from what was previously disclosed in our Annual Report on Form 10-K.

## RESULTS OF OPERATIONS

### Comparison of the Three and Nine Month Periods Ended September 30, 2005 and 2004

#### Revenues

There were no revenues during the three and nine months ended September 30, 2005 and 2004.

*Expenses*

*Research and Development.* Research and development expenses increased 23% to \$20.5 million for the three months ended September 30, 2005 from \$16.6 million for the comparable period in 2004, and 26% to \$56.0 million for the nine months ended September 30, 2005 from \$44.5 million in the comparable period in 2004. The increase in research and development expenses for the three and nine months ended September 30, 2005 was

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primarily due to clinical trial expenditures related to AGI-1067, principally the ARISE clinical trial, partially offset by reduced spending in the completed CART-2 clinical trial and the discontinued AGIX-4207 program.

*General and Administrative.* General and administrative expenses increased 48% to \$2.1 million for the three months ended September 30, 2005 from \$1.4 million for the comparable period in 2004, and 27% to \$6.1 million for the nine months ended September 30, 2005 from \$4.8 million in the comparable period in 2004. The increase in general and administrative expenses for the three and nine months ended September 30, 2005 was primarily due to pre-commercialization costs associated with AGI-1067, including market research and thought-leader awareness programs, recruiting and employment related costs associated with the expansion of our management team, and recruiting fees incurred to fill vacant board of directors seats. In addition, we have also incurred higher legal fees than in the prior year.

#### *Interest and Other Income*

Interest income was \$1.8 million and \$343,795 for the three months ended September 30, 2005 and 2004, respectively, and \$4.9 million and \$1.1 million for the nine months ended September 30, 2005 and 2004, respectively. The increase in interest income in the three and nine months ended September 30, 2005 is due to interest earned on the funds received from our \$200.0 million convertible debt offering in January 2005 and higher interest rates.

#### *Interest Expense*

Interest expense was \$2.3 million and \$1.3 million for the three months ended September 30, 2005 and 2004, respectively, and \$6.6 million and \$3.9 million for the nine months ended September 30, 2005 and 2004, respectively. The increase in interest expense for the three and nine months ended September 30, 2005 is due to our \$200.0 million convertible debt offering in January 2005.

## **LIQUIDITY AND CAPITAL RESOURCES**

Since inception, we have financed our operations primarily through sales of equity securities and convertible notes. At September 30, 2005, we had cash, cash equivalents and short-term investments of \$196.7 million, compared to \$66.9 million at December 31, 2004. Working capital at September 30, 2005 was \$190.4 million, compared to \$59.7 million at December 31, 2004. The increase in cash, cash equivalents, short-term investments and working capital is primarily due to the issuance of our 1.5% convertible notes in January 2005 that raised net proceeds of approximately \$193.6 million, partially offset by the use of funds for operating purposes and capital equipment purchases.

Net cash used in operating activities was \$63.5 million for the nine months ended September 30, 2005, compared to \$47.5 million for the comparable period in 2004. The increase in the use of cash in operating activities is principally due to funding a net loss of \$63.9 million. The increase in cash used to fund the net loss is primarily attributable to expenditures for our AGI-1067 compound including the ARISE clinical trial and other ongoing research and development activities. We anticipate net cash usage in 2005 and 2006 for ARISE to be an aggregate of approximately \$60.0 million. We anticipate total net cash usage in 2005 for ARISE and our other ongoing clinical programs, as well as our other operating activities, to be in a range of \$85.0 million to \$89.0 million.

Net cash used in investing activities was \$47.8 million for the nine months ended September 30, 2005, compared to \$19.7 million provided by investing activities for the comparable period in 2004. The increase in net cash used in investing activities during the nine months ended September 30, 2005 is due to purchasing short-term, available-for-sale securities using a portion of the funds received from the issuance of our 1.5% convertible notes. The net cash provided by investing activities in the nine months ended September 30, 2004 was primarily due to sales of short-term investments.

Net cash provided by financing activities was \$195.7 million for the nine months ended September 30, 2005, and \$2.2 million for the comparable period in 2004. The increase in net cash provided by financing activities in the nine months ended September 30, 2005 consisted primarily of net proceeds of approximately \$193.6 million

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from the issuance of our 1.5% convertible notes. Net cash provided by financing activities for the comparable period in 2004 consisted primarily of proceeds from 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. In March 2005, the equipment loan facility had been paid in full.

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. Interest on the 4.5% convertible notes is payable semi-annually in arrears on March 1 and September 1. Net proceeds were approximately \$96.7 million. As of September 30, 2005, there was \$375,000 of accrued interest related to the notes.

In January 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 initially 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 \$193.6 million. The net proceeds from the sale of the notes are being used 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. As of September 30, 2005, there was \$500,000 of accrued interest related to these notes.

In March 2005, we committed to purchase approximately \$3.5 million of commercial manufacturing equipment for AGI-1067, to be delivered in 2006. As of September 30, 2005, we have recorded \$1.9 million related to the purchase of this equipment.

The following table summarizes our long-term contractual obligations as of September 30, 2005.

	<b>Total</b>	<b>Remainder of 2005</b>	<b>2006-2007</b>	<b>2008-2009</b>	<b>Thereafter</b>
<b>Contractual obligations:</b>					
Operating leases, net of sublease income	\$ 4,307,003	\$ 262,026	\$ 2,663,488	\$ 1,381,489	\$ —
Long-term debt	300,095,777	8,197	69,219	100,018,361	200,000,000
<b>Total contractual obligations</b>	<b>\$ 304,402,780</b>	<b>\$ 270,223</b>	<b>\$ 2,732,707</b>	<b>\$ 101,399,850</b>	<b>\$ 200,000,000</b>

Based upon the current status of our product development and commercialization plans, we believe that our existing cash, cash equivalents and short-term investments 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.

## **FORWARD-LOOKING STATEMENTS**

The Private Securities Litigation Reform Act of 1995 (the "Reform Act") 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, such as projections about our future results of operations or 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 management's then current views and assumptions regarding future events and operating performance, and speak only as of their dates. AtheroGenics undertakes 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:

- AGI-1067 and AGI-1096 may fail in clinical trials;
- our ability to generate positive cash flow in light of our history of operating losses;
- our inability to obtain additional financing on satisfactory terms, which could preclude us from developing or marketing our products;
- our ability to successfully develop our other product candidates;
- our ability to commercialize our product candidates if we fail to demonstrate adequately their safety and efficacy;
- possible delays in our clinical trials;
- our inability to predict whether or when we will obtain regulatory approval to commercialize our product candidates or the timing of any future revenue from these product candidates;
- our need to comply with applicable regulatory requirements in the manufacture and distribution of

our products to avoid incurring penalties that may inhibit our ability to commercialize our products;

- our ability to protect adequately or enforce our intellectual property rights or secure rights to third party patents;
- the ability of our competitors to develop and market anti-inflammatory products that are more effective, have fewer side effects or are less expensive than our current or future product candidates;
- third parties' failure to synthesize and manufacture our product candidates, which could delay our clinical trials or hinder our commercialization prospects;
- our ability to create sales, marketing and distribution capabilities or enter into agreements with third



parties to perform these functions;

- our ability to attract, retain and motivate skilled personnel and cultivate key academic collaborations;
- our ability to obtain an adequate level of reimbursement or acceptable prices for our products;
- 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; and
- conversion of our \$100 million principal amount, 4.5% convertible notes and our \$200 million principal amount, 1.5% convertible notes will dilute the ownership interest of existing shareholders and could adversely affect the market price of our common stock.

The foregoing list of important factors is discussed in more detail in our Annual Report on Form 10-K and is not an exhaustive list.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Market risk represents the risk of loss that may impact our financial position, operating results or cash flows due to changes in U.S. interest rates. This exposure is directly related to our normal operating activities. Our cash, cash equivalents and short-term investments are invested with high quality issuers and are generally of a short-term nature. Interest rates payable on our convertible notes are fixed. As a result, we do not believe that near-term changes in interest rates will have a material effect on our future results of operations.

### **Item 4. Controls and Procedures**

*Evaluation of disclosure controls and procedures.* Our chief executive officer and chief financial officer are responsible for establishing and maintaining "disclosure controls and procedures" (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) and 15d-15(e)) for AtheroGenics. Our chief executive officer and chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures as of the end of the period covered by this quarterly report, have concluded that our disclosure controls and procedures are effective.

*Changes in internal control over financial reporting.* There were no 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.

## **PART II - OTHER INFORMATION**

### **Item 1. Legal Proceedings**

See *Note 9. Commitments and Contingencies* in the Notes to Condensed Financial Statements for a description of the pending legal proceedings, which description is incorporated herein by reference.

### **Item 5. Other Information**

Effective October 27, 2005, we entered into a Commercial Supply Agreement with The Dow Chemical Company that provides for the manufacture by Dow of the bulk active ingredient of AGI-1067, our oral drug candidate for the treatment of atherosclerosis. The agreement also provides for the manufacture, at our option, of ProbucoL USP, the starting material used in the manufacturing process of AGI-1067, that is available from several alternative sources. The initial term of the agreement is from the effective date until October 1, 2012, at which point the agreement continues automatically for a period of five years unless either party gives written notice, on or before October 1, 2010, of the party's intent to let the agreement expire at the end of the initial term.

The agreement sets forth minimum annual purchase requirements for us for AGI-1067, which may be satisfied in part by the purchase of specified quantities of ProbucoL USP. If annual orders are less than the minimum

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requirement for a production year, we must pay a fee which is reduced by an amount based on the percentage of the minimum requirement actually purchased. The minimum requirements are also subject to adjustment under certain circumstances, including delay in or failure to receive marketing approval from the FDA for AGI-1067, or to renegotiation if annual orders are lower than the minimum amount for two consecutive production years. The aggregate cost to us over the initial seven-year term of the agreement for the minimum purchase requirements is expected to be approximately \$19 million, subject to FDA marketing approval and to adjustment for other circumstances indicated above.

If we do not obtain FDA marketing approval for AGI-1067, we can renegotiate or terminate the agreement, with the payment of a termination fee to Dow. The amount of the termination fee can be up to \$750,000, subject to reduction based on the amount of capital costs incurred by Dow. If we request that Dow incur capital costs related to the production of ProbucoL, we may also incur an additional fee based on the amount of those costs. Any termination fees will be reduced based on the amount of purchases made by us prior to termination.

#### **Item 6. Exhibits**

##### Exhibits

Exhibit 10.1 - First Amendment dated August 3, 2005 to the License Agreement dated January 11, 1995 between Emory University and AtheroGenics, Inc.

Exhibit 31.1 - Certifications of Chief Executive Officer under Rule 13a-14(a).

Exhibit 31.2 - Certifications of Chief Financial Officer under Rule 13a-14(a).

Exhibit 32 - Certifications of Chief Executive Officer and Chief Financial Officer under Section 1350.



**SIGNATURES**

Pursuant to the requirements 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.

**ATHEROGENICS, INC.**

Date: November 2, 2005

/s/MARK P. COLONNESE

Mark P. Colonnese

Senior Vice President of Finance and

Administration and Chief Financial

Officer