

ATHEROGENICS INC
Form 10-Q
August 08, 2006

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

FORM 10-Q

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

For the quarterly period ended June 30, 2006

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)

(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 [X] No []

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Rule 12b-2 of the Act).

Large accelerated filer [] Accelerated filer [X] Non-accelerated filer []

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

As of August 4, 2006 there were 39,451,498 shares of the registrant's common stock outstanding.

ATHEROGENICS, INC.
FORM 10-Q
INDEX

PART I. FINANCIAL INFORMATION	Page No.
Item 1. Condensed Financial Statements (unaudited)	
Condensed Balance Sheets	
June 30, 2006 and December 31, 2005	1
Condensed Statements of Operations	
Three and six months ended June 30, 2006 and 2005	2
Condensed Statements of Cash Flows	
Six months ended June 30, 2006 and 2005	3
Notes to Condensed Financial Statements	4
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	8
Item 3. Quantitative and Qualitative Disclosures About Market Risk	15
Item 4. Controls and Procedures	15
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	15
Item 4. Submission of Matters to a Vote of Security Holders	15
Item 6. Exhibits	16
SIGNATURES	17

PART I. - FINANCIAL INFORMATION

Item 1. Financial Statements

ATHEROGENICS, INC.
CONDENSED BALANCE SHEETS
(Unaudited)

	June 30, 2006	December 31, 2005
Assets		
Current assets:		
Cash and cash equivalents	\$ 106,957,349	\$ 82,831,679
Short-term investments	86,859,737	99,672,844
Prepaid expenses	3,550,423	2,639,900
Interest and other receivables	2,091,275	900,192
Total current assets	199,458,784	186,044,615
Equipment and leasehold improvements, net of accumulated depreciation and amortization	4,816,528	4,108,462
Debt issuance costs and other assets	6,364,083	7,344,450
Total assets	\$ 210,639,395	\$ 197,497,527
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	\$ 2,095,873	\$ 2,188,461
Accrued research and development	2,889,599	3,946,970
Accrued interest	2,540,000	2,750,000
Accrued compensation	916,836	2,649,640
Accrued and other liabilities	687,925	1,344,876
Current portion of deferred revenue	25,000,000	—
Total current liabilities	34,130,233	12,879,947
Convertible notes payable and equipment loan, net of current portion	286,000,000	300,053,796
Long-term portion of deferred revenue	14,583,333	—
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 —		
39,450,874 and 38,143,678 shares at June 30, 2006		
and December 31, 2005, respectively	202,381,163	178,771,376
Warrants	613,021	620,223
Accumulated deficit	(326,955,904)	(294,674,874)
Accumulated other comprehensive loss	(112,451)	(152,941)
Total shareholders' deficit	(124,074,171)	(115,436,216)
Total liabilities and shareholders' deficit	\$ 210,639,395	\$ 197,497,527

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

1

ATHEROGENICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2006	2005	2006	2005
License fee revenue	\$ 6,250,000	\$ —	10,416,667	\$ —
Operating expenses:				
Research and development	16,447,180	19,380,868	32,707,802	35,535,938
Marketing, general and administrative	3,171,869	2,231,731	6,879,202	4,052,549
Total operating expenses	19,619,049	21,612,599	39,587,004	39,588,487
Operating loss	(13,369,049)	(21,612,599)	(29,170,337)	(39,588,487)
Interest and other income	2,401,424	1,677,608	4,606,658	3,125,512
Interest expense	(2,088,598)	(2,270,388)	(4,196,115)	(4,373,961)
Other expense	—	—	(3,521,236)	—
Net loss	\$ (13,056,223)	\$ (22,205,379)	\$ (32,281,030)	\$ (40,836,936)
Net loss per share -				
basic and diluted	\$ (0.33)	\$ (0.59)	\$ (0.82)	\$ (1.09)
Weighted average shares				
outstanding - basic and diluted	39,423,059	37,716,509	39,313,178	37,625,069

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

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

	Six months ended June 30,	
	2006	2005
Operating activities		
Net loss	\$ (32,281,030)	\$ (40,836,936)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Amortization of license fee	(10,416,667)	—
Loss on debt conversion	3,536,962	—
Stock-based compensation	4,341,492	81,632
Depreciation and amortization	453,683	378,277
Amortization of debt issuance costs	743,462	713,395
Changes in operating assets and liabilities:		
Interest and other receivables	(1,191,083)	(599,913)
Prepaid expenses	(910,523)	189,862
Accounts payable	(92,588)	174,715
Accrued compensation	(1,732,804)	(484,691)
Accrued research and development	(1,057,371)	(2,008,275)
Accrued and other liabilities	(623,167)	(14,428)
Accrued interest	—	1,408,333
Deferred revenue	50,000,000	—
Net cash provided by (used in) operating activities	10,770,366	(40,998,029)
Investing activities		
Sales and maturities of short-term investments	63,497,596	42,864,820
Purchases of short-term investments	(50,643,999)	(118,573,432)
Purchases of equipment and leasehold improvements	(1,161,749)	(1,153,735)
Net cash provided by (used in) investing activities	11,691,848	(76,862,347)
Financing activities		
Proceeds from the exercise of common stock options	1,751,036	1,262,830
Payments on equipment loan facility	(87,580)	(83,622)
Proceeds from the issuance of 1.5% convertible notes	—	193,566,977
Net cash provided by financing activities	1,663,456	194,746,185
Increase in cash and cash equivalents	24,125,670	76,885,809
Cash and cash equivalents at beginning of period	82,831,679	15,888,919
Cash and cash equivalents at end of period	\$ 106,957,349	\$ 92,774,728
Supplemental disclosures		
Interest paid	\$ 3,435,000	\$ 2,252,233

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 U.S. generally accepted accounting principles 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, 2005, filed with the SEC on March 10, 2006 (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. Revenue Recognition

AtheroGenics recognizes revenue in accordance with the SEC’s Staff Accounting Bulletin (“SAB”) No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*, (“SAB 104”). SAB 104 provides guidance in applying U.S. generally accepted accounting principles to revenue recognition issues, and specifically addresses revenue recognition for upfront, nonrefundable fees received in connection with research collaboration agreements.

In accordance with SAB 104, license fees, which are nonrefundable, are recognized over the period the related license agreements specify that efforts or obligations are required of AtheroGenics. In February 2006, AtheroGenics received a \$50 million license fee in connection with its license and collaboration agreement with AstraZeneca. The upfront license payment will be recognized on a straight-line basis over the 24-month period that AtheroGenics estimates it is obligated to provide services to the licensee. In 2006, revenues will be approximately \$23 million related to the amortization of the upfront license fee from AstraZeneca.

4. Net Loss per Share

Statement of Financial Accounting Standards (“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.

5. Stock-Based Compensation

In December 2004, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 123(R), *Share-Based Payment*, (“SFAS 123(R)”), which revises SFAS No. 123 *Accounting for Stock-Based Compensation* (“SFAS 123”).

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 expense associated with stock option grants and other equity instruments to employees in the financial statements. SFAS 123(R) is effective January 1, 2006 and applies to all grants after the effective date and to the unvested portion of stock options outstanding as of the effective date.

On January 1, 2006, AtheroGenics adopted SFAS 123(R) using the modified prospective method. For the three and six months ended June 30, 2006, AtheroGenics recorded approximately \$2.3 million and \$4.3 million, respectively of stock-based compensation expense. As a result of adopting SFAS 123(R), AtheroGenics’ net loss per share was impacted \$(0.06) and \$(0.11) for the three months and six months ended June 30, 2006, respectively. AtheroGenics has a net operating loss carryforward as of June 30, 2006, and therefore no excess tax benefits for tax deductions related to the stock-based awards were recognized. As of June 30, 2006, unamortized stock-based compensation expenses of approximately \$21.3 million remain to be recognized over a weighted average period of approximately three years.

AtheroGenics estimated the fair value of stock options granted during the three and six months ended June 30, 2006 using the Black-Scholes option valuation model. AtheroGenics has calculated a 6.92% forfeiture rate based on historical data. Expected volatility is based on historical volatility of AtheroGenics’ common stock. The expected term of the stock options granted is also based on historical data and represents the period of time that stock options granted are expected to be outstanding. The risk free rate is based on the U.S. Treasury rates in effect at the time of the grant for periods corresponding with the expected term of the options. The weighted average assumptions used in the Black-Scholes model for options granted are as follows:

	Three months ended June 30, 2006	Six months ended June 30, 2006
Expected volatility	67.79%	69.99%
Expected term	5 years	5 years
Risk free interest rate	5.04%	4.70%
Fair value of grants		\$9.40
	\$8.24	

Prior to the adoption of SFAS 123(R), AtheroGenics accounted for its stock-based compensation expenses under the provision of APB 25 and related interpretations. Under APB 25, if the exercise price of employee stock options equals or exceeds the market price of the underlying stock on the date of grant, no compensation expense is recognized. AtheroGenics had adopted the provisions of SFAS 123 as amended by SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure*, using pro forma disclosure only. 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 based on the provisions of SFAS 123.

	Three months ended June 30, 2005	Six months ended June 30, 2005
Net loss, as reported	\$ (22,205,379)	\$ (40, 836,936)
Add: Stock-based employee compensation expense included in reported net loss	—	—
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(2,247,990)	(4,658,715)

Edgar Filing: ATHEROGENICS INC - Form 10-Q

Pro forma net loss	\$	(24,453,369)	\$	(45,495,651)
Net loss per share:				
Basic and diluted, as reported	\$	(0.59)	\$	(1.09)
Basic and diluted, pro forma	\$	(0.65)	\$	(1.21)

5

For stock options granted during the three and six months ended June 30, 2005, the pro forma compensation expense under SFAS 123 was determined using the following weighted average assumptions:

	Three months ended June 30, 2005	Six months ended June 30, 2005
Expected volatility	77.91%	78.10%
Expected term	5 years	5 years
Risk free interest rate	4.13%	4.18%
Fair value of grants	\$8.00	\$8.61

AtheroGenics continues to 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*.

As of January 1, 2006, AtheroGenics had the following equity incentive plans from which stock-based compensation awards could be granted: the Equity Ownership Plan, the 2001 Equity Ownership Plan and the 2004 Equity Ownership Plan (the "Plans"). All of the Plans have been approved by AtheroGenics' shareholders.

Under the Plans, 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. As of June 30, 2006, AtheroGenics had 7,532,644 shares of common stock reserved for issuance under the Plans in connection with outstanding options or future grants. The Plans allow for grants of non-qualified options, incentive stock options and shares of restricted stock. Non-qualified options granted under the Plans may vest immediately for non-employees, but vest over a one to four-year period for employees and directors. Incentive stock options generally vest over four years.

The following is a summary of all stock option activity for the six months ended June 30, 2006.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at January 1, 2006	4,375,632	\$ 11.17		
Granted	1,256,609	15.28		
Exercised	(222,196)	7.88		
Canceled	(169,628)	18.79		
Outstanding at June 30, 2006	5,240,417	12.05	7.08	\$ 19,696,609
	3,055,794		5.73	

Exercisable at June 30, 2006	\$ 8.60	\$ 19,228,267
---------------------------------	------------	------------------

6. Convertible Notes Payable and Equipment Loan

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. In January 2006, AtheroGenics exchanged \$14.0 million in aggregate principal amount of the 4.5% convertible notes for approximately 1.1 million shares of AtheroGenics common stock. In accordance with SFAS No. 84, *Induced Conversion of Convertible Debt*, this transaction resulted

in a non-cash charge of approximately \$3.5 million related to the premium paid in excess of the conversion price in order to induce conversion of the notes.

In January 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.

The conversion rate for both series of notes is subject to adjustment for stock dividends and other dilutive transactions. In addition, AtheroGenics' Board of Directors may, to the extent permitted by applicable law, increase the conversion rate provided that the Board of Directors has determined that such increase is in the best interest of AtheroGenics and such increase remains effective for a period of at least twenty days. AtheroGenics may also be required to redeem the notes on an accelerated basis if AtheroGenics defaults on certain other debt obligations or if AtheroGenics common stock or consideration received in exchange for such common stock is not tradable on a national securities exchange or system of automated quotations.

As of June 30, 2006, AtheroGenics has reserved a total of 13,322,307 shares of common stock for future issuances in connection with the 4.5% convertible notes and the 1.5% convertible notes. In addition, as of June 30, 2006, there was approximately \$1.3 million of accrued interest expense related to the 4.5% notes, which is due September 1, 2006 and \$1.2 million of accrued interest expense related to the 1.5% convertible notes, which is due August 1, 2006.

7. 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"). The allegations in these lawsuits relate to AtheroGenics' disclosures regarding the results of the CART-2 clinical trial for AGI-1067. The complaint sought 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. 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. 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 14, 2005, the plaintiffs voluntarily dismissed the NDGA Actions. On May 22, 2006, AtheroGenics announced that the remaining securities class action lawsuit had been dismissed voluntarily, without prejudice, and without any payment or consideration to the plaintiffs or their counsel.

In March 2005, AtheroGenics committed to purchase approximately \$3.5 million of commercial manufacturing equipment for AGI-1067, to be delivered in 2006. The cost of this equipment will be shared by both AtheroGenics and AstraZeneca as part of the joint license and collaboration agreements that were signed in December 2005.

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, 2005. 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 Form 10-K. In this report, "AtheroGenics," "we," "us" and "our" refer to AtheroGenics, Inc.

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[®], technology platform to discover drugs to treat these types of diseases. Based on our v-protectant[®] 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[®] 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 Food and Drug Administration ("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. A Special Protocol Assessment is written confirmation from the FDA that the protocol is adequately designed to support a New Drug Application ("NDA") 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.

8

Edgar Filing: ATHEROGENICS INC - Form 10-Q

We have completed patient enrollment with a total of 6,127 patients in the study. The target number of events in the study of 990 will yield greater than 95 percent statistical power to detect a 20 percent difference in clinical events between the study arms. We expect to complete the ARISE trial at the end of 2006 and announce the results in early 2007. Assuming positive results, we plan to file an NDA with the FDA as soon as possible thereafter.

In the second half of 2006, we will commence conducting FOCUS (Follow-up Of Clinical Outcomes: The Long-term AGI-1067 plus Usual Care Study). FOCUS is a double-blind follow-up clinical trial in study subjects exiting ARISE, designed to collect more prolonged safety and efficacy information. AstraZeneca will be funding the entire cost of the trial, which could last two years beyond ARISE.

In December 2005, we announced a license and collaboration agreement with AstraZeneca for the global development and commercialization of AGI-1067. Under the terms of the agreement, we received an upfront license fee of \$50 million and, subject to the achievement of specific milestones, including a successful outcome in ARISE, we will be eligible for development and regulatory milestones of up to an aggregate of \$300 million. The agreement also provides for progressively demanding sales performance related milestones, the achievement of which could result in up to an additional \$650 million in the aggregate. In addition, we will also receive royalties on product sales. AstraZeneca has the right to terminate the license and collaboration agreement at specified periods as further described in our Annual Report on Form 10-K for the year ended December 31, 2005.

AGI-1096, our second v-protectant[®] candidate, is a novel antioxidant and selective anti-inflammatory agent that 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 Astellas Pharma Inc. (“Astellas”) to further develop AGI-1096 in preclinical and early-stage clinical trials. In a Phase I clinical trial investigating the safety and tolerability of oral AGI-1096 in combination with Astellas’ tacrolimus (Prograf[®]) conducted in healthy volunteers, results indicated that regimens of AGI-1096 administered alone, and concomitant with tacrolimus, were generally well-tolerated, and there were no serious adverse events associated with either regimen during the course of the study. AGI-1096 has also demonstrated pharmacological activity in certain preclinical studies that were conducted as part of the ongoing collaboration. In February 2006, we announced the extension of our collaboration with Astellas to conduct additional trials, with Astellas funding all development costs during the term of the agreement. Astellas will also retain the exclusive option to negotiate with us for late stage development and commercial rights to AGI-1096.

We have also identified additional potential v-protectant[®] candidates to treat other chronic inflammatory diseases, including rheumatoid arthritis and asthma. We are evaluating these v-protectants[®] 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.

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

	Three months ended		Six months ended	
	June 30,		June 30,	
	2006	2005	2006	2005
Direct external AGI-1067 costs	\$ 9,376,078	\$ 15,018,838	\$ 19,674,308	\$ 27,993,582
Unallocated internal costs and other programs	7,071,102	4,362,030	13,033,494	7,542,356
Total research and development	\$ 16,447,180	\$ 19,380,868	\$ 32,707,802	\$ 35,535,938

Edgar Filing: ATHEROGENICS INC - Form 10-Q

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. We will retain responsibility for the ongoing ARISE clinical trial and for regulatory filings in the United States. AstraZeneca will have full responsibility for pre-commercialization activities involving AGI-1067 and will oversee all aspects of the marketing, sales and distribution of AGI-1067 on a worldwide basis. AstraZeneca will also be responsible for all non-U.S. regulatory filings. Spending for the AGI-1096 program in 2006 and 2005 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 our risk factors included in our Form 10-K for the year ended December 31, 2005, under the headings “*Risks Related to Development and Commercialization of Our Product Candidates and Dependence on Third Parties*” and “*Risks Related to Regulatory Approval of Our Product Candidates.*”

We have not derived any commercial revenues from product sales. We expect to incur significant losses in most years prior to deriving any such product revenue as we continue to increase research and development costs. We have funded our operations primarily through sales of equity and debt securities. We have incurred significant losses since we began operations and, as of June 30, 2006, had an accumulated deficit of \$327.0 million. We cannot assure you that we will become profitable or receive any milestone-related revenues under our agreement with AstraZeneca. We expect that losses will fluctuate from quarter to quarter and that these fluctuations may be substantial. Our ability to achieve profitability depends upon our ability, alone or with others, to complete the successful development of our product candidates, to obtain required regulatory clearances and to manufacture and market our future products.

Critical Accounting Policies and Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions and select accounting policies that affect the amounts reported in our financial statements and the accompanying notes. Actual results could significantly differ from those estimates. We have identified the following policies and related estimates as critical to our business operations and the understanding of our results of operations. A description of these critical accounting policies and a discussion of the significant estimates and judgments associated with these policies are set forth below.

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

We recognize revenue in accordance with the SEC’s Staff Accounting Bulletin (“SAB”) No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*, (“SAB 104”). SAB 104 provides guidance in applying U.S. generally accepted accounting principles to revenue recognition issues, and specifically addresses revenue recognition for upfront, nonrefundable fees received in connection with research collaboration agreements.

In accordance with SAB 104, license fees, which are nonrefundable, are recognized when the related license agreements specify that no further efforts or obligations are required of us. In February 2006, we received a \$50 million license fee in connection with our license and collaboration agreement with AstraZeneca. The upfront license payment will be recognized on a straight-line basis over the 24-month period that we estimate we are obligated to provide services to the licensee. In 2006, revenues will be approximately \$23 million related to the amortization of the upfront license fee from AstraZeneca.

Stock-Based Compensation

Effective January 1, 2006, we adopted the provisions of the Financial Accounting Standards Board ("FASB") SFAS No. 123(R), *Share-Based Payment* ("SFAS 123(R)"), which revises SFAS No. 123, *Accounting for Stock-Based Compensation* and supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*. SFAS 123(R) requires that companies recognize compensation expense associated with stock option grants and other equity instruments to employees in the financial statements. 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 are no longer an alternative to financial statement recognition. We are using the modified-prospective method and the Black-Scholes valuation model for valuing the share-based payments. We will continue to 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*.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2006 and 2005

Revenues

Revenues for the three months and six months ended June 30, 2006 were \$6.3 million and \$10.4 million, respectively. The revenues for both periods are attributable to the license and collaboration agreement, effective January 2006, with AstraZeneca for the development and commercialization of AGI-1067. This amount represents the earned portion of the \$50.0 million license fee that is being amortized over 24 months. There were no revenues during 2005.

Expenses

Research and Development. Research and development expenses decreased 15% to \$16.4 million for the three months ended June 30, 2006 from \$19.4 million for the comparable period in 2005, and 8% to \$32.7 million for the six months ended June 30, 2006 from \$35.5 million for the comparable period in 2005. The decrease in research and development expenses for the three and six months ended June 30, 2006 is primarily due to lower development expenses for AtheroGenics' ongoing AGI-1067 clinical program, including clinical supplies and manufacturing scale-up activities. The decrease is partially offset by non-cash stock-based compensation expense of \$1.2 million and \$2.3 million for the three and six months ended June 30, 2006, respectively. AtheroGenics anticipates that research and development expense will increase in the second half of 2006, compared to the amount spent in the first half, as it undertakes activities to close down the ARISE clinical trial.

Marketing, General and Administrative. Marketing, general and administrative expenses increased 42% to \$3.2 million for the three months ended June 30, 2006 from \$2.2 million for the comparable period in 2005, and 70% to \$6.9 million for the six months ended June 30, 2006 from \$4.1 million for the comparable period in 2005. The increase for the three months ended June 30, 2006 is primarily due to \$1.1 million of non-cash stock-based compensation expense. The increase for the six months ended June 30, 2006 is primarily due to \$2.0 million of non-cash stock-based compensation expense as well as higher professional fees.

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 \$2.4 million and \$4.6 million for the three and six months ended June 30, 2006, respectively, compared to \$1.7 million and \$3.1 million for the three and six months ended June 30, 2005,

respectively. The increase for the three and six months ended June 30, 2006 is due to an increase in interest rates on our interest bearing accounts.

Interest Expense

Interest expense was \$2.1 million and \$4.2 million for the three and six months ended June 30, 2006, respectively and \$2.3 million and \$4.4 million for the three and six months ended June 30, 2005, respectively. The decrease for the three and six-month period is due to the lower aggregate principal amount of our 4.5% convertible notes outstanding compared to the prior year.

Other Expense

Other expense was \$3.5 million for the six months ended June 30, 2006. The increase in other expense is due to \$3.5 million of non-cash expense related to the exchange of \$14.0 million of AtheroGenics' 4.5% convertible notes for common stock in the first quarter of 2006.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through sales of equity securities and convertible notes. At June 30, 2006, we had cash, cash equivalents and short-term investments of \$193.8 million, compared with \$182.5 million at December 31, 2005. Working capital at June 30, 2006 was \$165.3 million, compared to \$173.2 million at December 31, 2005. The increase in cash, cash equivalents and short-term investments and working capital for the six months ended June 30, 2006 is due to the \$50.0 million license fee received from AstraZeneca in connection with our license and collaboration agreement, partially offset by the use of funds for operating purposes and capital equipment purchases.

Net cash provided by operating activities was \$10.8 million for the six months ended June 30, 2006 compared to net cash used in operating activities of \$41.0 million for the six months ended June 30, 2005. The increase in net cash provided by operating activities for the six months ended June 30, 2006 is principally due to the \$50.0 million license fee received from AstraZeneca, partially offset by cash used to fund our operating activities. These activities include the expenditures for our ARISE Phase III clinical trial and our other ongoing product development programs. For 2006, expenditures for the ARISE clinical trial are estimated to be approximately \$33.0 million. We anticipate net cash usage in 2006 for ARISE and our other ongoing preclinical and clinical programs, as well as our other operating activities, to be in a range of \$35.0 million to \$40.0 million, which is net of the \$50.0 million license fee received from AstraZeneca in February 2006.

Net cash provided by investing activities was \$11.7 million for the six months ended June 30, 2006 compared to net cash used in investing activities of \$76.9 million for the six months ended June 30, 2005. Net cash provided by investing activities for the six months ended June 30, 2006 consisted primarily of the sale of short-term investments and net cash used in investing activities for the six months ended June 30, 2005 consisted primarily of net purchases of available-for-sale securities.

Net cash provided by financing activities was \$1.7 million for the six months ended June 30, 2006 compared to \$194.7 million for the six months ended June 30, 2005. Net cash provided by financing activities for the six months ended June 30, 2006 consisted primarily of the proceeds received upon exercise of common stock options. Net cash provided by financing activities for the six months ended June 30, 2005 consisted primarily of \$193.6 million received from the issuance of 1.5% convertible notes in January 2005.

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. Interest on the 4.5% convertible notes is payable semi-annually in arrears on March 1 and September 1. In January 2006, we exchanged \$14.0 million in aggregate principal amount of

the 4.5% convertible notes for 1,085,000 shares of our common stock. From time to time, we may enter into additional exchange offers and/or purchases of these notes. As of June 30, 2006, we have recorded \$1.3 million of accrued interest expense related to the 4.5% notes, which is due September 1, 2006.

Edgar Filing: ATHEROGENICS INC - Form 10-Q

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 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. We are using the net proceeds from the sale of the 1.5% 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, 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 June 30, 2006, we have recorded \$1.2 million of accrued interest expense related to the 1.5% notes, which is due August 1, 2006.

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 June 30, 2006, we have recorded \$2.0 million related to the purchase of this equipment. The cost of this equipment will be shared by both AtheroGenics and AstraZeneca as part of the joint license and collaboration agreements that were signed in December 2005. We expect our portion of future construction and installation costs of the commercial manufacturing equipment to be approximately \$7.0 million over the life of the construction project.

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 following:

- the scope and results of our research, preclinical and clinical development activities;
 - the timing of, and the costs involved in, obtaining regulatory approvals;
- the timing, receipt and amount of sales and royalties, if any, from our potential product candidates;
 - the timing, receipt and amount of milestone and other payments, if any;
- our ability to maintain our collaborations with AstraZeneca and Astellas and the financial terms of our collaborations;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs; and
 - 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.

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

Edgar Filing: ATHEROGENICS INC - Form 10-Q

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;
- our substantial dependence on our AstraZeneca collaboration, which may ultimately be unsuccessful;
- 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;
- we may face product liability lawsuits which may cause us to incur substantial financial loss or we 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
- the conversion of our \$86 million principal amount, 4.5% convertible notes and our \$200 million principal amount, 1.5% convertible notes would 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 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 7. 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 4. Submission of Matters to a Vote of Security Holders

Our annual meeting of shareholders was held on April 26, 2006. At the annual meeting, the shareholders of AtheroGenics, (1) elected three Class III directors to serve until the 2009 Annual Meeting of Shareholders and (2) ratified the appointment of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2006.

We had 39,345,181 shares of common stock outstanding on March 1, 2006, the record date of the annual meeting. At the annual meeting, we had 34,051,420 shares of common stock present in person or represented by proxy for the two proposals indicated above. The following sets forth detailed information regarding the results of the voting at the annual meeting.

Proposal 1. Election of three Class III directors

<u>Name of Nominee</u>	<u>No. of Votes For</u>	<u>No. of Votes Withheld</u>
Michael A. Henos	33,263,516	787,904
Russell M. Medford	33,870,303	181,117
Arthur M. Pappas	33,870,083	181,337

Proposal 2. Ratification of the appointment of independent registered public accounting firm

<u>No. of Votes For</u>	<u>No. of Votes Against</u>	<u>Abstention</u>
-------------------------	-----------------------------	-------------------

33,993,489

45,556

12,375

15

Item 6. Exhibits

Exhibits

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.

16

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: August 8, 2006

/s/MARK P. COLONNESE

Mark P. Colonnese
Executive Vice President, Commercial
Operations
and Chief Financial Officer