

ATHEROGENICS INC
Form 10-Q
November 09, 2007

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 September 30, 2007

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 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 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

As of November 7, 2007 there were 39,518,492 shares of the registrant's common stock outstanding.

ATHEROGENICS, INC.
FORM 10-Q
INDEX

PART I. FINANCIAL INFORMATION	<u>Page</u> <u>No.</u>
Item 1. Condensed Financial Statements (unaudited)	
Condensed Balance Sheets	
September 30, 2007 and December 31, 2006	1
Condensed Statements of Operations	
Three and nine months ended September 30, 2007 and 2006	2
Condensed Statements of Cash Flows	
Nine months ended September 30, 2007 and 2006	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	
	14
Item 4. Controls and Procedures	
	15
PART II. OTHER INFORMATION	
Item 1A. Risk Factors	
	15
Item 6. Exhibits	
	15
SIGNATURES	
	16

PART I. – FINANCIAL INFORMATION

Item 1. Financial Statements

ATHEROGENICS, INC.
CONDENSED BALANCE SHEETS
(Unaudited)

	September 30, 2007	December 31, 2006
Assets		
Current assets:		
Cash and cash equivalents	\$ 82,214,256	\$ 87,846,079
Short-term investments	19,201,522	63,964,860
Accounts receivable	7,482,973	6,537,892
Prepaid expenses	3,434,112	4,038,419
Interest receivable	232,671	643,097
Total current assets	112,565,534	163,030,347
Equipment and leasehold improvements, net of accumulated depreciation and amortization	2,563,729	9,684,965
Debt issuance costs and other assets	4,286,145	5,624,352
Total assets	\$ 119,415,408	\$ 178,339,664
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	\$ 5,069,085	\$ 3,183,511
Accrued research and development	3,503,704	11,263,164
Accrued interest	906,538	2,540,000
Accrued compensation	1,525,287	1,465,644
Accrued and other liabilities	607,632	791,661
Current portion of deferred revenue	1,554,369	25,000,000
Current portion of convertible notes payable	48,000,000	—
Total current liabilities	61,166,615	44,243,980
Convertible notes payable, net of current portion	238,980,424	286,000,000
Long-term portion of deferred revenue	—	2,083,333
Shareholders' deficit:		
Preferred stock, no par value: Authorized—5,000,000 shares	—	—

Edgar Filing: ATHEROGENICS INC - Form 10-Q

Common stock, no par value:		
Authorized—100,000,000 shares; issued and outstanding —		
39,518,492 and 39,452,927 shares at September 30, 2007		
and December 31, 2006,		
respectively	214,108,950	207,388,894
Warrants	613,021	613,021
Accumulated deficit	(395,464,018)	(361,997,246)
Accumulated other comprehensive		
gain	10,416	7,682
Total shareholders' deficit	(180,731,631)	(153,987,649)
Total liabilities and shareholders'		
deficit	\$ 119,415,408	\$ 178,339,664

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

ATHEROGENICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three months ended		Nine months ended		
	September 30,		September 30,		
	2007	2006	2007	2006	
Revenues:					
License fees	\$	—	\$ 6,250,000	\$ 27,083,333	\$ 16,666,667
Research and development		7,438,867	4,042,683	22,075,490	4,042,683
Total revenues		7,438,867	10,292,683	49,158,823	20,709,350
Operating expenses:					
Research and development		16,818,119	21,806,971	59,112,592	54,514,773
Marketing, general and administrative		3,086,868	3,111,042	10,619,566	9,990,244
Restructuring and impairment costs		—	—	9,996,332	—
Total operating expenses		19,904,987	24,918,013	79,728,490	64,505,017
Operating loss		(12,466,120)	(14,625,330)	(30,569,667)	(43,795,667)
Interest income		1,310,322	2,391,460	4,798,125	6,998,118
Interest expense		(3,519,669)	(2,139,450)	(7,695,230)	(6,335,565)
Other expense		—	—	—	(3,521,236)
Net loss		\$ (14,675,467)	\$ (14,373,320)	\$ (33,466,772)	\$ (46,654,350)
Net loss per share –					
basic and diluted		\$ (0.37)	\$ (0.36)	\$ (0.85)	\$ (1.19)
Weighted average shares					
outstanding – basic and diluted		39,515,014	39,451,933	39,493,974	39,359,938

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,	
	2007	2006
Operating activities		
Net loss	\$ (33,466,772)	\$ (46,654,350)
Adjustments to reconcile net loss to net cash used in operating activities:		
Asset impairment costs	9,005,153	—
Amortization of deferred revenue	(27,083,333)	(16,666,667)
Stock-based compensation	6,696,982	6,724,633
Amortization of debt issuance costs	1,338,207	1,112,888
Amortization of discount on 4.5% convertible notes due 2011	980,424	—
Depreciation and amortization	710,357	688,295
Loss on debt conversion	—	3,521,236
Changes in operating assets and liabilities:		
Accounts receivable	(945,081)	(6,795,305)
Prepaid expenses	604,307	(2,579,841)
Interest receivable	410,426	171,989
Accounts payable	1,885,574	1,072,796
Accrued research and development	(7,759,460)	3,191,959
Accrued interest	(1,633,462)	(1,649,250)
Accrued compensation	59,643	(1,372,127)
Accrued and other liabilities	(184,029)	(570,750)
Deferred revenue	1,554,369	50,000,000
Net cash used in operating activities	(47,826,695)	(9,804,494)
Investing activities		
Sales and maturities of short-term investments	104,729,736	105,425,992
Purchases of short-term investments	(59,963,664)	(76,895,985)
Purchases of equipment and leasehold improvements	(2,594,274)	(2,502,930)
Net cash provided by investing activities	42,171,798	26,027,077
Financing activities		
Proceeds from the exercise of common stock options	23,074	1,762,357
Payments on equipment loan facility	—	(87,580)
Net cash provided by financing activities	23,074	1,674,777
(Decrease) increase in cash and cash equivalents	(5,631,823)	17,897,360
Cash and cash equivalents at beginning of period	87,846,079	82,831,679

Cash and cash equivalents at end of period	\$ 82,214,256	\$ 100,729,039
--	---------------	----------------

Supplemental disclosures

Interest paid	\$ 7,010,062	\$ 6,871,927
---------------	--------------	--------------

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 diabetes, coronary heart disease and organ transplant rejection.

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, 2006, filed with the SEC on March 8, 2007 (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. Accounts Receivable

Accounts receivable consists of billed and unbilled receivables related to our license and collaboration agreement with AstraZeneca (See Note 4). Unbilled receivables represent amounts earned, which have not been billed as of the current balance sheet date. These amounts are typically billed in the month following the delivery of service. As of September 30, 2007, billed accounts receivable were \$5.0 million and unbilled receivables were \$2.5 million.

4. Revenue Recognition

AtheroGenics recognizes license fee revenues 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 nonrefundable license payment was being recognized on a straight-line basis over the 24-month period that AtheroGenics estimated it was obligated to provide services to the licensee. In April 2007, AstraZeneca announced that it was ending the license and collaboration agreements and any further obligations required of AtheroGenics. As such, the remaining balance of approximately \$20.8 million in deferred revenue related to the license fee was recognized as revenue in the second quarter of 2007.

During the third quarter of 2006, AstraZeneca separately engaged AtheroGenics to perform FOCUS (Follow-up Of Clinical Outcomes: The Long-term AGI-1067 plus Usual Care Study), a follow-up Phase III clinical trial for patients

who have completed ARISE (Aggressive Reduction of Inflammation Stops Events). Revenues under the research and development agreement pertaining to FOCUS are recognized in accordance with Emerging Issues Task Force (“EITF”) Issue No. 99-19, *Reporting Gross Revenue as a Principal vs. Net as an Agent*.

According to the criteria established by EITF Issue No. 99-19, AtheroGenics is the primary obligor of the agreement because it is responsible for the selection, negotiation, contracting and payment of the third party suppliers. In addition, any liabilities resulting from the agreement are the responsibility of AtheroGenics. Research and development revenues are recognized, on a gross basis, as activities are performed under the terms of the related agreement. Revenues that have not been invoiced are reflected as unbilled receivables as described in the accounts receivable note above. Payments received from AstraZeneca, related to FOCUS, for activities not completed are recorded as deferred revenue. AtheroGenics has commenced closing FOCUS. Activities currently in progress will be billed to AstraZeneca in accordance with the agreement.

5. Restructuring and Impairment Costs

In May 2007, AtheroGenics implemented an organizational restructuring plan that reduced its workforce by approximately 50% to 67 employees. This action was designed to streamline company operations and was the first step in the strategic plan to continue advancing the development of AGI-1067. As a result, in accordance with Statement of Financial Accounting Standards ("SFAS") No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, AtheroGenics recorded a charge of approximately \$1.0 million for severance in the second quarter of 2007. As of September 30, 2007, there was \$111,000 remaining in accrued compensation related to the reduction in workforce.

In addition to the reduction in workforce, AtheroGenics determined that in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, certain excess laboratory equipment and related leasehold improvements, as well as commercial manufacturing equipment had been impaired. As AtheroGenics has no assurance that such assets will be utilized, an impairment test was performed in accordance with SFAS No. 144 based on estimates of cash flows associated with the equipment. AtheroGenics recorded a non-cash impairment charge of approximately \$9.0 million in the second quarter of 2007.

6. Income Tax

AtheroGenics files a U.S. federal and Georgia income tax return on an annual basis. AtheroGenics is no longer subject to U.S. federal income or state tax return examinations by tax authorities for years before 2002. However, since AtheroGenics has substantial tax net operating losses originating in years before 2002, the tax authorities may review the amount of the pre-2002 net operating losses. AtheroGenics is not currently under examination by any tax authority.

AtheroGenics adopted the provisions of the Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ("FIN 48") effective January 1, 2007. No cumulative adjustment was required or recorded as a result of the implementation of FIN 48. As of January 1, 2007, AtheroGenics had no unrecognized tax benefits. AtheroGenics will recognize accrued interest and penalties related to unrecognized tax benefits in income tax expense when and if incurred. AtheroGenics had no interest or penalties related to unrecognized tax benefits accrued as of January 1, 2007.

AtheroGenics does not anticipate that unrecognized benefits will be incurred within the next 12 months.

7. 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.

5

8. Stock-Based Compensation

AtheroGenics recognizes stock-based compensation in accordance with SFAS No. 123(R), *Share-Based Payment*. Stock-based compensation of \$1.9 million and \$6.7 million was recorded for the three and nine months ended September 30, 2007, respectively, and \$2.4 million and \$6.7 million for the comparable periods in 2006. AtheroGenics' net loss per share was increased by \$(0.05) and \$(0.17) for stock-based compensation related to stock options for the three and nine months ended September 30, 2007, respectively, compared to \$(0.06) and \$(0.17) for the same periods in 2006. As of September 30, 2007 and 2006, AtheroGenics has a net operating loss carryforward and therefore no excess tax benefits for tax deductions related to the stock options were recognized. During the three and nine months ended September 30, 2007, AtheroGenics granted 38,100 and 1,087,129 stock options, respectively, from the 2004 AtheroGenics, Inc. Equity Ownership Plan ("2004 Plan"). During the three and nine months ended September 30, 2006, AtheroGenics granted 143,500 and 1,400,109 stock options, respectively, from the 2004 Plan.

For the three months and nine months ended September 30, 2007 and 2006, AtheroGenics calculated a forfeiture rate of 8.65% and 6.44%, respectively, 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 interest 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. For stock options granted during the three and nine months ended September 30, 2007 and 2006 the following weighted average assumptions were used:

	Three months ended September 30, 2007		Nine months ended September 30, 2006	
Expected volatility	76.45%	66.37%	82.86%	69.62%
Expected term	5 years	5 years	3.5 years	5 years
Risk free interest rate	4.54%	4.67%	4.91%	4.70%
Fair value of grants	\$1.10	\$7.98	\$1.41	\$9.26

9. Convertible Notes Payable

In August 2003, AtheroGenics issued \$100.0 million in aggregate principal amount of 4.5% convertible notes due September 1, 2008 (the "2008 Notes") with interest payable semi-annually in March and September. Net proceeds to AtheroGenics were approximately \$96.7 million, after deducting expenses and underwriters' 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 2008 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.

On July 11, 2007, AtheroGenics exchanged \$38.0 million in aggregate principal amount of the 2008 Notes with certain holders for \$60.4 million in aggregate principal amount of 4.5% Convertible Notes due 2011 (the “2011 Notes”). The 2011 Notes were issued under an Indenture dated July 11, 2007 between AtheroGenics and The Bank of New York Trust Company of Florida N.A., as Trustee. This exchange was accounted for in accordance with EITF 96-19, *Debtor’s Accounting for a Modification or Exchange of Debt Instruments*. The \$22.4 million difference between the principal amount and the initial fair value of the 2011 Notes, the discount, will be accreted up to the face amount of \$60.4 million as additional interest expense over the remaining life of the new convertible notes. The effective interest rate on the notes is 18.6% and as of September 30, 2007, the remaining balance of the discount on these notes was approximately \$21.4 million.

Edgar Filing: ATHEROGENICS INC - Form 10-Q

The terms of the 2011 Notes are substantially similar to the 2008 Notes including the same customary default events except that the 2011 Notes will mature in March 2011 as opposed to September 2008. The 2011 Notes, like the 2008 Notes, bear an interest rate of 4.5%, payable semiannually in arrears on March 1 and September 1.

Like the 2008 Notes, the 2011 Notes are convertible into shares of AtheroGenics common stock (“Shares”) at any time prior to the close of business on the final maturity date, subject to AtheroGenics’ right to redeem the 2011 Notes prior to their maturity. The initial conversion rate for the 2011 Notes is 65.1890 Shares per \$1,000 principal amount of 2011 Notes.

Also like the 2008 Notes, AtheroGenics may be required to redeem the 2011 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.

In January 2005, AtheroGenics issued \$200.0 million in aggregate principal amount of 1.5% convertible notes due February 1, 2012 (the “2012 Notes”) with interest payable semi-annually in February and August. Net proceeds to AtheroGenics were approximately \$193.6 million, after deducting expenses and underwriters' 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 2012 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 all of the 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 September 30, 2007, AtheroGenics has reserved a total of 14,783,193 shares of common stock for future issuances in connection with all of the convertible notes. In addition, as of September 30, 2007, there was approximately \$407,000 of accrued interest expense related to the 2008 and 2011 Notes, which is due March 1, 2008, and \$500,000 of accrued interest expense related to the 2012 Notes, which is due February 1, 2008.

The following table summarizes our convertible notes as of September 30, 2007:

2008 Notes	\$ 48,000,000
2011 Notes	60,410,000
2012 Notes	200,000,000
Face value of convertible notes	260,410,000
Discount on the 2011 Notes	(21,429,576)
Total 2011 Notes and 2012 Notes	\$ 238,980,424

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, 2006. 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 for the fiscal year ended December 31, 2006 under the headings "Risk Factors" and "Forward-Looking Statements" below as well as the risks described in Part II, Item 1A.. "Risk Factors" in this quarterly report on Form 10-Q. 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 diabetes, coronary heart disease and organ transplant rejection. 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 clinical stage drug development programs.

AGI-1067 is our v-protectant[®] candidate that is most advanced in clinical development. AGI-1067 is an investigational drug with demonstrated anti-inflammatory and anti-oxidant properties that is being investigated to determine its ability to control blood sugar levels in patients with diabetes and to reduce clinical events in patients with cardiovascular disease. Diabetes is a chronic, metabolic disease in which the body does not produce or properly use insulin. Insulin is a hormone that is needed to convert sugar and other food into energy needed for daily life. Oxidative stress and inflammation are believed to play a key role in insulin resistance, impaired insulin secretion and the development of serious complications, including cardiovascular events, in patients with diabetes.

In 2003, we initiated a Phase III trial, referred to as ARISE (Aggressive Reduction of Inflammation Stops Events), which was conducted in cardiac centers in the United States, Canada, the United Kingdom and South Africa. ARISE evaluated the impact of AGI-1067 on a composite measure of heart disease outcomes, including death due to coronary disease, myocardial infarction (heart attack), stroke, coronary re-vascularization and unstable angina, and on diabetes in patients who have coronary heart disease. The study assessed 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, received other appropriate heart disease and diabetes medications, including statins and other cholesterol-lowering therapies, and glycemic control agents.

We completed patient enrollment with more than 6,100 patients in the study. The ARISE trial results were reported in March 2007 and showed that while AGI-1067 did not show a difference from placebo in the composite primary endpoint, the study did achieve a number of other important predefined endpoints. These endpoints included a reduction in the composite of "hard" atherosclerotic clinical endpoints, composed of cardiovascular death, resuscitated cardiac arrest, myocardial infarction and stroke. In a measure of these hard endpoints, AGI-1067 achieved a significant reduction of 19%. A subgroup analysis indicated that this result was consistent across important sub-populations such as: patients with and without diabetes, and men and women. There were also improvements in the key diabetes parameters of new onset diabetes and glycemic control. Patients taking AGI-1067 were 63% less likely to develop new onset diabetes. Our analysis of the safety data indicated that the most common adverse event was diarrhea-related; however, it did not frequently result in patient discontinuation. There was also an observed increase in abnormal liver function tests in a small number of patients compared to those on standard of care. Based on our review to date of the ARISE results, we intend to continue to pursue development of the compound, initially as

a diabetes medication and will continue to evaluate associated safety data. We expect that two controlled registration studies in patients with diabetes will be required to submit a New Drug Application (NDA) for marketing approval. There can ultimately be no assurance that these studies will be successful or that the Food and Drug Administration (FDA) will ultimately accept or approve an NDA.

Edgar Filing: ATHEROGENICS INC - Form 10-Q

In August 2007, we commenced the first registration study called ANDES (AGI-1067 as Novel Anti-Diabetic Agent Evaluation Study), a multi-center, double-blind study with 6-month dosing using three doses, designed to compare the effects of AGI-1067 versus placebo on glycemic endpoints in subjects with confirmed diabetes mellitus. The trial was designed to confirm the pre-specified diabetes findings from the ARISE Phase III clinical trial. In November 2007, after discussions with the FDA, we decided to discontinue the 300 mg dose of AGI-1067 in ANDES based on further review of the overall risk/benefit profile observed in the ARISE clinical trial. The ANDES trial will continue with the two other doses being studied, 75 mg and 150 mg. Patient enrollment began in the third quarter of 2007 and is expected to be completed by the end of 2007. The study protocol provides for an interim analysis which we expect to occur by mid-2008. We believe that ANDES will serve as one of the registration studies needed for an NDA submission, and that at least one additional trial will be required.

In 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 non-refundable license fee of \$50 million. On April 20, 2007, AstraZeneca notified us that pursuant to the terms of the agreement, it was ending the collaboration. The agreement was terminated in July 2007.

In the second half of 2006, we were engaged by AstraZeneca to conduct FOCUS (Follow-up Of Clinical Outcomes: The Long-term AGI-1067 plus Usual Care Study). FOCUS is a follow-up Phase III clinical trial for patients exiting ARISE, designed to collect extended safety information. Pursuant to the terms of our license agreement, AstraZeneca is responsible for funding the entire cost of the trial, which is being concluded.

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 have been working with Astellas Pharma Inc. (“Astellas”) to further develop AGI-1096, with Astellas funding the costs for development activities under the agreement. Astellas has an exclusive option to negotiate with us for late stage development and commercial rights to AGI-1096. 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 study. Astellas has informed us that they have completed their current development activities and do not presently have further development plans.

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2007	2006	2007	2006
Direct external AGI-1067 costs	\$ 14,106,187	\$ 12,256,126	\$ 44,351,188	\$ 31,930,434
Unallocated internal costs and other programs	2,711,932	9,550,845	14,761,404	22,584,339
Total research and development	\$ 16,818,119	\$ 21,806,971	\$ 59,112,592	\$ 54,514,773

From inception, we have devoted the large majority of our research and development efforts and financial resources to support development of the AGI-1067 product candidate. Spending for the AGI-1096 program in 2007 and 2006 was funded by our collaborative development partner, Astellas.

Based on the results of the ARISE clinical trial, AtheroGenics has developed a new business plan to streamline operations and focus on development of AGI-1067. In May 2007, as part of the strategic plan AtheroGenics implemented the following:

Edgar Filing: ATHEROGENICS INC - Form 10-Q

- announced the focus on diabetes as the next step in the development of AGI-1067 and commenced a new Phase III clinical trial, called ANDES, studying the effect of AGI-1067 in patients with diabetes;
- reduced AtheroGenics' near term cash requirements by exchanging \$38.0 million of the 4.5% convertible notes due September 2008 (2008 Notes) for \$60.4 million of 4.5% convertible notes that will be due in March 2011 (2011 Notes);

9

- reduced the workforce by approximately 50%, resulting in a staff of 67 employees; and
- implemented a retention/incentive program for key executive officers and employees.

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, evolving regulatory requirements, 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, 2006, 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*” as well as the risks described in this quarterly report on Form 10-Q.

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. 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 September 30, 2007, had an accumulated deficit of \$395.5 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 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. 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 Months Ended September 30, 2007 and 2006

Revenues

Total revenues were \$7.4 million and \$10.3 million for the three months ended September 30, 2007 and 2006, respectively, and \$49.2 million and \$20.7 million for the nine months ended September 30, 2007 and 2006, respectively. The decrease in revenue for

the three months ended September 30, 2007 is primarily due to the absence of license fee revenues, related to the AGI-1067 license agreement with AstraZeneca, compared to the \$6.3 million of license revenue for the comparable period in 2006. The increase in license fee revenues to \$27.1 million for the nine months ended September 30, 2007 from \$16.7 million in the comparable period in 2006, reflects the recognition of the unamortized balance of the upfront license fee from AstraZeneca, due to the termination of the agreement in April 2007. Research and development revenues increased to \$22.1 million for the nine months ended September 30, 2007 from \$ 4.0 million for the comparable prior year period. The revenues in both periods are for services performed for AstraZeneca related to the FOCUS clinical trial, which began in August 2006. Due to the results of the ARISE clinical trial, AtheroGenics commenced closing the FOCUS clinical trial. AtheroGenics will continue to incur costs and to earn revenue associated with FOCUS during the fourth quarter of 2007.

Expenses

Research and Development. Research and development expenses were \$16.8 million and \$21.8 million for the three months ended September 30, 2007 and 2006, respectively, and \$59.1 million and \$54.5 million for the nine months ended September 30, 2007 and 2006, respectively. The decrease in research and development expenses for the three months ended September 30, 2007 is primarily due to lower costs incurred for the ARISE clinical trial, which was completed in the first half of 2007, and reduced staff costs as a result of the organizational restructuring in the second quarter of 2007. The increase in research and development expense for the nine months ended September 30, 2007 is primarily due to costs of the FOCUS clinical trial, which began in the third quarter of 2006, and start-up costs for the ANDES clinical trial. This increase was partially offset by a decrease in expenses for the ARISE clinical trial.

Marketing, General and Administrative. Marketing, general and administrative expenses were \$3.1 million for the three months ended September 30, 2007 and 2006, and \$10.6 million and \$10.0 million for the nine months ended September 30, 2007 and 2006, respectively. The increase in the nine months ended September 30, 2007 was primarily due to higher staff-related costs.

Restructuring and Impairment Costs. AtheroGenics implemented a new business plan that involved streamlining company operations and focusing on the development of AGI-1067 in diabetes. In connection with the new business plan, restructuring and impairment costs of \$10.0 million were incurred in the nine months ended September 30, 2007. AtheroGenics recorded non-cash asset write-downs of \$7.5 million as a result of the termination of the collaboration and transition of commercial manufacturing activities from AstraZeneca. Other restructuring and impairment costs include severance of approximately \$1.0 million associated with the reduction in workforce and asset impairment costs of approximately \$1.5 million for certain excess laboratory equipment and leasehold improvements that were recorded in the second quarter.

Interest Income

Interest income is primarily comprised of income earned on our cash and short-term investments. Interest income decreased to \$1.3 million for the three months ended September 30, 2007 from \$2.4 million for the comparable period in 2006, and to \$4.8 million for the nine months ended September 30, 2007 from \$7.0 million for the comparable period in 2006. The decrease for the three and nine months ended September 30, 2007 was due to the lower balance of cash and short-term investment funds than in the comparable period in 2006.

Interest Expense

Interest expense is primarily comprised of interest expense related to our convertible notes. Interest expense increased to \$3.5 million for the three months ended September 30, 2007 from \$2.1 million for the comparable period in 2006, and to \$7.7 million for the nine months ended September 30, 2007 from \$6.3 million for the comparable period in 2006. This increase in both periods is due to the write-off of debt issuance costs of approximately \$282,000 related to the \$38.0 million of the 2008 Notes that were exchanged for \$60.4 million of the 2011 Notes, as well as additional

interest of \$604,000 and accretion of the discount of \$980,000 for the newly issued notes.

Other Expense

Other expense was \$3.5 million for the nine months ended September 30, 2006 which reflected non-cash expense related to the exchange of \$14.0 million of AtheroGenics' 2008 Notes for common stock in January 2006.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through sales of equity securities and convertible notes. At September 30, 2007, we had cash, cash equivalents and short-term investments of \$101.4 million, compared with \$151.8 million at December 31, 2006. Working capital at September 30, 2007 was \$51.4 million, compared to \$118.8 million at December 31, 2006. The decrease in cash, cash equivalents and short-term investments and working capital for the nine months ended September 30, 2007 is due to the use of funds for operating purposes and capital equipment purchases, and the current portion of the 2008 Notes.

Net cash used in operating activities was \$47.8 million for the nine months ended September 30, 2007 compared to \$9.8 million for the nine months ended September 30, 2006. The net cash used in operating activities

Edgar Filing: ATHEROGENICS INC - Form 10-Q

for the nine months ended September 30, 2007 was principally for expenditures related to the close-out of ARISE, the close-out of FOCUS and the start-up of ANDES, including the increase in accounts receivable due to expenses incurred for FOCUS that are reimbursable by AstraZeneca. The net cash used in operating activities for the nine months ended September 30, 2006 was principally for ARISE and our other ongoing product development programs, partially offset by the \$50 million license fee received from AstraZeneca. Direct external development costs for ANDES are expected to be approximately \$20 million through the end of 2008.

Net cash provided by investing activities was \$42.2 million for the nine months ended September 30, 2007 compared to \$26.0 million for the nine months ended September 30, 2006. Net cash provided by investing activities for the nine months ended September 30, 2007 and 2006 consisted primarily of the net sales of short-term investments, partially offset by the purchases of equipment and leasehold improvements.

Net cash provided by financing activities was \$23,074 for the nine months ended September 30, 2007 compared to \$1.7 million for the nine months ended September 30, 2006. Net cash provided by financing activities in both periods consisted primarily of the proceeds received upon exercise of common stock options.

In August 2003, we issued \$100 million in aggregate principal amount of 2008 Notes 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 2008 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 2008 Notes for 1,085,000 shares of our common stock. In July 2007, we exchanged \$38.0 million of the 2008 Notes for \$60.4 million of 2011 Notes. The \$22.4 million difference between the principal amount and the initial fair value of the debt, the discount, will be accreted up to the face amount as additional interest expense over the remaining life of the 2011 Notes. As of September 30, 2007, the remaining balance of the discount on these notes was approximately \$21.4 million. In addition, as of September 30, 2007, we have recorded \$407,000 of accrued interest expense related to the 2008 and 2011 Notes, which is due March 1, 2008. From time to time, we may enter into additional exchange offers and/or purchases of these notes.

In January 2005, we issued \$200 million in aggregate principal amount of 1.5% convertible notes due 2012 (2012 Notes) 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 2012 Notes is payable semi-annually in arrears on February 1 and August 1. Net proceeds were approximately \$193.6 million. As of September 30, 2007, we have recorded \$500,000 of accrued interest expense related to the 2012 Notes, which is due February 1, 2008.

The following table summarizes our long-term contractual obligations as of September 30, 2007:

	Total	Payments Due by Period			Thereafter
		2007	2008-2009	2010-2011	
Contractual obligations					
Operating leases	\$ 1,790,093	\$ 341,837	\$ 1,446,501	\$ 1,755	\$ —
Convertible notes	308,410,000	—	48,000,000	60,410,000	200,000,000
Interest on convertible notes	25,174,175	—	13,596,900	10,077,675	1,500,000
Total contractual obligations	\$ 335,374,668	\$ 341,837	\$ 63,043,401	\$ 70,489,430	\$ 201,500,000

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 evolving requirements for, timing of, and the costs involved in, obtaining regulatory approvals;
- the timing of, and the costs involved in, transitioning the AstraZeneca collaboration;

- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs;
- if our common stock is no longer traded on a national securities exchange or system of automated quotations, the holders of our convertible notes have the right to require us to immediately repay amounts outstanding under such notes, together with accrued interest up to such date; 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. However, there can be no assurance we will have access to capital on terms acceptable to us or at all.

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. 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, our financial condition, our access to capital, our 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:

- our inability to successfully develop and commercialize AGI-1067;
- the actual results of clinical studies of AGI-1067 to treat diabetes and related regulatory judgments concerning AGI-1067 for use in diabetes management;
- if our common stock is no longer traded on a national securities exchange or system of automated quotations, the holders of our convertible notes have the right to require us to immediately repay amounts outstanding under such notes, together with accrued interest up to such date;
- 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;
- generally evolving regulatory requirements for drug product approval and marketing;
- our ability to successfully develop AGI-1096 or 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 product;
- regulatory authorities may require that we conduct additional clinical trials or modify existing clinical trials
- 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
- our ability to repay \$48 million principal amount on the 4.5% convertible notes due September 1, 2008; and our other notes as they become due; and
- the conversion of our 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 as well as under the heading “Risk Factors” 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 1A. Risk Factors

Our business is heavily dependent on AGI-1067. If we are unable to commercialize this product or are unsuccessful in completing our ANDES trial, our business will be materially adversely affected.

We have commenced ANDES (AGI-1067 as Novel Anti-Diabetic Agent Evaluation Study), a multi-center, double-blind study with 6-month dosing of AGI-1067 of 300 mg, 150 mg and 75 mg that is designed to compare the effects of AGI-1067 versus placebo on glycemic endpoints in subjects with confirmed Type 2 diabetes mellitus.

After discussions with the FDA about the overall risk/benefit profile of the 300 mg dose, the 300 mg dose will be discontinued in the ANDES trial and we will continue ANDES with the 150 mg and 75 mg doses. Much of the clinical data generated to date regarding AGI-1067 is based upon the results of our ARISE clinical trial, which evaluated the impact of AGI-1067 on a composite measure of heart disease outcomes and used a 300 mg dose of AGI-1067. The 300 mg dose of AGI-1067 used in ARISE resulted in a small increase in the number of patients with abnormal liver function. There can be no assurance that the lower dosage to be used in ANDES will not have similar side effects. AGI-1067 could fail in the ANDES trial if we are unable to show that it has an effect or if AGI-1067 causes unacceptable side effects in the treated patients.

The failure of AGI-1067 in the ANDES trial would have a material adverse effect on our business. If we are not successful in commercializing AGI-1067, or are significantly delayed or limited in doing so, our business will be materially adversely affected.

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.

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 9, 2007

/s/MARK P. COLONNESE

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