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ATHEROGENICS INC Form 8-K October 09, 2001

1

SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM 8-K

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

Date of report (Date of earliest event reported): October 4, 2001

ATHEROGENICS, INC. (Exact Name of Registrant as Specified in its Charter)

GEORGIA (State or other jurisdiction (Commission (IRS Employer of incorporation) File Number) Identification No.)

0-31261

58-210832

8995 WESTSIDE PARKWAY ALPHARETTA, GA 30004 (Address of principal executive offices)

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

2

ITEM 5. OTHER EVENTS

On October 4, 2001, AtheroGenics, Inc. issued the following press release:

ATHEROGENICS REACOUIRES FULL RIGHTS TO AGI-1067 TO EXPEDITE DEVELOPMENT OF NOVEL CARDIOVASCULAR DRUG

ATLANTA, GA - October 4, 2001 - AtheroGenics, Inc. (Nasdaq: AGIX), an emerging pharmaceutical company focused on the treatment of chronic inflammatory diseases, today announced that it has reached an agreement with Schering-Plough Corporation (NYSE: SGP) to reacquire AGI-1067, a novel orally-available cardiovascular compound discovered by AtheroGenics scientists. AGI-1067 was co-developed during a two-year collaboration between AtheroGenics and Schering-Plough. The reacquisition of rights to AGI-1067 was mutually agreed upon by both parties and will enable AtheroGenics to expedite its clinical development process.

"This is an exciting opportunity for AtheroGenics, to resume control over the development of this compound that has shown a clear benefit to patients in a large Phase II clinical trial," stated Russell M. Medford, M.D., Ph.D.,

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AtheroGenics' President and C.E.O. "We have made significant progress through our collaboration with Schering-Plough over the past two years, and are pleased that they have allowed us to regain all rights to this potential breakthrough treatment."

Medford added, "Our primary objective is to accelerate the development of AGI-1067. With the combined resources from our IPO and our recent Private Investment in Public Equity (PIPE) financing, the Company is well positioned to advance the development of AGI-1067 for the treatment of restenosis and atherosclerosis. Accordingly, the Company plans to initiate its next Phase II clinical study for AGI-1067 before the end of this year."

AGI-1067 is the first of a promising new class of orally-deliverable compounds targeting chronic inflammatory diseases, known as vascular protectants, or v-protectants. In May 2001, AtheroGenics announced encouraging top-line results from a Phase II clinical trial involving 305 patients, which assessed the tolerability and efficacy of AGI-1067 as an agent to prevent post-angioplasty restenosis. An analysis of these top-line results indicated that six months after angioplasty, patients who received AGI-1067 had greater luminal diameters of their coronary arteries than those patients who received placebo. This improvement showed a statistically significant dose response. There were no deaths or increase in the incidence of serious adverse events when comparing AGI-1067 to placebo.

A complete analysis of the safety and efficacy data on AGI-1067 will be presented in November at the American Heart Association Scientific Sessions 2001 in Anaheim, California.

3

CONFERENCE CALL

AtheroGenics will host a conference call at 9:00 a.m. EST on Friday, October 5, 2001 to discuss these developments. Investors, analysts, brokers and media wishing to participate in this call may dial 1-800-296-6518 five minutes prior to the start time. For those who are unable to listen to the call live, a telephone postview service will be in place from approximately one hour after the conference ends until midnight (EDT) Friday, October 12, 2001. The postview can be accessed by dialing 1-800-633-8284 (domestic) or +1-858-812-6440 (international) and entering reservation number 19814922.

ABOUT ATHEROGENICS

AtheroGenics (Nasdaq: AGIX) is focused on the discovery, development and commercialization of novel drugs for the treatment of chronic inflammatory diseases, such as heart disease (atherosclerosis), rheumatoid arthritis and asthma. In May, the Company announced top-line results from its Phase II clinical trial with its lead compound, AGI-1067, a novel oral agent being developed for the treatment and prevention of post-angioplasty restenosis. AtheroGenics has two products in Phase I clinical trials. AGIX-4207, the Company's second clinical compound derived from its proprietary v-protectant technology platform, is a novel oral agent being developed for the treatment of rheumatoid arthritis. AGIX-4207 I.V. is an intravenous treatment designed for rheumatoid arthritis patients in whom the rapid attainment of target drug levels in the blood is desirable. For more information about AtheroGenics, please visit www.atherogenics.com.

This press release may contain forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements are subject to certain factors, risks and uncertainties that may cause actual results, events and performances to differ materially from those referred to in such statements. These risks include statements which address

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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, our collaborative efforts with Schering-Plough Corporation, the development of our product candidates, anticipated trends in our business, and other risks that could cause actual results to differ materially. These risks are discussed in AtheroGenics' Securities and Exchange Commission filings, including the Company's registration statements on Form S-1, Registration Nos. 333-31140 and 333-64228, filed with the SEC, and including but not limited to the risks discussed in AtheroGenics' Form 10-K for fiscal 2000, and our most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2001, all of which are incorporated by reference into this press release. These documents may also be examined at public reference facilities maintained by the SEC or, to the extent filed via EDGAR, accessed through the SEC's web site (http://www.sec.gov).

4

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, hereunto duly authorized.

ATHEROGENICS, INC.

Date: October 9, 2001 By: /s/ RUSSELL M. MEDFORD

RUSSELL M. MEDFORD, M.D., PH.D. President and Chief Executive Officer

riesident and chief Executive Office.

(Principal Executive Officer)

Date: October 9, 2001 By: /s/ MARK P. COLONNESE

MARK P. COLONNESE

Vice President of Finance and

Administration and Chief Financial Officer (Principal Accounting and Financial Officer)