ATHEROGENICS INC
Form 8-K
May 22, 2001

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): May 21, 2001

ATHEROGENICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Georgia	0-31261	58-210832
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

8995 Westside Parkway
Alpharetta, GA 30004

(Address of principal executive offices)

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

Item 5. Other Events

On May 21, 2001, AtheroGenics, Inc. issued the following press release:

ATHEROGENICS REPORTS PHASE II CLINICAL RESULTS FOR AGI-1067
IN POST-ANGIOPLASTY RESTENOSIS
Preliminary Analysis Indicates Dose-Related Increase in Luminal Diameter at Six Months

ATLANTA, Georgia, May 21, 2001 -- AtheroGenics, Inc. (Nasdaq: AGIX), an emerging pharmaceutical company focused on the treatment of chronic inflammatory diseases, today announced encouraging preliminary results of a Phase II clinical trial of AGI-1067, an oral agent for the treatment of restenosis after percutaneous coronary intervention (PCI), a procedure commonly known as "angioplasty".

An analysis of the results indicated that six months after angioplasty, the blood vessels of 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. At the highest dose of AGI-1067, the increase in the size of the target blood vessel was similar to that achieved with probucol, the active control drug in CART-1 (Canadian Antioxidant Restenosis Trial), which has been shown in previous clinical studies to reduce restenosis rates significantly following angioplasty without stent deployment.

An unexpected apparent benefit of drug treatment affected the use of the method typically specified for analyzing primary endpoint in a restenosis study. Because of this apparent early drug benefit on coronary arteries, AtheroGenics has not yet determined whether CART-1 met its primary statistical endpoint as pre-specified in the protocol. A full analysis of the safety and efficacy data is underway and expected to be announced later this year.

There were no deaths or increase in the incidence of serious adverse events when comparing AGI-1067 to placebo. In CART-1, an important safety issue was whether AGI-1067 would cause a prolongation of the QTc interval, which is an electrophysiological abnormality of the heart. The study showed that AGI-1067 did not cause QTc prolongation. Conversely, probucol did cause QTc prolongation in a statistically significant proportion of patients.

"CART-1 results confirm and extend the findings from the MVP clinical study of probucol for the treatment of restenosis, which were published in the New England Journal of Medicine," said Jean-Claude Tardif, M.D., FRCPC, Director of Clinical Research at the Montreal Heart Institute and Principal Investigator of CART-1. "In CART-1, AGI-1067 appears to exhibit the benefit of probucol therapy without the potential shortcomings associated with QTc prolongation."

This multi-center, randomized, double-blinded, placebo-controlled study, known as CART-1, comprised 305 men and women who were treated by angioplasty, with or without intracoronary stenting. The study was conducted at five clinical sites in Canada, led by the Montreal Heart Institute and included four other major cardiovascular teaching hospitals. Prior to angioplasty, patients were randomized to one of five treatment arms: AGI-1067 doses of either 70 mg, 140 mg or 280 mg, once daily, probucol 500 mg twice daily or placebo.

"This clinical study represents an important achievement in AtheroGenics' clinical development program," said Russell M. Medford, M.D., Ph.D., President and Chief Executive Officer of AtheroGenics. "We are all very excited about these statistically significant results, which are the first demonstration of biological activity of AGI-1067 in patients."

CART-1 study investigators have submitted abstracts for presentation at the American Heart Association meeting in November 2001.

Schering-Plough Corporation has exclusive worldwide rights to develop and commercialize AGI-1067 and is funding all development and commercialization costs. Under the license agreement, AtheroGenics receives upfront and milestone payments totaling as much as $189 million, plus royalties on sales of any approved product covered by the license agreement.

To date, there are no approved drugs for the prevention or treatment of restenosis after angioplasty. Restenosis is the re-narrowing or reclosure of coronary arteries after angioplasty in patients with coronary artery disease. Angioplasty procedures have been proven to be very effective in opening clogged arteries and have become widely used by cardiologists. More than one million patients around the world underwent the procedure last year. Unfortunately,

angioplasty induces an inflammatory response that contributes to restenosis within approximately six months in up to 40% of the patients who undergo the procedure.

About AtheroGenics

AtheroGenics 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. The company recently commenced enrollment in a Phase I clinical study for AGIX-4207, AtheroGenics' second v-protectant clinical candidate, a novel oral agent being developed for the treatment of the signs and symptoms of rheumatoid arthritis. For more information about AtheroGenics, please visit "www.atherogenics.com".

About Schering-Plough

Schering-Plough Corporation of Kenilworth, N.J., is a research-based company engaged in the discovery, development, manufacturing and marketing pharmaceutical products worldwide.

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 performance to differ materially from those referred to in such statements. These risks include statements which address operating performance, events or developments that we expect or anticipate will occur in the future, such as projections about our future results of operations or 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 statement on Form S-1, Registration No. 333-31140, 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 March 31, 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 website(http://www.sec.gov).

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: May 22, 2001

By: /s/RUSSELL M. MEDFORD
RUSSELL M. MEDFORD, M.D., PH.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 22, 2001

By: /s/MARK P. COLONNESE
MARK P. COLONNESE
Vice President of Finance and
Administration and Chief Financial Officer
(Principal Accounting and Financial Officer)