
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): September 16, 2003

AVI BioPharma, Inc.

(Exact name of registrant as specified in its charter)

Oregon
(State or other jurisdiction of
incorporation or organization)

0-22613
(Commission File Number)

93-0797222
(IRS Employer
Identification Number)

One S.W. Columbia, Suite 1105
Portland, OR 97258
(Address of principal executive offices)

(503) 227-0554
Registrant's telephone number, including area code

Item 5. Other Events

On June 20, 2001, AVI BioPharma, Inc. ("AVI") entered into a License and Development Agreement ("License Agreement") with Medtronic, Inc. ("Medtronic"), under which AVI granted Medtronic an exclusive worldwide license to certain antisense compounds, including Resten-NG[®], for use specifically in conjunction with certain medical devices, including stents, to treat cardiovascular disease. AVI retained exclusive rights to the use of its antisense compounds for all other applications. A copy of the License Agreement was filed as Exhibit 10.39 to AVI's quarterly report on Form 10-Q on August 14, 2001. The License Agreement provided that if certain development milestones were not met or waived AVI could convert the exclusive license to a nonexclusive license. Based upon a certain development milestone not having been met or waived, AVI has converted the license to a nonexclusive license.

With the conversion of the license to a nonexclusive license, AVI intends to pursue other strategic partners or relationships to develop antisense compounds, including Resten-NG, in treating cardiovascular disease in conjunction with medical devices. The ultimate commercial application and sale of products using the technology is subject to further product development, clinical testing and trials, governmental approvals (including Food and Drug Administration approval for United States sales) and other actions which could take several years and could depend on additional funding being raised by AVI through financings or other strategic relationships.

On September 18, 2003, AVI issued a press release relating to clinical trials involving the compounds covered by the License Agreement and the conversion of the referenced license to a nonexclusive license. A copy of the press release is filed as Exhibit 99.1 hereto.

Item 7. Financial Statements, Pro Forma Financial Information and Exhibits.

(c) **Exhibits**

99.1 Press Release of AVI BioPharma, Inc. dated September 18, 2003.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Portland, State of Oregon, on September 19, 2003.

AVI BioPharma, Inc.

By: /s/ ALAN P. TIMMINS
Alan P. Timmins
President and Chief Operating Officer
(Principal Operating Officer)

AVI BioPharma Reports Positive Phase II Clinical Results in Restenosis
Company Modifies Relationship with Medtronic

PORTLAND, Ore. — Sept. 18, 2003 — AVI BioPharma, Inc. (Nasdaq: AVII), today reported positive Phase II clinical trial data on its NEUGENE[®] antisense drug Resten-NG[®] at the 15th annual scientific symposium of Transcatheter Cardiovascular Therapeutics in Washington, D.C. The multicenter clinical trial evaluated the safety and effectiveness of Resten-NG in patients at high risk of cardiovascular restenosis following angioplasty and stent placement. Resten-NG inhibits the expression of the c-myc gene, which plays a key role in the development of the pathology leading to restenosis.

Fifty-seven patients were enrolled in the trial, known as the AVAIL study, and were randomized into three groups: a control arm, a subtherapeutic dose (3 mg) treatment arm, and a therapeutic dose (10 mg) treatment arm. Patients in the therapeutic dose and subtherapeutic dose treatment arms received the drug via a coronary delivery catheter directly to the site of angioplasty and stent placement.

The primary efficacy endpoint was angiographic analysis at six months. The restenosis rate was 33.3 percent in both the control and subtherapeutic dose treatment arms, and 8.3 percent in the therapeutic dose treatment arm. This 75 percent reduction in the rate of restenosis was statistically significant (p=0.02).

The secondary endpoint of the study was late loss, which is the decrease in vessel lumen diameter at six months. The therapeutic dose treatment arm showed a significant reduction of late loss and lesion length compared with the control arm and the subtherapeutic treatment arm. There were no increases in toxicity or adverse events in either of the treatment arms. The therapeutic dose treatment arm also experienced a lower rate of target lesion revascularization than the other arms.

“These results provide additional data supporting the safety and efficacy of AVI’s antisense therapeutics in treating cardiovascular disease,” said Nicholas Kipshidze, M.D., Ph.D., of Lenox Hill Hospital in New York. “The patients treated in this trial were at high risk for restenosis, giving us the ability to evaluate efficacy with a small sample size. The data indicate Resten-NG provided a substantial and statistically significant benefit for these high-risk patients.”

Cardiovascular Program Update

AVI also announced today that it had exercised its option to convert the Resten-NG license it had granted to Medtronic Inc. from exclusive to nonexclusive.

“Our cardiovascular program continues to move forward on several levels,” said Denis R. Burger, Ph.D., chief executive officer at AVI. “In addition to the AVAIL results and the recently announced initiation of our microbubble trial, we now can offer Resten-NG to

other partners on a nonexclusive basis, allowing for potentially greater flexibility and faster commercialization of the drug.”

In August, AVI initiated a Phase II clinical study of Resten-NG delivered using AVI’s proprietary microbubble delivery system. The study will evaluate efficacy and safety of Resten-NG delivered systemically with AVI’s microbubble preparation, compared with angioplasty and stent placement alone. Successful systemic delivery of Resten-NG could make the drug available for broad application with stent placement and for multiple applications after angioplasty. AVI plans to initiate a Phase III clinical trial in Europe with Resten-NG on a stent platform around the end of this year.

About AVI BioPharma

AVI BioPharma develops therapeutic products for the treatment of life-threatening diseases using two technology platforms: third-generation NEUGENE[®] antisense drugs and cancer immunotherapy. AVI’s lead NEUGENE antisense compound is designed to target cardiovascular restenosis, cancer, polycystic kidney disease and other cell proliferation disorders. In addition to targeting specific genes in the body, AVI’s antiviral program uses NEUGENE antisense compounds to target single-stranded RNA viruses, including West Nile virus, SARS coronavirus, calicivirus, and hepatitis C. AVI’s second technology, AVICINE[®], is a therapeutic cancer vaccine with late-stage trials planned for the treatment of pancreatic and colorectal cancer. More information about AVI is available on the company’s Web site at <http://www.avibio.com/>.

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“Safe Harbor” Statement under the Private Securities Litigation Reform Act of 1995: The statements that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties, including, but not limited to, the results of research and development efforts, the results of preclinical and clinical testing, the effect of regulation by the FDA and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, and other risks detailed in the Company’s Securities and Exchange Commission filings.