
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): **December 23, 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 and Regulation FD Disclosure.

The information set forth below pursuant to Item 12 shall also be deemed filed pursuant to Item 5.

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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated December 23, 2003 reporting confirmatory data supporting the Phase II clinical trial data on AVI BioPharma, Inc.'s (the "Company") NEUGENE [®] antisense drug Resten-NG [®] .

Item 12. Results of Operations and Financial Condition.

Company issued a press release on December 23, 2003, before the opening of trading in its Common Stock on the Nasdaq National Market System. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

The Press Release December 23, 2003 reported confirmatory data supporting the Phase II clinical trial data on the Company's NEUGENE[®] antisense drug Resten-NG[®].

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 December 29, 2003.

AVI BioPharma, Inc.

By: /s/ ALAN P. TIMMINS

Alan P. Timmins

President and Chief Operating Officer

(Principal Operating Officer)

Text of Press Release

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For Release 6 a.m. PST

Dec. 23, 2003

AVI BioPharma Reports Confirmation of Positive Phase II Clinical Results
In Restenosis
Analysis of Data From Intravascular Ultrasound at Six Months Supports September
Report
Of Phase II Efficacy

PORTLAND, Ore. — Dec. 23, 2003 — AVI BioPharma, Inc. (Nasdaq: AVII), today reported confirmatory data supporting the Phase II clinical trial data on its NEUGENE[®] antisense drug Resten-NG[®]. In September 2003, AVI reported a 75% reduction in the restenosis rate from angiographic analysis at six months. Further analysis of the vessel lumen diameter and vessel wall thickness by Intravascular Ultrasound (IVUS) supports the angiographic data.

A 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.

As presented and reported in September, the primary efficacy endpoint was angiographic analysis at six months. The restenosis rate was 33.3% in both the control and subtherapeutic dose treatment arms, and 8.3% in the therapeutic dose treatment arm. This 75% 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.

The recently received IVUS data confirmed these results. In addition, these data suggest a dose response benefit of increased lumen diameter and decreased vessel wall thickness, which was not observed in the previous data.

“These results provide additional data supporting the safety and efficacy of AVI’s antisense therapeutics in treating cardiovascular disease,” said Patrick L. Iversen, Ph.D., senior vice president of research and development at AVI. “The patients treated in this trial were at high risk for restenosis, giving us the ability to evaluate efficacy with a small sample size. These additional confirmatory data increase our confidence that Resten-NG provided a substantial benefit for these high-risk patients.”

Cardiovascular Program Update

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 in the first quarter of 2004.

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 cell proliferation disorders, including cardiovascular restenosis, cancer and polycystic kidney disease. 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 cancer. More information about AVI is available on the company’s Web site at <http://www.avibio.com/>.

“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.
