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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## 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 10, 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

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#### **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 10, 2003 announcing presentation of preclinical data on AVI's microbubble drug delivery and AVI's NEUGENE <sup>®</sup> antisense anti-cancer strategies.

#### **Item 12. Results of Operations and Financial Condition.**

AVI BioPharma, Inc. (the "Company") issued a press release on December 10, 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 announced the presentation of preclinical data on AVI's microbubble drug delivery and AVI's NEUGENE<sup>®</sup> antisense anti-cancer strategies.

#### **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 15, 2003.

AVI BioPharma, Inc.

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

**Text of Press Release**AVI Contact:

AVI BioPharma, Inc.  
 Michael Hubbard (hubbard@avibio.com)  
 (503) 227-0554

Investor Contacts:

Lippert/Heilshorn & Associates Inc.  
 Bruce Voss (bvoss@lhai.com)  
 Jody Cain (jcain@lhai.com)  
 (310) 691-7100

Press Contact:

Waggener Edstrom Bioscience  
 Jenny Moede (jmoede@wagged.com)  
 (503) 443-7000

**For Release 6 a.m. PST****Dec. 10, 2003**

**AVI Presents Preclinical Data on Microbubble Drug Delivery  
 And NEUGENE Antisense Anti-Cancer Strategies**

**PORTLAND, Ore. — Dec. 10, 2003** — AVI BioPharma, Inc. (Nasdaq: AVII), announced the presentation of preclinical data at two international conferences this week. The first presentation detailed a novel drug delivery mechanism, AVI's proprietary microbubble technology, which is currently being evaluated in clinical studies for the systemic delivery of cardiovascular restenosis-inhibitory drugs. The second presentation highlights the advantages of AVI's NEUGENE<sup>®</sup> antisense drugs in a solid tumor anti-cancer strategy.

Nick Kipshidze, M.D., Ph.D., of the Lenox Hill Heart and Vascular Institute, presented "Novel Drug Delivery for Restenosis and Vulnerable Plaque: Targeted Systemic Delivery of Sirolimus with Microbubble Carrier" at the 5th International Meeting on Interventional Cardiology: Frontiers in Interventional Cardiology, on Monday, Dec. 8, in Tel Aviv, Israel. The presentation included results from animal studies with AVI's microbubble technology in which there was an observed reduction in restenosis 30 days after treatment. Microbubble drug delivery involves a simple intravenous (systemic) injection with the drug targeting the site of vascular injury. The advantages include ease of repeated drug administration and reduced drug dose requirements. Vulnerable plaque is associated with acute coronary syndrome and is a leading health problem in the United States.

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*"These data demonstrate the feasibility of treating cardiovascular restenosis using our proprietary microbubble delivery technology in combination with a drug to prevent restenosis," said Denis R. Burger, Ph.D., CEO of AVI BioPharma. "In addition, we are evaluating the safety and efficacy of systemic delivery of our restenosis drug Resten-NG<sup>®</sup>, a NEUGENE antisense agent, in a Phase II clinical study. Systemic delivery could make the drug available for broad application with stent placement and for multiple applications after angioplasty."*

The second study will be presented by Gayathri Devi, Ph.D., senior scientist at AVI, at the 12th International Conference on Gene Therapy of Cancer in San Diego Dec. 11–14. Titled "Neutrally Charged Phosphorodiamidate Morpholino Oligomers: In Vivo Bioavailability, Pharmacokinetics, and Anti-Cancer Strategies," the presentation will highlight three distinct advantages of AVI's NEUGENE molecules in cancer treatment. First, in both preclinical and human clinical trials, AVI's NEUGENE molecules were found to have penetrated solid tumor tissue, which has been a challenge for many other therapies. Second, high concentration of the drug in tumor tissue supports a lower-dose strategy. Finally, the data support the fact that AVI's antisense NEUGENEs may be effective as single agents, in combination with additional antisense agents or with chemotherapy.

"We are excited by the favorable features of safety, localization in solid tumor tissues, feasible lower dose strategies and effective anti-cancer studies," Burger said. "We will continue to evaluate our molecules against the targets we have identified as specific to the progression of cancer in the human body."

**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<sup>®</sup>, 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/>.

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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.*

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