

---

---

# 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 6, 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 12. Results of Operation and Financial Condition.

AVI BioPharma, Inc. (the "Company") issued a press release on May 6, 2003, before the opening of trading in its Common Stock on the Nasdaq National Market System, a copy of which is attached as Exhibit 99.1.

The Press Release announces First Quarter Financial Results and updates the Company's product research and clinical trials.

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

None

#### 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 May 8, 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 BIOPHARMA ANNOUNCES FIRST QUARTER FINANCIAL RESULTS

PORTLAND, Ore. (May 6, 2003) – AVI BioPharma, Inc. (Nasdaq: AVII, AVIIW, AVIIZ), a biopharmaceutical company developing treatments for life-threatening diseases based on antisense and cancer immunotherapy technologies, today reported financial results for the three months ended March 31, 2003.

For the first quarter of 2003, AVI reported a net loss of \$3.4 million, or \$0.13 per share, compared with a net loss of \$7.8 million, or \$0.33 per share, for the first quarter of 2002. Revenues for the 2003 first quarter were \$257,923, compared with \$237,695 for the 2002 first quarter. Research and development expenses during the first quarter of 2003 decreased to \$2.8 million from \$7.0 million for the comparable prior-year quarter, and general and administrative expenses decreased to \$933,401 from \$1,084,519 for the first quarter of 2002. The decrease in research and development was primarily due to lower manufacturing costs associated with the company's clinical development efforts, partially offset by increases in outside collaborations and regulatory affairs costs, and additional preclinical and clinical testing of the company's products.

The company had cash, cash equivalents and short-term securities of \$11.7 million as of March 31, 2003, a decrease of \$7.6 million from December 31, 2002. This decrease was due primarily to \$6.3 million used in operations and \$882,755 used for capital expenditures and patent-related costs, and a net \$376,173 decline in the value of the company's short-term securities, offset by the receipt of \$26,152 from the exercise of options. Cash balances are exclusive of \$15 million in gross proceeds from a private equity placement announced yesterday.

"This has been among the most exciting times in our corporate history," commented Denis R. Burger, Ph.D., chief executive officer of AVI. "We developed a NEUGENE<sup>®</sup> antisense compound, AVII-4179, for treating the coronavirus implicated in Severe Acute Respiratory Syndrome (SARS) within 10 days of receiving the genetic sequence for the virus. There is not another technology in the world today that could have responded in this short timeframe. Further, we announced last month that we plan to initiate Phase I clinical trials with AVI-4020 to treat another high-profile virus, West Nile virus, by the end of this year.

"We developed these drug candidates with unprecedented speed because these viruses are ideal targets for our third-generation NEUGENE antisense technology," explained Dr. Burger. "These are single-stranded RNA viruses that are characterized by a simple genetic structure. Our antisense drugs are small polymers designed to specifically recognize gene sequences and prevent replication.

"The implications of our SARS and West Nile programs are far-reaching for our company," he added. "They provide additional evidence of our ability to quickly develop drugs, to support our ongoing contention that NEUGENE antisense is a broadly applicable technology platform, and to bring us closer to our goal of having an impact on life-threatening diseases."

### Product Pipeline Update

#### *Antisense*

#### **NEUGENES**

Antisense compounds are designed to bind to specific disease-causing gene sequences to disable or inactivate the disease process. AVI has developed proprietary third-generation antisense compounds, called NEUGENES, which are characterized by a fully synthetic backbone, instead of the natural or modified backbones of competing technologies. This chemistry allows NEUGENE antisense agents to be more stable, specific, efficacious and safer than second-generation antisense compounds in clinical development by others.

#### Resten-NG<sup>®</sup>

Resten-NG is a NEUGENE compound for treating cardiovascular restenosis, or the re-narrowing of a coronary artery following balloon angioplasty. Resten-NG targets a transcription factor, and upon entering arterial cells, it blocks the underlying cause of the disease: smooth muscle cell activation and proliferation. A global license has been granted to Medtronic, Inc. for AVI's antisense compounds deployed on stents or other devices for treating restenosis. At the September 2002 Transcatheter Cardiovascular Therapeutics (TCT) conference, AVI announced interim Phase II clinical trial data showing that Resten-NG delivered via catheter during balloon angioplasty procedures resulted in an approximate 80% reduction in the restenosis rate. At the April 2003 American College of Cardiology meeting, results from two independent studies were presented that demonstrate the feasibility of treating cardiovascular restenosis by delivering Resten-NG systemically, using the company's proprietary microbubble delivery technology, to treat arteries, potentially foregoing or lessening the need to use special drug delivery catheters or drug coated stents.

#### Prostate Cancer

In January 2003, the company received a \$250,000 grant from the National Cancer Institute to target prostate cancer. AVI plans to initiate a Phase Ib clinical study later this year in prostate cancer.

#### Drug Metabolism

AVI has successfully completed clinical trials demonstrating that the company's antisense drug improved the pharmacokinetic profile of two different test drugs in modifying the function of a liver enzyme that is critical to the body's processing of many drugs. The company announced that pharmacokinetic analyses of data from one liver enzyme study showed that the subcutaneous route of administration resulted in dose-dependent elevations in blood concentrations of NEUGENES. Also, in October 2002 AVI announced that animal studies indicated that the topical application of NEUGENES produced systemic changes in gene expression in the liver. Two clinical studies completed in late 2002, one consisting of treatment with a single intravenous injection of 300 mg of AVI-4557, and the other consisting of treatment with five consecutive daily intravenous injections of 90 mg of AVI-4557, showed that AVI-4557 had a statistically significant effect on down-regulating the targeted liver enzyme in healthy volunteers.

#### Polycystic Kidney Disease

AVI completed a Phase Ib clinical trial in 2002 to evaluate the safety and pharmacokinetics of three doses of AVI-4126 in patients with polycystic kidney disease and with varying degrees of compromised kidney function. Results of the study showed an excellent safety profile and no adverse effect on kidney function. Phase Ib study results are crucial in designing Phase II studies, which will test AVI-4126's efficacy and further define its safety profile.

Antiviral Programs

AVI is currently focusing on single-stranded RNA viruses using the company's proprietary NEUGENE antisense agents to target these families of viruses. These families include many of the viruses on the Domestic Homeland Security list of bioterrorism viruses, as well as hepatitis C virus, West Nile virus, Calicivirus, and the coronavirus implicated in SARS. AVI expects to submit an Investigational New Drug (IND) application to the FDA and to initiate a Phase I clinical trial later this year in West Nile virus. The company has developed a drug candidate, AVI-4179, to combat the coronavirus implicated in SARS. AVI-4179 has been sent to the National Institutes of Health and to laboratories affiliated with the World Health Organization for preclinical testing.

**Cancer Immunotherapy****AVICINEÒ**

AVICINE is a therapeutic cancer vaccine designed to elicit an immune response to a well-characterized, tumor-associated antigen, human chorionic gonadotropin (hCG). The hCG hormone is naturally produced during pregnancy and is believed to stimulate growth and shield the embryo from immune system attack. The hCG hormone is expressed in most, if not all, cancers as a membrane-associated tumor marker, and is believed to promote tumor growth and vascularization, and to render patients immunologically unresponsive to the tumor. The role of hCG in cancer is widely believed to be analogous to its role in pregnancy. Thus, AVICINE stimulates the immune system to mount an attack against cancer cells expressing this hormone.

Pancreatic Cancer

In December 2001, AVI reported Phase II data demonstrating that AVICINE provided a survival benefit to patients with pancreatic cancer. In this study, patients were treated with AVICINE alone, or with AVICINE in combination with the chemotherapy agent Gemzar®. Those treated with AVICINE reported one-year survival data similar to historical results for those treated with Gemzar, without the chemotherapy-related side effects often associated with Gemzar. A one-year survival rate of 30% was reported for patients treated with AVICINE plus Gemzar, which is approximately double the survival rate for either treatment alone. In May 2002, AVI presented complete survival data from the Phase II pancreatic cancer study at the American Society of Clinical Oncology (ASCO) meeting. The company plans to begin a Phase III clinical program with AVICINE for treating pancreatic cancer during 2003.

AVI BioPharma has scheduled an investor conference call regarding this announcement to be held today, beginning at 11:00 a.m. Eastern Time. Those interested in listening to the conference call live via the Internet may do so by visiting the company's Web site at [www.avibio.com](http://www.avibio.com). A replay will be available on the site for 14 days. A telephone replay will be available for 48 hours following the conclusion of the call by dialing (800) 642-1687 and entering reservation number 9695236.

**About AVI BioPharma**

AVI BioPharma develops therapeutic products for the treatment of life-threatening diseases using two technology platforms: NEUGENE antisense drugs and cancer immunotherapy. Its lead cancer agent, AVICINE, a therapeutic cancer vaccine, has completed three Phase II trials in colorectal and pancreatic cancer and the company plans to initiate a Phase III pivotal trial in pancreatic cancer, with a supporting study in colorectal cancer. The first application of its NEUGENE compounds, Resten-NG is designed to treat cancer, cardiovascular restenosis and other cell

proliferation disorders by inhibiting the production of a cellular transcription factor, the oncogene c-myc. The company is in a Phase II trial for restenosis and in a Phase Ib trial for cancer. AVI has completed four Phase I NEUGENE antisense studies that successfully down-regulated the liver enzyme cytochrome P-450 and modified drug metabolism, and a Phase Ib trial in polycystic kidney disease. More information about AVI is available on the company's Web site at [www.avibio.com](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 press 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.*

[Tables to Follow]

**AVI BIOPHARMA, INC.**

(A Development-Stage Company)

**STATEMENTS OF OPERATIONS**

(unaudited)

	Three months ended March 31,	
	2003	2002
Revenues from license fees, grants and research contracts	\$ 257,923	\$ 237,695
Operating expenses:		
Research and development	2,805,895	7,049,120
General and administrative	933,401	1,084,519
	<u>3,739,296</u>	<u>8,133,639</u>
Other income:		

Interest income, net	62,556	79,851
Net loss	\$ (3,418,817)	\$ (7,816,093)
Net loss per share – basic and diluted	\$ (0.13)	\$ (0.33)
Shares used in per share calculations	26,567,968	23,442,127

**BALANCE SHEET HIGHLIGHTS**

	March 31, 2003 (unaudited)	December 31, 2002
Cash, cash equivalents and short-term securities	\$ 11,712,734	\$ 19,293,645
Total current assets	12,581,400	20,401,988
Total assets	21,332,738	28,603,757
Total current liabilities	1,619,953	5,122,134
Total shareholders' equity	\$ 19,712,785	\$ 23,481,623