
FORM 8-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 9, 2004**

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

Not Applicable
(Formal name and address, if changed from last report)

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

Exhibits

99.1. Press release dated March 9, 2004 announcing financial results for the quarter and year ended December 31, 2003.

Item 12. Results of Operations and Financial Condition.

On March 9, 2004, AVI BioPharma, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2003. The press release is attached to this Form 8-Ka as Exhibit 99.1.

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Note: The information contained in this report on Form 8-K (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section.

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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 March 11, 2004

AVI BioPharma, Inc.

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

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99.1 Press release dated March 9, 2004 issued by AVI BioPharma, Inc.

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For Immediate Release

**AVI BioPharma Announces 2003 Fourth Quarter
 and Full Year Financial Results**

PORTLAND, Ore. (March 9, 2004) – AVI BioPharma, Inc. (Nasdaq: AVII) today reported financial results for the three and 12 months ended December 31, 2003.

For the fourth quarter of 2003, AVI reported a net loss of \$3.1 million, or \$0.10 per share, compared with a net loss of \$4.0 million, or \$0.15 per share, for the fourth quarter of 2002. Revenues for the fourth quarter of 2003 were \$135,181, compared with \$169,206 for the fourth quarter of 2002. Research and development expenses increased to \$6.4 million from \$3.5 million and general and administrative expenses increased to \$888,440 from \$774,417 in the fourth quarter of 2003 compared to the fourth quarter of 2002. These increases were primarily due to additional expenses associated with outside collaborations, expansion of the company's clinical development and regulatory affairs efforts, and additional preclinical and clinical testing of the company's product candidates. During the fourth quarter of 2003 AVI had a realized gain on sale of short-term securities—available-for-sale of \$3,765,752.

For the year 2003, AVI reported a net loss of \$14.6 million, or \$0.49 per share, compared with a net loss of \$29.4 million, or \$1.14 per share, in 2002. Revenues in 2003 were \$969,866, compared with \$836,784 in 2002. Research and development expenses during 2003 were \$15.3 million, down from \$22.4 million in the prior year. This decrease was primarily due to lower manufacturing costs associated with the company's clinical development efforts. General and administrative expenses increased to \$4.6 million in 2003 from \$3.8 million in 2002, reflecting additional legal expenses, and an increase in the cost of director and officer insurance, consistent with industry trends.

AVI had cash, cash equivalents and short-term securities of \$37.6 million as of December 31, 2003, an increase of \$18.3 million from December 31, 2002. This increase was due primarily to the receipt of \$34.7 million in net proceeds from two private equity financings with several institutional investors completed during 2003, offset by \$17.5 million used in operations and \$2.0 million used for purchases of property and equipment and patent-related costs.

“We have been very aggressive in our NEUGENE® antisense clinical development programs over the past three years, having now completed 11 clinical trials involving 242 patients,” said Denis R. Burger, Ph.D., chief executive officer of AVI. “Our clinical results continue to demonstrate a significant safety profile for our novel gene-targeted drugs. Using four different routes of administration, we have not observed a single drug-related serious adverse event in any of these trials. Moreover, we have now

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shown efficacy in three of our more advanced clinical studies involving two distinct gene targets. Based on our clinical progress, we believe that we are well positioned for future late-stage trials and significant partner discussions.

“The year 2004 should be exciting as we move forward with clinical trials in each of our areas of focus, including cardiovascular disease, infectious diseases and cancer, along with a key trial in polycystic kidney disease,” added Dr. Burger.

Product Pipeline Update**Technology Overview**

AVI is developing products principally based on its NEUGENE antisense technology. 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 novel synthetic backbone, instead of the modified backbones of competing technologies. AVI believes that this chemistry allows NEUGENE antisense agents to be more stable, specific, efficacious and safer than second-generation antisense compounds in clinical development by others.

AVI focuses on three program areas including cardiovascular disease, infectious disease, and cancer. In addition, AVI applies its technology to certain other clinical applications that are particularly amenable to antisense drug development.

In the cancer program, AVI has a second technology called AVICINE®. 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 expressed in most cancers and is believed to promote tumor growth and to shield the tumor from immune attack.

Cardiovascular Disease Program

Resten-NG® is a NEUGENE antisense drug for treating cardiovascular restenosis, or the re-narrowing of a coronary artery following angioplasty. Resten-NG inhibits the expression of the c-myc gene, which plays a key role in the development of the pathology leading to restenosis. A nonexclusive license has been granted to Medtronic, Inc. for AVI's antisense compounds deployed on stents or certain other devices for treating restenosis. At the September 2003 Transcatheter Cardiovascular Therapeutics conference, AVI announced Phase II clinical trial data showing that Resten-NG delivered via catheter during

balloon angioplasty procedures resulted in an approximate 75% reduction in the restenosis rate. At the April 2003 American College of Cardiology meeting, results from two independent studies were presented that additionally demonstrated the potential of treating cardiovascular restenosis by delivering Resten-NG systemically using the company's proprietary delivery technology, possibly lessening the need for, or as an adjunct to, special drug delivery catheters or drug-coated stents. In August 2003, AVI initiated a Phase II clinical trial with Resten-NG coupled with this patented delivery technology at the University of Nebraska Medical Center. AVI intends to have clinical trials initiated in the first half of 2004 in Europe with Resten-NG delivered on a stent with an additional strategic partner. These trials are designed to lead into studies to meet the regulatory requirements for a CE Mark, constituting marketing approval for the European Union.

Infectious Disease Program

AVI is using its proprietary NEUGENE antisense agents to focus on RNA viruses to target West Nile virus (WNV), the SARS coronavirus, Hepatitis C virus, and Dengue virus as well as many of the viruses included on the Domestic Homeland Security list of bioterrorism viruses. In its WNV program, the company filed an application with the FDA in May 2003 to obtain Orphan Drug designation for its

NEUGENE drug candidate, AVI-4020, and submitted an IND the following month. The company initiated a Phase Ib clinical trial to treat WNV in September 2003. AVI filed an application for Orphan designation for AVI-4179 targeting the coronavirus implicated in SARS in August 2003. In the following month, the company received positive preclinical test results from The Scripps Research Institute. AVI plans to focus its future anti-viral drug development program on viral diseases with large and stable markets, the first of which is HCV, with Dengue virus to follow.

Cancer Program

AVI has completed a Phase Ib clinical trial with its NEUGENE drug candidate AVI-4126, which demonstrated the effectiveness of systemic delivery into solid tumor tissues for both breast and prostate cancer patients. AVI-4126 targets the oncogene c-myc. Over-expression of c-myc has been described in many types of cancers. In January 2003, the company received a \$250,000 grant from the National Cancer Institute to target prostate cancer. AVI plans to conduct a multiple dosing study with AVI-4126 early in 2004 and a Phase II clinical trial later in 2004.

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 chemotherapeutic agent 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 initiate an additional Phase II clinical program with AVICINE in pancreatic cancer in the first half of 2004, instead of an originally planned Phase III. This Phase II program was selected due to considerations of cost, timeline and study design. The company anticipates moving into a future Phase III clinical trial if an appropriate partner, with whom to share the costs of the program, is identified.

Other Clinical Opportunities

Drug Metabolism Program

AVI has successfully completed clinical trials demonstrating that its antisense drug improved the pharmacokinetic profile of two different test drugs by down-regulating the liver enzyme that is critical to the body's processing of many drugs. Two clinical studies completed in late 2002 showed that AVI-4557 down-regulated cytochrome P450, which resulted in an improved pharmacokinetic profile of a test drug. In September 2003, AVI initiated an oral dosing study of AVI-4557 to evaluate the oral route of administration and results are expected to be reported in the first half of 2004. Additional Phase II trials will be designed after establishing strategic relationships with pharmaceutical partners.

Polycystic Kidney Disease Program

AVI completed a Phase Ib clinical trial in 2002 to evaluate the safety and pharmacokinetics of AVI-4126 in adult patients with polycystic kidney disease (PKD) and with varying degrees of compromised kidney function. Results of the study showed an excellent safety profile and no adverse effect on kidney function. The company has designed a Phase II clinical study in the early onset form of PKD that is often lethal for children. AVI plans to initiate this trial in the second half of 2004.

Conference Call

AVI BioPharma has scheduled an investor conference call regarding this announcement, and its current and planned business activities, 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. 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 in the U.S. and Canada or (706) 645-9291 Internationally and entering reservation number 5828498.

About AVI BioPharma

AVI BioPharma develops therapeutic products for the treatment of life-threatening diseases principally using its third-generation NEUGENE antisense technology. 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, Hepatitis C, and Dengue virus. 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 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.

AVI BioPharma, Inc.
(A Development-Stage Company)
STATEMENTS OF OPERATIONS
(unaudited)

	<u>Three Months Ended</u> <u>December 31,</u>		<u>Year Ended</u> <u>December 31,</u>	
	<u>2003</u>	<u>2002</u>	<u>2003</u>	<u>2002</u>
Revenues from license fees, grants & research contracts	\$ 135,181	\$ 169,206	\$ 969,866	\$ 836,784
Operating expenses:				
Research and development	6,405,351	3,546,654	15,284,396	22,413,892
General and administrative	888,440	774,417	4,558,948	3,763,941
	<u>7,293,791</u>	<u>4,321,071</u>	<u>19,843,344</u>	<u>26,177,833</u>
Other income (loss):				
Interest income, net	296,630	158,031	491,098	460,258
Realized gain on sale of short- term securities—available-for-sale	3,765,752	—	3,765,752	—
Write-down of short-term securities—available-for-sale	—	—	—	(4,478,260)
Net loss	<u>\$ (3,096,228)</u>	<u>\$ (3,993,834)</u>	<u>\$ (14,616,628)</u>	<u>\$ (29,359,051)</u>
Net loss per share, basic and diluted	<u>\$ (0.10)</u>	<u>\$ (0.15)</u>	<u>\$ (0.49)</u>	<u>\$ (1.14)</u>
Shares used in per share calculations	<u>32,024,069</u>	<u>26,485,626</u>	<u>29,808,539</u>	<u>25,691,549</u>

BALANCE SHEET HIGHLIGHTS
(unaudited)

	<u>December 31,</u> <u>2003</u>	<u>December 31,</u> <u>2002</u>
Cash, cash equivalents and short-term securities	\$ 37,599,136	\$ 19,293,645
Total current assets	38,390,519	20,401,988
Total assets	47,145,023	28,603,757
Total current liabilities	3,750,993	5,122,134
Total shareholders' equity	\$ 43,394,030	\$ 23,481,623

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