

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 8, 2005**

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)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On March 8, 2005, AVI BioPharma, Inc. issued a press release announcing its financial results for the three and twelve months ended December 31, 2004. The press release is attached to this Form 8-K as Exhibit 99.1.

Item 7.01 Regulation FD Disclosure

Information furnished under Item 2.02.

Item 9.01 Financial Statements, Pro Forma Financial Information and Exhibits.

Exhibits

99.1. Press release dated March 8, 2005, announcing financial results for the three and twelve months ended December 31, 2004.

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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 8, 2005.

AVI BioPharma, Inc.

By: /s/ ALAN P. TIMMINS
Alan P. Timmins

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Document Description</u>
99.1	Press release dated March 8, 2005 issued by AVI BioPharma, Inc.

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For Immediate Release

**AVI BioPharma Announces 2004 Fourth Quarter
 and Full Year Financial Results**

PORTLAND, Ore. (March 8, 2005) — AVI BioPharma, Inc. (Nasdaq: AVII) today reported financial results for the three and 12 months ended December 31, 2004.

For the fourth quarter of 2004, AVI reported a net loss of \$5.0 million, or \$0.14 per share, compared with a net loss of \$3.1 million, or \$0.10 per share, for the fourth quarter of 2003. Revenues for the fourth quarter of 2004 were \$285,588, compared with \$135,181 for the fourth quarter of 2003. Research and development (R&D) expenses decreased to \$3.8 million in the fourth quarter of 2004, compared with \$6.4 million in the fourth quarter of 2003. Approximately \$2.3 million of this R&D decrease was due to lower contracting costs for the production of GMP subunits. General and administrative expenses increased to \$1.4 million from \$888,440 in the fourth quarter of 2004 compared with the fourth quarter of 2003.

For the year 2004, AVI reported a net loss of \$24.8 million, or \$0.69 per share, compared with a net loss of \$14.6 million, or \$0.49 per share, in 2003. Revenues in 2004 were \$430,461, compared with \$969,866 in 2003. This decrease was due primarily to lower research contract revenues, partially offset by an increase in grant revenues. R&D expenses during 2004 increased to \$20.7 million, compared with \$15.3 million in the prior year. Approximately \$4.2 million of the R&D increase was due to contracting costs for the production of GMP subunits, which are used by the company to manufacture compounds for future clinical trials. General and administrative expenses increased to \$4.7 million in 2004 from \$4.6 million in 2003.

AVI had cash, cash equivalents and short-term securities of \$19.5 million as of December 31, 2004, a decrease of \$18.1 million from December 31, 2003. This decrease is due primarily to \$23.8 million used in operations, and \$1.5 million used for purchases of property and equipment and patent related costs, offset by the receipt of \$7.0 million in net proceeds from the exercise of warrants issued to several institutional investors for the purchase of 1,623,377 shares of the company's common stock at \$4.62 per share. These warrants had been issued pursuant to a direct equity placement of the company's common stock in December 2003 under the company's effective shelf registration.

The company was informed in 2004 that it had been allocated \$5 million in government funding for the 2005 fiscal year, for work on two viral disease research projects. These funds have not been received and are not reflected in the financial statements.

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“Our work last year with numerous, very promising drug candidates incorporating our NEUGENE® third-generation antisense continues to further support our belief in its potential to revolutionize drug therapy,” said Denis R. Burger, Ph.D., chief executive officer of AVI. “While several earlier generation antisense compounds of other companies experienced late-stage clinical failures, our NEUGENE technology continues to demonstrate stability, specificity and safety in clinical trials that to date have involved more than 300 patients.

“During the past year we strengthened our NEUGENE drug development knowledge base. We believe that this puts us in a strong position to initiate clinical research with a product candidate to treat the hepatitis C virus (HCV). Data from our viral studies, many of which are being conducted through collaborations with governmental agencies and prestigious institutions, are better preparing us to move into HCV efficacy trials,” added Dr. Burger. “We also continued to lay the groundwork last year for entry into late-stage clinical trials with our cardiovascular program, while working toward securing corporate partnerships to support our longer-term programs.”

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. NEUGENE technology is the only third-generation antisense drug technology in mid- to late-stage clinical trials.

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

Infectious Disease Program

AVI's infectious disease program is extensive, encompassing research on 45 different viruses representing 17 viral families and involving collaborations with approximately 50 different scientific investigators worldwide. The results from these studies have enhanced AVI's capability in designing effective agents for both emerging and engineered pathogens. AVI's antiviral research program has produced antisense drugs shown to be active against a range of single-stranded RNA viruses, including HCV, West Nile virus (WNV), dengue virus, SARS coronavirus, influenza virus and Ebola virus in preclinical studies. AVI plans to focus its antiviral drug development program on infectious diseases with large markets, the first of which is anticipated to be HCV, with dengue fever/dengue hemorrhagic fever (DF/DHF) anticipated to follow. The company intends to file an investigation new drug (IND) application with the U.S. Food and Drug Administration (FDA) and initiate clinical trials in HCV later this year.

In its WNV program, the company filed an IND application with the FDA in June 2003 and initiated a Phase Ib clinical trial with its drug candidate, AVI-4020, to treat WNV in September 2003. This trial met

its primary safety endpoint and also demonstrated a favorable pharmacokinetic profile with drug detected in cerebrospinal fluid. In August 2004, the company initiated a clinical trial with AVI-4020 for the treatment of patients with acute WNV disease who have serious neurological impairment. This trial remains open for enrollment for the 2005 WNV season and is referenced on the Centers for Disease Control and Prevention (CDC) and National Institute of Allergy and Infectious Diseases (NIAID) Web sites.

Cardiovascular Disease Program

Resten-NG[®] (AVI-4126) 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. In a Phase II study, AVI demonstrated that Resten-NG delivered by a catheter into the site of balloon angioplasty demonstrated statistically significant efficacy in preventing restenosis as measured by angiography and intravascular ultrasound at six months. Based on these findings, AVI has acquired expertise with a drug-eluting stent (DES) platform and plans to initiate studies leading to marketing approval in Europe with its own DES incorporating the advantageous characteristics of AVI-4126. AVI is also using a proprietary micro-particle formulation in clinical studies of AVI-4126 delivered systemically after angioplasty, which may ultimately be used with all types of bare and drug-eluting stents.

Oncology 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. The over-expression of c-myc has been described in many types of cancers. AVI plans to initiate additional cancer studies in a broad cancer screening trial and a Phase II bladder cancer study.

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.

Individuals interested in listening to the conference call may do so by dialing (888) 803-8271 toll free within the U.S. and Canada, or (706) 634-2467 for international callers. A telephone replay of the conference call will be available for 48 hours beginning March 8 within two hours after the conclusion of the call, by dialing (800) 642-1687 domestically, or (706) 645-9291 internationally and entering reservation number 4387351.

The live conference call will also be available to private investors via the Internet at www.avibio.com. A replay of the call will be available on the company's Web site for 14 days following the completion of the call.

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, hepatitis C virus 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 <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.

[Tables to Follow]

AVI BioPharma, Inc. (A Development-Stage Company)

STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended December 31,		Year Ended December 31,	
	2004	2003	2004	2003
Revenues from license fees, grants & research contracts	\$ 285,588	\$ 135,181	\$ 430,461	\$ 969,866
Operating expenses:				
Research and development	3,805,658	6,405,351	20,738,725	15,284,396
General and administrative	1,416,803	888,440	4,735,731	4,558,948
	<u>5,222,461</u>	<u>7,293,791</u>	<u>25,474,456</u>	<u>19,843,344</u>

Other income (loss):				
Interest income (loss), net	(53,381)	296,630	266,301	491,098
Realized gain on sale of short-term securities— available-for-sale	—	3,765,752	—	3,765,752
Net loss	\$ (4,990,254)	\$ (3,096,228)	\$ (24,777,694)	\$ (14,616,628)
Net loss per share, basic and diluted	\$ (0.14)	\$ (0.10)	\$ (0.69)	\$ (0.49)
Shares used in per share calculations	36,133,472	32,024,069	35,994,976	29,808,539

BALANCE SHEET HIGHLIGHTS
(unaudited)

	<u>December 31, 2004</u>	<u>December 31, 2003</u>
Cash, cash equivalents and short-term securities	\$ 19,515,316	\$ 37,599,136
Total current assets	20,198,391	38,390,519
Total assets	28,518,631	47,145,023
Total current liabilities	2,249,598	3,750,993
Total shareholders' equity	\$ 26,269,033	\$ 43,394,030

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