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): **November 4, 2004**

AVI BioPharma, Inc.

(Exact name of registrant as specified in its charter)

Oregon	**0-22613**	**93-0797222**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 November 4, 2004, AVI BioPharma, Inc. issued a press release announcing its financial results for the three and nine months ended September 30, 1004. 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 November 4, 2004 announcing financial results for the three and nine months ended September 30, 2004.

* * *

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.

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 November 4, 2004

AVI BioPharma, Inc.

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

EXHIBIT INDEX

Exhibit No.	Document Description
99.1	Press release dated November 4, 2004 issued by AVI BioPharma, Inc.

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

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

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

For Immediate Release

AVI BIOPHARMA ANNOUNCES THIRD QUARTER FINANCIAL RESULTS

PORTLAND, Ore. (November 4, 2004) – AVI BioPharma, Inc. (Nasdaq: AVII) today reported financial results for the three and nine months ended September 30, 2004.

For the third quarter of 2004, the company reported a net loss of $5.1 million, or $0.14 per share, compared with a net loss of $4.6 million, or $0.15 per share, for the third quarter of 2003. Revenues for the third quarter of 2004 were $9,151, compared with $414,352 for the third quarter of 2003. This decrease was due primarily to lower grant and research contract revenues.

Third quarter 2004 research and development (R&D) expenses increased to $4.2 million from $3.5 million, and general and administrative expenses decreased to $964,700 from $1.6 million, both compared with the third quarter of 2003. Approximately $500,000 of the increase in R&D expenses was due to contracting costs for the production of GMP subunits, which will be used by the company to manufacture compounds for future clinical trials. This increase was anticipated and was reflected in 2004 financial guidance.

For the nine months ended September 30, 2004, AVI BioPharma reported a net loss of $19.8 million, or $0.55 per share, compared with a net loss of $11.5 million, or $0.40 per share, for the comparable period in 2003. Revenues for the first nine months of 2004 were $144,873, compared with $834,685 for the comparable period in 2003. This decrease was due primarily to lower grant and research contract revenues.

R&D expenses for the first nine months of 2004 increased to $16.9 million, compared with $8.9 million for the comparable period in 2003. Approximately $6.5 million of the R&D increase was due to contracting costs for the production of GMP subunits. General and administrative expenses decreased to $3.3 million for the nine months ended September 30, 2004, from $3.7 million for the comparable period last year.

AVI had cash, cash equivalents and short-term securities of $23.1 million as of September 30, 2004, a decrease of $14.5 million from December 31, 2003. This decrease is due primarily to $20.3 million used in operations, and $1.2 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 the third quarter 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.

"We are delighted that collaborative efforts are further demonstrating the versatility of our third-generation NEUGENE® antisense technology, and the potential that our rapid response therapeutics may have in fighting infectious diseases that threaten public health," said Denis R. Burger, Ph.D., chief executive officer of AVI. "Earlier this week and only three months since announcing our collaboration with the U.S. Army Medical Research Institute of Infectious Disease (USAMRIID), we jointly announced promising preclinical results from experiments testing the effect of our NEUGENE antisense drugs against Ebola virus. Additionally, data from experiments conducted at the Massachusetts Institute of Technology (MIT) showed that several NEUGENE antisense compounds significantly impacted the influenza A virus in infected cells."

Dr. Burger added, "Collaborative programs ideally complement our business strategy as they allow us to focus our internal resources on NEUGENE drug candidates that target large market opportunities and can be developed relatively quickly, while continuing to broaden our pipeline of clinical prospects and advance other development 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 viral disease, cardiovascular disease and oncology. In addition AVI applies its technology to certain other clinical applications that are particularly amenable to antisense drug development.

Viral Disease Program

AVI has used its proprietary NEUGENE antisense agents to focus on RNA viruses to target West Nile virus (WNV), the severe acute respiratory syndrome (SARS) coronavirus, Hepatitis C virus (HCV) and Dengue virus, as well as many of the viruses included on the Domestic Homeland Security list of bioterrorism viruses. AVI plans to focus its antiviral drug development program on viral diseases with large markets, the first of which is HCV, with Dengue virus to follow. The company intends to file an investigation new drug (IND) with the U.S. Food and Drug Administration (FDA) for HCV after completing preclinical studies around the end of 2004.

In its WNV program, the company filed an IND application with the FDA in June 2003 and initiated a Phase Ib clinical trial 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.

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. 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. AVI intends to initiate Phase III clinical trials in Europe with Resten-NG delivered via stent. These trials are designed to lead to studies to meet the regulatory requirements for a CE Mark, constituting marketing approval for the European Union. During the CE Mark approval process, AVI intends to seek partnership opportunities for U.S. studies and commercialization. In June 2004 AVI announced that its nonexclusive licensing agreement with Medtronic for its antisense compounds deployed on stents or certain other devices for treating restenosis had been terminated, allowing AVI a greater opportunity to move forward with this program. AVI has an ongoing Phase Ib clinical trial with Resten-MP at the University of Nebraska Medical Center. Resten-MP is Resten-NG delivered via intravenous injection using AVI's patented microparticle delivery technology.

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. Over-expression of c-myc has been described in many types of cancers. AVI plans to initiate two additional studies with this drug in cancer in the next six months.

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 March 2004 AVI announced positive clinical results from a study of AVI-4557 to evaluate the oral route of administration. Additional Phase II trials will be designed after establishing strategic relationships with pharmaceutical partners.

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 November 4 within two hours after the conclusion of the call, by dialing (800) 642-1687 domestically, or (706) 645-9291 internationally and entering reservation number 1469008.

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.

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]

(A Development-Stage Company)

STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenues, from license fees, grants and research contracts	$ 9,151	$ 414,352	$ 144,873	$ 834,685
Operating expenses:				
Research and development	4,167,209	3,533,868	16,933,067	8,879,045
General and administrative	964,700	1,560,026	3,318,928	3,670,508
	5,131,909	5,093,894	20,251,995	12,549,553
Other income:				
Interest income, net	15,792	75,887	319,682	194,468
Net loss	$ (5,106,966)	$ (4,603,655)	$ (19,787,440)	$ (11,520,400)
Net loss per share—basic and diluted	$ (0.14)	$ (0.15)	$ (0.55)	$ (0.40)
Shares used in per share calculations	36,123,790	31,186,464	35,948,473	29,061,913

BALANCE SHEET HIGHLIGHTS

(unaudited)

	September 30, 2004	December 31, 2003
Cash, cash equivalents and short-term securities	$ 23,104,825	$ 37,599,136
Total current assets	23,803,614	38,390,519
Total assets	32,373,194	47,145,023
Total current liabilities	1,349,437	3,750,993
Total shareholders' equity	$ 31,023,757	$ 43,394,030

# # #