# 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): **November 4, 2003**

# 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

**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.

**Third Quarter Earnings Release**

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

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated November 4, 2003 announcing financial results for the third quarter ended September 30, 2003. |

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

AVI BioPharma, Inc. (the "Company") issued a press release on November 4, 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 announces Third Quarter Financial Results and updates the Company's Business Overview. The Company's Business Overview should be read in conjunction with the Company's other public filings with the Securities and Exchange Commission

**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, 2003.

AVI BioPharma, Inc.

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

**Exhibit 99.1**

**Text of Press Release**

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November 4, 2003

## AVI BIOPHARMA ANNOUNCES THIRD QUARTER FINANCIAL RESULTS

PORTLAND, Ore. (November 4, 2003) – AVI BioPharma, Inc. (Nasdaq: AVII) today reported financial results for the three and nine months ended September 30, 2003.

For the third quarter of 2003, the company reported a net loss of $4.6 million, or $0.15 per share, compared with a net loss of $7.1 million, or $0.27 per share, for the third quarter of 2002, which included a non-cash write-down of short-term securities – available-for-sale of $1.8 million.

Research and development expenses during the third quarter of 2003 decreased to $3.5 million from $4.6 million in the comparable quarter last year. This decrease was largely due to moving NEUGENEÒ manufacturing in-house to the company's GMP manufacturing facility, thereby substantially reducing manufacturing costs for those clinical development programs.

For the nine months ended September 30, 2003, AVI BioPharma reported a net loss of $11.5 million, or $0.40 per share, compared with a net loss of $25.4 million, or $1.00 per share, for the comparable period in 2002.

Operating expenses for the nine months of 2003 were $12.5 million, compared with $21.9 million for the comparable period of 2002. Year-to-date 2003 research and development expenses decreased to $8.9 million, compared with $18.9 million for the comparable period in 2002, reflecting the in-house manufacturing of NEUGENE drug candidates. Year-to-date 2003 general and administrative expenses increased to $3.7 million, from $3.0 million last year.

The company had cash, cash equivalents and short-term securities of $27.7 million as of September 30, 2003, an increase of approximately $8.4 million from December 31, 2002. This increase was due primarily to the receipt of $20.8 million in net proceeds from a May 2003 private equity financing and $363,367 from the exercise of options and employee stock purchase plan, offset by $12.9 million used in operations and $1.6 million used for purchases of property and equipment and patent related costs.

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"As to our continued clinical progress, we have plans to bring two drugs, Resten-NG® for the treatment of cardiovascular restenosis and our proprietary cancer therapeutic vaccine AVICINE®, into Phase III clinical trials," said Denis R. Burger, Ph.D., chief executive officer of AVI.

"Additionally, we have two clinical trials underway for the treatment of West Nile virus, which could result in initiating a pivotal trial for this disease during next year's West Nile season," commented Dr. Burger. "We also are enthusiastic about preclinical results reported by two reputable research laboratories with our NEUGENE compound for the treatment of Severe Acute Respiratory Syndrome (SARS). We plan to manufacture sufficient quantity of this compound for a small overseas clinical trial if SARS should reappear the coming winter.

"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," added Dr. Burger.

### Product Pipeline Update

Technology Overview
AVI is developing products based on two distinct core technologies, its NEUGENE antisense program and its AVICINE cancer vaccine. 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.

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, 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.

Cardiovascular Disease Program
Resten-NG is a NEUGENE antisense drug for treating cardiovascular restenosis, or the re-narrowing of a coronary artery following balloon 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 global 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 microbubble delivery technology, possibly lessening the need to use special drug delivery catheters or drug-coated stents. In August 2003, AVI initiated a Phase II clinical trial with Resten-NG coupled with the microbubble delivery technology at the University of Nebraska Medical Center. AVI is planning a Phase III trial to be initiated in the first quarter of 2004 in Europe with Resten-NG delivered on a stent platform 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 single-stranded RNA viruses to target West Nile virus (WNV), the SARS coronavirus, Norovirus, hepatitis C 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 and began a second clinical study the following month, designed to potentially expand access to AVI-4020. AVI's NEUGENE drug candidate AVI-4179, designed to combat the SARS coronavirus, is being evaluated at National Institutes of Health and World Health Organization (WHO) laboratories. 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, and in October 2003 received confirmatory data from a WHO-associated laboratory on AVI-4179's efficacy.

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 Ib clinical trial in Lymphoma 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 begin a Phase III clinical program with AVICINE for treating pancreatic cancer by the first quarter of 2004.

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 3a4, which resulted in an improved pharmacokinetic profile of the test drug. In September 2003, AVI initiated an oral dosing of AVI-4557 with the agent to evaluate the oral route of administration. This study is currently ongoing. 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 three doses of AVI-4126 in 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 usually lethal for children. This form of PKD is very similar



genetically to the pre-clinical PKD models that AVI has used to produce efficacy data for our antisense drug. AVI plans to initiate this trial in the second half of 2004.

AVI BioPharma has scheduled an investor conference call regarding this announcement to be held today, beginning at 11:00 a.m. Eastern Time. The conference call is regarding this announcement and AVI BioPharma's current and planned business and activities. 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 3414105.

**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®, 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**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2003* | 2002* | 2003* | 2002* |
| Revenues, from license fees, grants and research contracts | $ 414,352 | $ 232,192 | $ 834,685 | $ 667,578 |
| Operating expenses: | | | | |
| Research and development | 3,533,868 | 4,594,023 | 8,879,045 | 18,867,238 |
| General and administrative | 1,560,026 | 1,009,299 | 3,670,508 | 2,989,524 |
| | 5,093,894 | 5,603,322 | 12,549,553 | 21,856,762 |
| Other income (loss): | | | | |
| Interest income, net | 75,887 | 111,169 | 194,468 | 302,227 |
| Write-down of short-term securities-available-for-sale | — | (1,791,304) | — | (4,478,260) |
| | 75,887 | (1,680,135) | 194,468 | (4,176,033) |
| Net loss | $ (4,603,655) | $ (7,051,265) | $ (11,520,400) | $ (25,365,217) |
| Net loss per share— | | | | |
| Basic and diluted | $ (0.15) | $ (0.27) | $ (0.40) | $ (1.00) |
| Shares used in per share calculations | 31,186,464 | 26,444,102 | 29,061,913 | 25,424,078 |

**BALANCE SHEET HIGHLIGHTS**

| | September 30, 2003* | December 31, 2002** |
|---|---|---|
| Cash, cash equivalents and short-term securities | $ 27,659,510 | $ 19,293,645 |
| Total current assets | 28,314,248 | 20,401,988 |
| Total assets | 37,115,097 | 28,603,757 |
| Total current liabilities | 2,308,872 | 5,122,134 |
| Total shareholders' equity | $ 34,806,225 | $ 23,481,623 |

* Unaudited
** Derived from audited statements

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