# 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): August 5, 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 August 5, 2004 announcing financial results for the three and six months ended June 30, 2004.

# Item 9. Regulation FD Disclosure

Information furnished under Item 12.

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

On August 5, 2004, AVI BioPharma, Inc. issued a press release announcing its financial results for the three and six months ended June 30, 2004. The press release is attached to this Form 8-K as Exhibit 99.1.

\* \* \*

*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 August 5, 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 August 5, 2004 issued by AVI BioPharma, Inc.

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#### **Company Contact:**

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#### **Investor Contacts:**

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**For Immediate Release** 

# AVI BIOPHARMA ANNOUNCES SECOND QUARTER FINANCIAL RESULTS

**PORTLAND, Ore.** (August 5, 2004) – AVI BioPharma, Inc. (Nasdaq: AVII) today reported financial results for the three and six months ended June 30, 2004.

For the second quarter of 2004, the company reported a net loss of \$7.1 million, or \$0.20 per share, compared with a net loss of \$3.5 million, or \$0.12 per share, for the second quarter of 2003. Revenues for the second quarter of 2004 were \$36,271, compared with \$162,410 for the second quarter of 2003. This decrease was due primarily to lower grants and research contracts revenues.

Research and development expenses increased to \$6.2 million from \$2.5 million, and general and administrative expenses decreased to \$1.1 million from \$1.2 million in the second quarter of 2004, compared with the second quarter of 2003. Approximately \$3.0 million of the increase in research and development was due to the company contracting 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 included in the calculation of the 2004 financial guidance.

For the six months ended June 30, 2004, AVI BioPharma reported a net loss of \$14.7 million, or \$0.41 per share, compared with a net loss of \$6.9 million, or \$0.25 per share, for the comparable period in 2003. Revenues for the six months ended June 30, 2004 were \$135,722, compared with \$420,333 for the comparable period in 2003. This decrease was due primarily to lower grants and research contracts revenues.

Operating expenses for the first six months of 2004 were \$15.1 million, compared with \$7.5 million for the comparable period of 2003. First half 2004 research and development expenses increased to \$12.8 million, compared with \$5.3 million for the comparable period in 2003. Approximately \$6.0 million of this increase in research and development was due to the company contracting 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 included in the calculation of the 2004 financial guidance. Year-to-date 2004 general and administrative expenses increased to \$2.4 million, compared with \$2.1 million last year.

AVI had cash, cash equivalents and short-term securities of \$29.2 million as of June 30, 2004, a decrease of \$8.4 million from December 31, 2003. This decrease is due primarily to \$14.7 million used in

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operations and \$627,607 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.

In June 2004, the Company was informed that \$10 million of government funding for fiscal year 2005 had been allocated for work on two viral disease research projects. Subsequently, the allocation to the Company was modified to \$5 million, subject to final approval by the President.

"We have numerous drug development opportunities based on the versatility of our third generation NEUGENE<sup>®</sup> antisense technology and our strategy is to dedicate our internal resources to drug candidates that can be developed relatively quickly and target large market opportunities," said Denis R. Burger, Ph.D., chief executive officer of AVI. "Our restenosis and viral disease programs remain at the forefront of our internal efforts. Additionally, our research efforts in conjunction with the government funding, give us a unique opportunity to showcase our technology while contributing to important biodefense efforts."

Dr. Burger added, "We will also be seeking corporate partners for other longer-term programs. Importantly, we have built a solid framework for proceeding with our NEUGENE programs by demonstrating both safety and efficacy of our compounds in our initial clinical trials, with no drug-related serious adverse events in treating more than 250 patients in 11 clinical studies."

# 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.

In the oncology 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. AVICINE has demonstrated a benefit in combination with standard cancer treatments, including chemotherapy.

#### Viral Disease Program

AVI has used its proprietary NEUGENE antisense agents to focus on RNA viruses to target West Nile virus (WNV), the SARS coronavirus, Hepatitis C virus (HCV), and Dengue virus as well as many of the

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viruses included on the Domestic Homeland Security list of bioterrorism viruses. AVI plans to focus its anti-viral 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 in 2005.

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. This trial met its primary safety endpoint and also demonstrated a favorable pharmacokinetic profile with drug detected in cerebrospinal fluid. AVI filed an application for Orphan Drug 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.

#### Cardiovascular Disease Program

Resten-NG<sup>®</sup> 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 the second half of 2004 in Europe with Resten-NG delivered via stent. These trials are designed to lead into 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.

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<sup>®</sup>. 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 after establishing strategic relationships with pharmaceutical partners.

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# 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 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.

# 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 clinical study in the early onset form of PKD that is life threatening for children. AVI plans to initiate this trial in the second half of 2004 in adolescent children and then move into infants as additional safety data are gathered.

### **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 8897856.

# **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/.

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"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]

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

	Three Months Ended June 30,				Six Months Ended June 30,			
		2004		2003		2004		2003
Revenues, from license fees, grants and research contracts	\$	36,271	\$	162,410	\$	135,722	\$	420,333
Operating expenses:								
Research and development		6,151,870		2,539,282		12,765,858		5,345,177
General and administrative		1,116,027		1,177,081		2,354,228		2,110,482
		7,267,897		3,716,363		15,120,086		7,455,659
Other income:								
Interest income, net		83,664		56,025		303,890		118,581
Net loss	\$	(7,147,962)	\$	(3,497,928)	\$	(14,680,474)	\$	(6,916,745)
Net loss per share—basic and diluted	\$	(0.20)	\$	(0.12)	\$	(0.41)	\$	(0.25)
Shares used in per share calculations		36,109,016		29,380,554		35,859,852		27,982,031

# BALANCE SHEET HIGHLIGHTS (unaudited)

	June 30, 2004	December 31, 2003		
Cash, cash equivalents and short-term securities	\$ 29,174,139	\$	37,599,136	
Total current assets	29,648,455		38,390,519	
Total assets	38,142,082		47,145,023	
Total current liabilities	2,166,913		3,750,993	
Total shareholders' equity	\$ 35,975,169	\$	43,394,030	

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