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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## 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): August 5, 2003

### 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

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

AVI BioPharma, Inc. (the "Company") issued a press release on August 5, 2003, before the opening of trading in its Common Stock on the Nasdaq National Market System, a copy of which is attached as Exhibit 99.1.

The Press Release announces Second Quarter Financial Results and updates the Company's product research and clinical trials.

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

None

#### 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 8, 2003.

AVI BioPharma, Inc.

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

**For Immediate Release****AVI BioPharma Announces Second Quarter Financial Results***Company Advances Clinical Development Programs, Strengthens Cash Position*AVI Contact:

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PORTLAND, Ore. (August 5, 2003) - AVI BioPharma, Inc. (Nasdaq: AVII, AVIHW, AVIIZ), a biopharmaceutical company developing treatments for life-threatening diseases based on antisense and cancer immunotherapy technologies, today reported financial results for the three and six months ended June 30, 2003.

For the second quarter of 2003, the company reported a net loss of \$3.5 million, or \$0.12 per share, compared with a net loss of \$10.5 million, or \$0.40 per share, for the second quarter of 2002, which included a non-cash write-down of \$2.7 million.

Research and development expenses during the second quarter of 2003 decreased to \$2.5 million from \$7.2 million for the comparable quarter last year. This decrease was largely due to moving NeuGene® manufacturing in-house to the company's GMP manufacturing facility, thereby substantially reducing manufacturing costs.

For the six months ended June 30, 2003, AVI BioPharma reported a net loss of \$6.9 million, or \$0.25 per share, compared with a net loss of \$18.3 million, or \$0.74 per share, for the comparable period in 2002.

Operating expenses for the first six months of 2003 were \$7.5 million, compared with \$16.3 million for the comparable period of 2002. First-half 2003 research and development expenses decreased to \$5.3 million, compared with \$14.3 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 \$2.1 million, compared with \$2.0 million last year.

The company had cash, cash equivalents and short-term securities of \$30.3 million as of June 30, 2003, an increase of approximately \$11 million from

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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 \$250,453 from the exercise of options and warrants, offset by \$9.4 million used in operations and \$1.3 million used for purchases of property and equipment and patent-related costs.

"In addition to making important clinical progress during recent months, we raised a significant amount of equity capital and are now in a stronger position to move forward with our drug development programs," said Denis R. Burger, Ph.D., chief executive officer of AVI.

"Yesterday, we announced that we have satisfied the regulatory requirements and are cleared to begin clinical trials with our drug candidate AVI-4020, targeting the West Nile virus," commented Dr. Burger. "In June, the company filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) to begin testing AVI-4020 in humans, and subsequently manufactured initial lots of this drug in preparation for clinical testing.

"On June 25, we commenced an exchange offer relating to our proposed acquisition of eXegenics (Nasdaq:EXEG - News) during the current quarter," added Dr. Burger. "In addition to gaining proprietary antisense drug discovery technology and three validated cancer targets, we expect to receive up to \$10 million in cash from this transaction, if completed. The additional funds will further support our clinical development work, helping us to achieve our dual goals of developing drugs for life-threatening diseases and creating shareholder value. Successful completion of the acquisition is subject to various conditions, including the tender of at least a majority of eXegenics shares in the exchange offer."

**Product Pipeline Update***Antisense***NeuGenes**

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.

## Resten-NG®

Resten-NG is a NeuGene antisense drug for treating cardiovascular restenosis, or the re-narrowing of a coronary artery following balloon angioplasty. Resten-NG targets a key regulatory gene involved in the disease process. A global license has been granted to Medtronic, Inc. for AVI's antisense compounds deployed on stents or other devices for treating restenosis. At the September 2002 Transcatheter Cardiovascular Therapeutics (TCT) conference, AVI announced interim Phase II clinical trial data showing that Resten-NG delivered via catheter during balloon angioplasty procedures resulted in an approximate 80% reduction

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in the restenosis rate. At the April 2003 American College of Cardiology meeting, results from two independent studies were presented that additionally demonstrate 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. AVI plans to enter a Phase II clinical trial with Resten-NG coupled with the microbubble delivery technology at the University of Nebraska Medical Center later this quarter.

## 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 initiate a Phase Ib clinical study with a NeuGene antisense agent later this year in prostate cancer.

## Drug Metabolism

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 - one consisting of treatment with a single intravenous injection of 300 mg of AVI-4557, and the other consisting of treatment with five consecutive daily intravenous injections of 90 mg of AVI-4557 - showed that AVI-4557 down-regulated cytochrome P450 3a4, which resulted in an improved pharmacokinetic profile of the test drug.

## Polycystic Kidney Disease

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 and with varying degrees of compromised kidney function. Results of the study showed an excellent safety profile and no adverse effect on kidney function. Phase Ib study results are crucial in designing Phase II studies, which will evaluate efficacy in PKD patients.

## Antiviral Programs

AVI is currently focusing on single-stranded RNA viruses using the company's proprietary NeuGene antisense agents to target many of the viruses included on the Domestic Homeland Security list of bioterrorism viruses, as well as hepatitis C virus, West Nile virus, Calicivirus and the SARS coronavirus. In May 2003, AVI filed an application with the FDA to obtain Orphan Drug designation for its West Nile NeuGene drug candidate, AVI-4020, and submitted an IND the following month. AVI has manufactured several lots of AVI-4020 in preparation for its plan to enter a Phase Ib clinical trial in West Nile patients during the summer of 2003. The company's NeuGene drug candidate AVI-4179, designed to combat the SARS

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coronavirus, is being evaluated at National Institutes of Health and World Health Organization laboratories.

## ***Cancer Immunotherapy***

### **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, 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.

## Pancreatic Cancer

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®. Those treated with Avicine alone reported one-year survival data similar to historical results for those treated with Gemzar, without the chemotherapy-related side effects often associated with 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 during 2003.

AVI BioPharma has scheduled an investor conference call regarding this announcement 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](http://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 and entering reservation number 1874784.

## **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 cardiovascular restenosis, cancer, polycystic kidney disease and other cell proliferation disorders. 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 and colorectal cancer. More information about AVI is available on the company's Web site at [www.avibio.com](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

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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**

|  | <u>Three Months Ended June 30,</u> |                    | <u>Six Months Ended June 30,</u> |                    |
|--|------------------------------------|--------------------|----------------------------------|--------------------|
|  | <u>2003*</u>                       | <u>2002*</u>       | <u>2003*</u>                     | <u>2002*</u>       |
| Revenues, from license fees, grants & research contracts | \$ 162,410                         | \$ 197,691         | \$ 420,333                       | \$ 435,386         |
| Operating expenses:                                      |                                    |                    |                                  |                    |
| Research and development                                 | 2,539,282                          | 7,224,095          | 5,345,177                        | 14,273,215         |
| General and administrative                               | 1,177,081                          | 895,706            | 2,110,482                        | 1,980,225          |
|  | <u>3,716,363</u>                   | <u>8,119,801</u>   | <u>7,455,659</u>                 | <u>16,253,440</u>  |
| Other income (loss):                                     |                                    |                    |                                  |                    |
| Interest income, net                                     | 56,025                             | 111,207            | 118,581                          | 191,058            |
| Write-down of short-term securities-available-for-sale   | —                                  | (2,686,956)        | —                                | (2,686,956)        |
|  | <u>56,025</u>                      | <u>(2,575,749)</u> | <u>118,581</u>                   | <u>(2,495,898)</u> |
| Net income (loss)  | \$ (3,497,928)                     | \$ (10,497,859)    | \$ (6,916,745)                   | \$ (18,313,952)    |
| Net income (loss) per share basic and diluted            | \$ (0.12)                          | \$ (0.40)          | \$ (0.25)                        | \$ (0.74)          |
| Shares used in per share calculations                    | 29,380,554                         | 26,353,017         | 27,982,031                       | 24,905,613         |

**BALANCE SHEET HIGHLIGHTS**

|  | <u>June 30, 2003*</u> | <u>December 31, 2002**</u> |
|--|-----------------------|----------------------------|
| Cash, cash equivalents and short-term securities | \$ 30,340,489         | \$ 19,293,645              |
| Total current assets                             | 30,777,764            | 20,401,988                 |
| Total assets                                     | 39,624,493            | 28,603,757                 |
| Total current liabilities                        | 1,296,276             | 5,122,134                  |
| Total shareholders' equity                       | \$ 38,328,217         | \$ 23,481,623              |

\* Unaudited

\*\* Derived from audited statements

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