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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): **November 5, 2002**

### **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 5. Other Events.**

AVI BioPharma, Inc. (the "Company") issued a press release on November 5, 2002, before the opening of trading in its Common Stock on the Nasdaq National Market System, a copy of which is attached as Exhibit 99.

The Press Release announces Third 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 November 5, 2002.

AVI BioPharma, Inc.

By:           /s/ ALAN P.TIMMINS          

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Alan P. Timmins  
*President and Chief Operating Officer*  
*(Principal Operating Officer)*

## Text of Press Release

*AVI Contacts:*

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 Alan P. Timmins, President and COO  
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For Immediate Release

**AVI BIOPHARMA REPORTS THIRD QUARTER FINANCIAL RESULTS**

PORTLAND, Ore. (November 5, 2002)—AVI BioPharma, Inc. (Nasdaq: AVII, AVIIW, 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 nine months ended September 30, 2002.

For the third quarter of 2002, the Company reported a net loss of \$7.1 million, or \$0.27 per share, compared with a net loss of \$15.6 million, or \$0.67 per share, for the third quarter of 2001. The 2002 and 2001 third quarter net losses included non-cash write-downs of short-term securities—available-for-sale for an other-than-temporary impairment of an equity investment in accordance with generally accepted accounting principles of \$1.8 million and \$12.5 million, respectively. The net losses for the 2002 and 2001 third quarters excluding these non-cash write-downs were \$5.3 million, or \$0.20 per share, and \$3.1 million, or \$0.13 per share, respectively.

Research and development expenses during the third quarter of 2002 increased to \$4.6 million from \$2.8 million for the comparable quarter last year, primarily due to costs of GMP manufacturing of NeuGenes® by an outside contractor in preparation for Phase III clinical trials and for potential future commercial launch of the Resten-NG™ product. General and administrative expenses for the 2002 third quarter were \$1.0 million, up from \$878,000 in the 2001 third quarter owing to additional expenses associated with outside collaborations, expansion of the Company's clinical development and regulatory affairs efforts, and additional preclinical and clinical testing of the Company's products.

For the nine months ended September 30, 2002, AVI BioPharma reported a net loss of \$25.4 million, or \$1.00 per share, compared with a net loss of \$22.3 million, or \$1.01 per share, for the comparable period in 2001. The net loss for the 2002 and 2001 nine-month periods included non-cash write-downs of short-term securities—available-for-sale for an other-than-temporary impairment of an equity investment in accordance with generally accepted accounting principles of \$4.5 million and

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\$12.5 million, respectively. The net losses for the 2002 and 2001 periods excluding these non-cash write-downs were \$20.9 million, or \$0.82 per share, and \$9.8 million, or \$0.44 per share, respectively.

Research and development expenses for the first nine months of 2002 increased to \$18.9 million from \$8.5 million for the comparable period in 2001, and year-to-date 2002 general and administrative expenses increased to \$3 million from \$2.6 million last year. The reasons behind increases in nine-month expenses largely mirror those impacting the third quarter.

The Company had cash, cash equivalents and short-term securities of approximately \$22 million as of September 30, 2002, a decrease of \$3.1 million from December 31, 2001. This decrease was due primarily to \$16.6 million used in operations, \$2.4 million used for purchases of property and equipment and patent-related costs, and a net \$5.8 million decline in the value of the Company's short-term securities, offset by the receipt of \$21.3 million in net proceeds from a private equity financing with several institutional investors.

"During the third quarter, we continued to make excellent progress in advancing our numerous clinical programs," stated Denis R. Burger, Ph.D., AVI BioPharma's chief executive officer. "Among recent highlights, in September we presented Phase II clinical trial data with Resten-NG delivered via catheter into the coronary arteries that indicated an approximate 80% reduction in the restenosis rate. Last week, we announced that data collected during our metabolic redirection studies with NeuGenes confirm subcutaneous availability in humans. Also last week, we reported that a preclinical study presented in a peer reviewed scientific publication has provided us the first evidence that topically applied NeuGenes can produce systemic changes in gene expression in the liver. Our proprietary NeuGene antisense has already demonstrated extensive applicability, and the delivery of NeuGenes through multiple routes further broadens their utility.

"In the coming weeks," he added, "we intend to report results of our NeuGene polycystic kidney disease Phase Ib study, and we expect to complete our Phase II NeuGene trial with cancer later this year. Early next year, we will initiate a Phase III AVICINE® trial for pancreatic cancer. Additionally, next year, we intend to

introduce new drugs into clinical trials for cholesterol lowering, prostate cancer and Hepatitis C."

## **Product Pipeline Update**

### ***Antisense***

#### **NeuGene**

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 compound for treating cardiovascular restenosis, or the re-narrowing of an artery following balloon angioplasty. Resten-NG targets a transcription factor, and upon entering arterial cells, it blocks the underlying cause of the disease: smooth muscle cell activation and proliferation. AVI has demonstrated in preclinical studies that Resten-NG significantly reduced coronary restenosis. 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 Phase II clinical trial

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data showing that Resten-NG delivered via catheter during balloon angioplasty procedures resulted in an approximate 80% reduction in the restenosis rate.

#### ***Cancer***

AVI is conducting a Phase I/II clinical study with its NeuGene antisense technology in patients with solid tumors. The Company expects to complete this study and to report preliminary results near the end of 2002. Previous studies have shown that this antiproliferative antisense drug is both safe and effective at shutting down cell division, a hallmark of cancer progression.

#### ***Prostate Cancer***

In August 2001, AVI announced the initiation of a study in prostate cancer, funded by the Department of Defense. AVI presented preclinical study results at the Annual CaP Cure prostate cancer conference in September 2001 showing that AVI's antisense compounds inhibit cancer cell growth and cause cell death in prostate tumors. In December 2001, AVI was awarded a Department of Defense Prostate Cancer Research Program grant to pursue development of therapeutics to fight both the initial stages and the incurable metastatic forms of prostate cancer using AVI's NeuGenes. Also in December, AVI presented preclinical study results at the 10th International Conference on Gene Therapy of Cancer. In April 2002 and in June 2002, the Company presented research showing NEUGENE directed against the c-myc gene caused cell growth inhibition and cell death in human prostate cancer cells. AVI plans to initiate human testing in prostate cancer during 2003.

#### ***Liver Enzyme Modification***

AVI successfully completed a clinical trial demonstrating that the Company's antisense drug improves the pharmacokinetic profile of a test drug in modifying the function of a liver enzyme that is critical to the body's processing of many drugs. The study is based on the results of preclinical studies using AVI's NeuGene antisense technology targeting liver cytochrome enzymes, which control metabolism of most drugs. Data from the trial will be presented at future scientific forums. As noted, the Company announced that its clinical study of NeuGenes pharmacokinetic analyses of data from the liver enzyme study completed earlier this year showed that the subcutaneous route of administration resulted in dose-dependent elevations in blood concentrations of NeuGenes. Also, in October 2002 AVI announced that animal studies indicated that topical application of NeuGene produced systemic changes in gene expression in the liver.

#### ***Polycystic Kidney Disease***

In December 2001, AVI initiated a Phase I clinical study in patients with polycystic kidney disease (PKD). Preclinical studies have demonstrated that AVI-4126 is effective in preventing some of the clinical manifestations of PKD. In August 2002, AVI announced that it had completed a clinical study that evaluated the safety and pharmacokinetics of three doses of AVI-4126 in patients with PKD and with varying degrees of compromised kidney function. Patients in this study did not demonstrate serious adverse experience, nor was their kidney function adversely affected. Results of the trial are expected to be reported during the fourth quarter of 2002.

#### ***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 naturally produced during pregnancy and is believed to stimulate growth and shield the embryo from immune system attack. The hCG hormone is expressed in most, if not all, cancers as a membrane-associated

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tumor marker and is believed to promote tumor growth and vascularization and to render patients immunologically unresponsive to the tumor. The role of hCG in cancer and pregnancy is widely believed to be analogous. Thus, Avicine stimulates the immune system to mount an attack against cancer cells expressing this hormone.

#### ***Pancreatic Cancer***

In December 2001, AVI reported Phase II data demonstrating that Avicine provided substantial survival benefit to patients with pancreatic cancer. In this study, patients were treated with Avicine alone, or with Avicine in combination with the chemotherapy agent Gemzar®. Those treated with Avicine 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. Early next year, the Company plans to begin a Phase III clinical program with Avicine for treating pancreatic cancer.

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 (888) 642-1687 and entering reservation number 6323859.

#### About AVI BioPharma

AVI BioPharma develops therapeutic products for the treatment of life-threatening diseases using two technology platforms: NeuGene antisense drugs and cancer immunotherapy. Its lead cancer agent, Avicine, a therapeutic cancer vaccine, has completed three Phase II trials in colorectal and pancreatic cancer and is initiating a Phase III pivotal trial in pancreatic cancer, with a supporting study in colorectal cancer. The first application of its NeuGene compounds, Resten-NG, is designed to treat cancer, cardiovascular restenosis and other cell proliferation disorders by inhibiting the production of a cellular transcription factor, the oncogene c-myc. It is currently in Phase II trials for restenosis and in a Phase I/II trial for cancer. AVI has recently completed a Phase I NeuGene antisense study that successfully down-regulated the liver enzyme Cytochrome P450 and modified drug metabolism. 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 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 Companies' Securities and Exchange Commission filings.

[Tables to Follow]

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002*	2001*	2002*	2001*
Revenues, from license fees, grants & research contracts	\$ 232,192	\$ 307,549	\$ 667,578	\$ 410,793
Operating expenses:				
Research and development	4,594,023	2,774,979	18,867,238	8,530,261
General and administrative	1,009,299	877,615	2,989,524	2,551,273
	<u>5,603,322</u>	<u>3,652,594</u>	<u>21,856,762</u>	<u>11,081,534</u>
Other income (loss):				
Interest income, net	111,169	271,939	302,227	872,910
Write-down of short-term securities — available-for-sale	(1,791,304)	(12,523,088)	(4,478,260)	(12,523,088)
	<u>(1,680,135)</u>	<u>(12,251,149)</u>	<u>(4,176,033)</u>	<u>(11,650,178)</u>
Net loss	\$ (7,051,265)	\$ (15,596,194)	\$ (25,365,217)	\$ (22,320,919)
Net loss per share — basic and diluted	\$ (0.27)	\$ (0.67)	\$ (1.00)	\$ (1.01)
Shares used in per share calculations	26,444,102	23,122,839	25,424,078	22,151,720

**BALANCE SHEET HIGHLIGHTS**

	September 30, 2002*	December 31, 2001**
Cash, cash equivalents and short-term securities	\$ 22,467,028	\$ 25,597,121
Total current assets	23,029,158	27,511,076
Total assets	30,743,002	33,815,113
Total current liabilities	4,915,861	3,281,066
Total shareholders' equity	\$ 25,827,141	\$ 30,534,047

\* Unaudited

\*\* Derived from audited statements