

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): **March 12, 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

Item 5. Other Events.

AVI BioPharma, Inc. (the "Company") issued a press release on March 12, 2002, before the start of trading in its Common Stock on the Nasdaq National Market System, announcing the fourth quarter 2001 and full calendar year 2001 financial results for the Company, a copy of which is attached as Exhibit 99.

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 March 12, 2002.

AVI BioPharma, Inc.

By: /s/ ALAN P. TIMMINS

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

EXHIBIT 99

Text of Press Release

Company Contacts:

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**AVI BioPharma Announces 2001 Fourth Quarter
And Full Year Financial Results**

PORTLAND, Ore.—March 12, 2002—AVI BioPharma, Inc. (Nasdaq: AVII, AVIIW, AVIIZ), a biopharmaceutical company that develops products based on antisense drug development and cancer immunotherapy, today reported financial results for the three and 12 months ended December 31, 2001.

For the fourth quarter of 2001, the company reported a net loss of \$4.6 million, or \$0.20 per share, compared with a net loss of \$3.0 million, or \$0.14 per share, for the fourth quarter of 2000. Research and development expenses during the fourth quarter of 2001 increased to \$4.2 million from \$2.7 million for the comparable quarter last year, and general and administrative expenses increased to \$806,544 from \$786,143 last year. These increases were primarily due 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 year 2001, the company recorded a net loss of \$26.9 million, or \$1.20 per share, compared with a net loss of \$9.2 million, or \$0.49 per share, reported in 2000. The 2001 net loss included a \$12.5 million one time, non-cash write-down of securities in accordance with SEC accounting rules. The 2001 net loss excluding this write-down was \$14.4 million, or \$0.64 per share. Revenues for the year 2001 were \$706,102, compared with \$1.3 million in 2000, which included a \$1 million payment for expansion of a license for diagnostic applications. Research and development expenses during 2001 were \$12.8 million, compared with \$9.3 million in 2000, and general and administrative expenses were \$3.4 million, compared with \$2.3 million last year. These increases were primarily due 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.

The company had cash, cash equivalents and short-term securities of \$25.6 million as of December 31, 2001, a decrease of \$6.5 million from December 31, 2000. This decrease was due primarily to \$12.6 million used in operations and \$4.9 million used for capital expenditures and patent-related costs. This decrease was net of proceeds of \$10 million from the stock purchase agreement with Medtronic, Inc., \$0.8 million from the exercise of options and warrants, and a net \$0.2 million increase in the value of the company's short-term securities.

For 2001, AVI's operations were led by a growing investment in R&D, construction of a Good Manufacturing Practices (GMP) facility to produce antisense drugs for clinical trials, and continued expansion of the company's clinical development and regulatory affairs efforts. For 2002, the company expects higher operating costs as a result of a growing investment in R&D and expanded clinical trials, with an anticipated burn rate for the year of approximately \$20 million.

"The year was outstanding for AVI because we achieved several major milestones with our NEUGENE® and AVICINE® platform technologies," said Denis R. Burger, Ph.D., chief executive officer of AVI. "Among the many highlights, we started the year by initiating a Phase III pivotal trial with AVICINE for colorectal cancer. In April, we announced a strategic alliance with Exelixis Inc. to apply its expertise in genetic model systems to discover, validate and screen novel targets suitable for inhibition by our antisense therapeutics. The following month, we signed a licensing agreement with Medtronic to use NEUGENES to coat stents for coronary restenosis. As a result, Medtronic has undertaken an aggressive development and regulatory program to bring coated stents to market both in the United States and in Europe.

"Our momentum continued into the fourth quarter," said Dr. Burger. "In November, we announced results of an initial Phase I metabolic redirection study with NEUGENE, which showed no drug-related toxicity or safety issues, and we are completing a Phase Ib trial to determine whether NEUGENE improves the pharmacokinetic profile of a test drug. In December, we announced positive results of our Phase II AVICINE trial for pancreatic cancer, which demonstrated a significant improvement in the one-year survival of patients who received AVICINE in combination with Eli Lilly's drug gemcitabine (Gemzar). In addition, in December, we entered a Phase I/II study with NEUGENE for polycystic kidney disease (PKD)."

Dr. Burger said, "Among our milestones in the current year with NEUGENE, we intend to complete the Phase I/II Oncomyc-NG trial in cancer, complete the Phase I/II PKD trial and complete the Phase Ib metabolic redirection trial. With AVICINE, we anticipate continued progress on all fronts, including presentation of our pancreatic cancer Phase II results at the American Society of Clinical Oncology (ASCO) meeting in the spring."

Product 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 backbone 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 relogging 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 Resten-NG significantly reduced coronary restenosis. A global license has been granted to Medtronic for AVI's antisense compounds deployed on stents or other devices for treating restenosis.

Cancer

AVI is conducting a Phase I/II clinical study with its NEUGENE antisense technology in patients with solid tumors. This study is expected to be completed around 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 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 demonstrating that a combination of two proprietary NEUGENE drugs had a synergistic effect in halting cell growth of refractory cancer cells in prostate cancer. AVI plans to initiate a human clinical trial in prostate cancer later this year.

Metabolic Redirection

In November 2001, AVI successfully completed a Phase I clinical trial to collect safety and pharmacokinetic data of its antisense technology 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. AVI hopes to show improved pharmacokinetics of existing FDA-approved drugs by down-regulating liver cytochrome enzymes. The company has completed the second part of the metabolic redirection study, which will evaluate whether AVI's antisense drug improves the pharmacokinetic profile of a test drug. Data from this trial will be presented at upcoming scientific forums later this year.

Polycystic Kidney Disease

AVI initiated a Phase I/II clinical study in patients with polycystic kidney disease in December 2001. Preclinical studies have demonstrated that AVI-4126 is effectiveness in preventing some of the clinical manifestations of PKD. The study will evaluate the safety and pharmacokinetics of three doses of AVI-4126 in patients with PKD and varying degrees of compromised kidney function.

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 attack. 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. 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.

Colorectal Cancer

The company is in a Phase III pivotal trial with AVICINE for the treatment of colorectal cancer. This study was initiated in January 2001 and involves first-line therapy for 800 patients randomized in two arms: AVICINE in combination with chemotherapy, and chemotherapy alone. The trial design is based on an analysis of data from five completed clinical trials, including a multicenter Phase II study in advanced colorectal cancer, and following discussions with the FDA.

Pancreatic Cancer

In December 2001, AVI reported that AVICINE provided substantial survival benefit to patients with pancreatic cancer as a result of a completed Phase II clinical study. In this study, patients were treated with AVICINE alone, or with AVICINE in combination with Gemzar. Those treated with AVICINE reported one-year survival data similar to historical results for those treated with Gemzar, without the vaccine-related side effects often associated with Gemzar. A one-year survival rate of 30 percent was

reported for patients treated with AVICINE plus Gemzar, which is approximately double the survival rates for either treatment alone.

AVI BioPharma has scheduled an investor conference call regarding this announcement to be held today, March 12 beginning at 11 a.m. Eastern Time. Those who want to participate in the live call via telephone may call (800) 252-8302. A telephone replay will be available until 10 a.m. Eastern Time March 14, by

dialing (800) 633-8284, and entering reservation number 20209039.

Those interested in listening to the conference call live via the Internet may do so by visiting the company's Web site at <http://www.avibio.com/>. A replay will be available on the site for 14 days.

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 in a Phase III pivotal trial 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 Phase I/II trials for cancer and polycystic kidney disease. 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.

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

	Three Months Ended December 31, (unaudited)		Year Ended December 31,	
	2001	2000	2001	2000
Revenues from license fees, grants & research contracts	\$ 295,309	\$ 25,000	\$ 706,102	\$ 1,297,338
Operating expenses:				
Research and development	4,220,640	2,692,377	12,750,901	9,268,330
General and administrative	806,544	786,143	3,357,817	2,270,302
	5,027,184	3,478,520	16,108,718	11,538,632
Other income (loss):				
Interest income, net	127,620	445,963	1,000,530	1,001,338
Write-down of short-term securities—available-for-sale	—	—	(12,523,088)	—
Net loss	\$ (4,604,255)	\$ (3,007,557)	\$ (26,925,174)	\$ (9,239,956)
Net loss per share, basic and diluted	\$ (0.20)	\$ (0.14)	\$ (1.20)	\$ (0.49)
Shares used in per share calculations	23,186,945	21,477,556	22,399,001	18,724,533

BALANCE SHEET HIGHLIGHTS

	December 31, 2001	December 31, 2000
Cash, cash equivalents and short-term securities	\$ 25,597,121	\$ 32,112,099
Total current assets	27,511,076	33,131,265
Total assets	33,815,113	35,088,393
Total current liabilities	3,281,066	1,722,792
Total shareholders' equity	\$ 30,534,047	\$ 33,365,601

QuickLinks

[Text of Press Release](#)