

**UNITED STATES
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): **October 29, 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 No.)

93-0797222
(IRS Employer
Identification No.)

One S.W. Columbia, Suite 1105, Portland, OR 97258

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(503) 227-0554**

Item 5. Other Events.

On October 29, 2003, AVI BioPharma, Inc., an Oregon corporation ("the Company") ("Nasdaq") issued a press release updating progress on its infectious disease program, which uses the Company's NeuGene® antisense technology to combat single stranded RNA viruses, including the West Nile Virus (WNV), the Severe Acute Respiratory Syndrome (SARS), the Norovirus (Norwalk Virus)/Calicivirus and Hepatitis C.

A copy of the press release issued by the Company on October 29, 2003 updating the progress on its infectious disease program is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

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

(C) EXHIBITS.

Exhibit No.	Description of Exhibit
99.1	Press Release, dated October 29, 2003, of the Company.

SIGNATURE

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 Boston, Commonwealth of Massachusetts, on October 29, 2003.

AVI BioPharma, Inc.

By: _____ /s/ ALAN P. TIMMINS

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

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For Release 6 a.m. PST

Oct. 29, 2003

**AVI BioPharma Updates Progress on Infectious Disease Program
Using NeuGene Antisense For RNA Viruses**

PORTLAND, Ore.—Oct. 29, 2003—AVI BioPharma, Inc. (Nasdaq: AVII), today announced a year-to-date progress report on its infectious disease program, which uses the company's proprietary NeuGene® antisense technology to combat single-stranded RNA viruses. AVI's antiviral research program has produced antisense drugs shown to be active against a range of single-stranded RNA viruses, including West Nile virus, SARS coronavirus, hepatitis C virus and norovirus in preclinical testing. Because of their simple genetic structure, these and other single-stranded RNA viruses are attractive targets for NeuGene drugs.

West Nile Virus (WNV)

Early in 2003, AVI completed toxicology and pharmacokinetic analysis of AVI-4020, a NeuGene antisense compound targeting WNV. The company then completed preclinical development and filed an Investigational New Drug application (IND) with the Food and Drug Administration (FDA) to begin human clinical studies. AVI also has submitted an application to the FDA for Orphan Drug designation of AVI-4020, which is currently under review.

For WNV, the time from identification of the drug candidate to initiation of the clinical program was approximately nine months. The objective of the current clinical studies is to gather the data necessary to evaluate the potential of a pivotal trial in the 2004 WNV season.

Enrollment and treatment in a Phase Ib clinical trial began in September at several U.S. locations. In October, the company began a second WNV clinical study, allowing expanded access to AVI-4020. This study was developed in response to physician requests to use the drug for seriously ill WNV patients who face limited treatment options.

So far this year, the Centers for Disease Control and Prevention (CDC) have reported 7,386 human cases of WNV infection in the U.S., resulting in 155 deaths. In 2002, 4,156 cases and 284 deaths were reported. So far in 2003, all but five states have reported human WNV infections, compared with fewer than half the states reporting WNV infection last year.

Severe Acute Respiratory Syndrome (SARS)

AVI has developed an experimental antisense compound, AVI-4179, targeting the SARS coronavirus. Ten days after receiving the genetic sequence information of the SARS coronavirus from the CDC and World Health Organization (WHO) laboratories, AVI synthesized and purified its NeuGene antisense compound at the company's research facilities in Corvallis, Ore. In May, AVI provided the compound to the National Institute of Allergy and Infectious Disease (NIAID), WHO and other outside laboratories for preclinical testing. In August, the company filed with the FDA for Orphan Drug designation of AVI-4179, which is currently under review.

In September, the company received positive preclinical test results from The Scripps Research Institute (TSRI) in La Jolla, Calif. TSRI evaluated the effectiveness of AVI-4179 against the SARS coronavirus and determined that AVI-4179 protected infected cells from viral-induced cell death, limited the growth of the virus and reduced the spread of the virus in cell culture. The report further indicated that the AVI antisense approach was approximately 10 times more effective than an antibiotic previously found to be effective against some coronaviruses, but also found to be too toxic for human use.

Earlier this month, the company received confirmatory data from a WHO-associated laboratory on the efficacy of the AVI compound in additional laboratory tests. AVI plans to manufacture AVI-4179 for a small clinical study outside the U.S. should SARS reappear this winter.

According to the CDC, SARS was first reported in Asia in February 2003. Within months SARS had spread to over two dozen countries in North America, South America, Europe and Asia. The WHO reported 8,098 cases and 774 deaths internationally from SARS in 2003. Over the same time period, there were 192 cases of SARS in the U.S., but no deaths. International disease monitoring organizations remain on alert for a recurrence of SARS infections this winter.

Norovirus (Norwalk Virus)/Calicivirus

Norovirus, named after the original Norwalk virus, is the virus that causes the intestinal disease that has plagued the cruise ship industry, military ships and nursing homes for the past several years and has become a significant medical and economic concern. The preclinical model suited for the study of norovirus is the related calicivirus, which is believed to infect many species. AVI has completed two preclinical trials targeting feline calicivirus. In 2002, AVI conducted a calicivirus trial in a naturally occurring outbreak of hemorrhagic calicivirus in kittens. AVI's antisense drug was shown to be efficacious in this setting. In March 2003, AVI completed a second preclinical trial against feline calicivirus in mature cats. In this study, the symptoms of the virus, which included upper respiratory problems, conjunctivitis, peripheral edema and hemorrhages, were greatly reduced.

AVI plans to manufacture its norovirus antisense drug for additional preclinical and Phase Ib clinical studies in the second half of 2004.

The CDC estimates that 23 million cases of acute gastroenteritis are due to norovirus infection, and it is now thought that at least 50% of all food-borne outbreaks of gastroenteritis can be attributed to noroviruses.

Hepatitis C

AVI has developed a NeuGene antisense agent targeting hepatitis C virus (HCV). Several cell culture and animal model systems have been employed in preclinical studies at AVI, or by collaborators, providing efficacy data against this important virus.

Independent confirmation of the effectiveness of NeuGene antisense compounds against HCV has been published in both in vitro laboratory experiments (Journal of Virology, November 2000, vol. 74, issue 22, pp. 10,430-10,437) and recently in controlled animal model (Hepatology, August 2003, vol. 38, issue 2, pp. 503-508). In the recent study from Stanford University School of Medicine, the authors

conclude that morpholino antisense oligonucleotides are potent inhibitors of HCV in a preclinical mouse model and have potential as molecular therapeutics for treating HCV and other viral infections.

AVI plans to begin preclinical studies with its NeuGene antisense drug for HCV in the first quarter of 2004 and, if successful, initiate human clinical trials in late 2004.

HCV infects one in every 40 people worldwide. Chronic liver disease is the 10th leading cause of death among adults in the U.S. The CDC estimates that 40% of chronic liver disease is HCV-related, resulting in an estimated 8,000-10,000 deaths each year and accounting for estimated medical and work-loss costs of over \$600 million annually. Current treatments are ineffective, and HCV is the leading cause of liver failure leading to transplantation in the U.S. and Europe.

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/>.

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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.

QuickLinks

[Exhibit 99.1](#)