

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

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**FORM 8-K**

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**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 3, 2011

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**AVI BioPharma, Inc.**

(Exact name of registrant as specified in its charter)

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**Oregon**  
(State or other jurisdiction  
of incorporation)

**001-14895**  
(Commission  
File Number)

**93-0797222**  
(IRS Employer  
Identification No.)

**3450 Monte Villa Parkway, Suite 101**  
**Bothell, WA 98021**  
(Address of principal executive offices, including zip code)

**(425) 354-5038**  
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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**Item 2.02 Results of Operations and Financial Condition.**

On November 3, 2011, AVI BioPharma, Inc. (the “Company”) announced via press release the Company’s results for the three and nine month periods ended September 30, 2011. A copy of the Company’s press release is attached hereto as Exhibit 99.1. The information in this Item 2.02 and the attached exhibit are furnished to, but not filed with, the Securities and Exchange Commission.

**Item 9.01 Financial Statements and Exhibits.****(d) Exhibits.**

Pursuant to the rules and regulations of the Securities and Exchange Commission, the attached exhibit is deemed to have been furnished to, but not filed with, the Securities and Exchange Commission:

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated November 3, 2011.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**AVI BioPharma, Inc.**

By: /s/ Christopher Garabedian

Christopher Garabedian

President and Chief Executive Officer

Date: November 3, 2011

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**EXHIBIT INDEX**

Exhibit Number

Description

99.1

Press release dated November 3, 2011.



AVI Investor and Media Contact:  
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**AVI BioPharma Announces Third Quarter 2011 Financial Results  
and Recent Corporate Developments**

— *Completed Enrollment With All Patients Receiving Ongoing Doses in Phase IIB Study of Eteplirsen, the Company's Lead Exon-Skipping Therapeutic Candidate for the Treatment of Duchenne Muscular Dystrophy*

— *Completed Final Dosing Following Positive Safety Results in Initial Cohorts of Phase I Trials of AVI-6002 and AVI-6003, AVI's Lead Drug Candidates for the Treatment of Ebola and Marburg, Respectively*

**BOTHELL, WA, Nov 3, 2011** — AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based therapeutics, today reported financial results for the three and nine months ended September 30, 2011, and provided an update of recent corporate developments.

“In the past quarter, significant developments have taken place for our DMD and infectious diseases programs, including continued dosing of our fully-enrolled Phase IIB clinical study of eteplirsen in DMD patients and the promising interim safety data reported for our Ebola and Marburg therapeutic candidates,” said Chris Garabedian, President and CEO of AVI. “These accomplishments validate our unique PMO-based chemistries and continue to enable the development of our therapeutics to treat life-threatening diseases.”

**Financial Results**

For the third quarter of 2011, AVI reported an operating loss of \$11.3 million compared with an operating loss of \$3.8 million in the third quarter of 2010. The increase in the quarterly operating loss was primarily the result of increased research and development expenses of \$6.5 million and lower government contract revenue of \$1.2 million.

Research and development expenses were \$15.6 million in the third quarter of 2011 compared to \$9.1 million in the third quarter of 2010, an increase of \$6.5 million. The



increase was primarily due to a \$4.4 million increase in DMD-related program costs, a \$3.4 million increase in spending related to the Ebola Marburg government contract and a \$1.6 million increase in other non-government projects. These increases were partially offset by \$2.6 million in reduced spending for the H1N1 government contracts which concluded in 2011.

General and administrative expenses in the third quarter of 2011 were \$3.2 million, compared to \$3.4 million in the third quarter of 2010.

Revenue for the third quarter of 2011 decreased \$1.2 million to \$7.5 million from the third quarter of 2010 as a result of \$5.8 million in lower revenue from the H1N1 contracts and the 2006 government contracts. This decrease was partially offset by a \$4.6 million increase in revenue from the Ebola Marburg government contract.

In the first nine months of 2011, the operating loss was \$26.9 million, compared with an operating loss of \$19.2 million in the first nine months of 2010. The increase in the operating loss was the result of increased research and development expenses of \$26.1 million and increased general and administrative costs of \$1.1 million, partially offset by increased revenue of \$19.5 million.

Research and development expenses were \$48.2 million in the first nine months of 2011, compared to \$22.1 million in the first nine months of 2010, an increase of \$26.1 million. The increase was primarily due to a \$20.5 million increase in spending related to the Ebola Marburg government contract, a \$5.3 million increase in DMD-related program costs and \$3.3 million in non-government projects and other research and development costs. This increase was partially offset by a \$3.0 million decrease in spending on AVI's H1N1 and 2006 government contracts.

General and administrative expenses in the first nine months of 2011 were \$12.1 million, compared to \$11.0 million in the first nine months of 2010, an increase of \$1.1 million. The increase is primarily due to \$3.3 million in salaries, severance and employee related costs, \$0.4 million in higher costs for professional services, and \$0.3 million in increased costs for facilities. These increases were partially offset by a \$2.6 million decrease in severance related costs for the former chief executive officer that were incurred in the first nine months of 2010 and \$0.3 million in lower legal fees in the first nine months of 2011.

Revenue for the first nine months of 2011 increased to \$33.4 million from \$13.9 million in the first nine months of 2010 primarily as a result of the increased revenue associated with the Ebola Marburg government contract.

The net loss for the third quarter of 2011 was \$4.0 million, or \$0.03 per share, compared to a net loss for the third quarter of 2010 of \$7.3 million, or \$0.07 per share. The \$3.3

million decrease was due to a \$10.6 million variance resulting from the decrease in the valuation of certain warrants described below, offset by a \$7.5 million increase in the operating loss. The net loss for the first nine months of 2011 was \$0.9 million, or \$0.01 per share, compared to a net loss for the first nine months of 2010 of \$24.5 million, or \$0.22 per share. The \$23.6 million decrease was due to a \$31.1 million variance resulting from the decrease in the valuation of certain warrants described below, offset by a \$7.7 million increase in the operating loss.

In connection with prior equity financings, AVI issued warrants that are classified as current liabilities and are adjusted to fair value on a quarterly basis with the change in fair value being included in net income (loss). The amount of the warrant liability is primarily affected by changes in AVI's stock price during each financial reporting period which causes the warrant liability to fluctuate as the market price of AVI's stock fluctuates. In the third quarter of 2011, the warrant valuation decreased by \$7.1 million compared to an increase in the warrant valuation of \$3.6 million in the third quarter of 2010. In the first nine months of 2011, the warrant valuation decreased by \$25.6 million compared to an increase in the warrant valuation of \$5.5 million in the first nine months of 2010.

AVI had cash and cash equivalents of \$46.4 million as of September 30, 2011, an increase of \$12.8 million from December 31, 2010. This increase was primarily due to the \$32.1 million in net proceeds raised in the April 2011 equity financing partially offset by cash used in operations during the first nine months of 2011 of \$18.0 million, and cash used for property and equipment purchases and patent-related costs of \$1.5 million.

## **Recent Corporate Developments**

### *Duchenne Muscular Dystrophy (DMD) Program*

— Completed enrollment of the Phase IIB trial of eteplirsen with all patients receiving multiple doses in this placebo-controlled study in ambulatory DMD patients taking place at Nationwide Children's Hospital in Columbus, Ohio.

— Presented comparative pharmacokinetics (PK) data in primates and humans from AVI's lead drug candidate, eteplirsen, for treating DMD patients, at the 16<sup>th</sup> International World Muscle Society Congress.

### *Infectious Disease Programs*

— Completed dosing of 9.0 mg/kg in the sixth and final cohorts of healthy volunteers following positive safety results from the first five cohorts, which evaluated doses from



0.01 mg/kg to 6.0 mg/kg in these Phase I single ascending dose trials of AVI-6002 and AVI-6003, AVI's lead drug candidates for the treatment of Ebola and Marburg viruses, respectively.

— Presented efficacy data in oseltamivir-resistant H1N1 infected ferrets and toxicity and toxicokinetic data from its lead therapeutic candidate AVI-7100, at the 51st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) Annual Meeting.

— Presented data from AVI-6003 single ascending-dose study program for Marburg at the 49<sup>th</sup> Annual Meeting of Infectious Diseases Society of America.

### **2011 Guidance**

AVI anticipates that its full year 2011 revenue will be in the \$40 million to \$50 million range due to the requirement to finalize the Ebola and Marburg contract modification with respect to costs and timing of activities, which was signed September 26, 2011. This modification, though it does not impact the total revenue AVI expects to receive under the contract, resulted in a delay of certain third party manufacturing, preclinical and clinical activities, which shifted some revenue from the latter part of 2011 into 2012. This deferral of revenue impacts the expected overall net contribution from the government contracts in 2011 and, therefore, AVI is increasing its 2011 cash burn guidance to the \$30 million to \$35 million range. AVI believes it will continue to receive funding from government contracts and has assumed certain revenue from these awards in providing this guidance. If AVI does not continue to receive the funding from its current contracts, its guidance may change.

### **Conference Call**

AVI BioPharma will hold a financial results and corporate update conference call today at 5:00 p.m., Eastern Time (2:00 p.m., Pacific Time). The conference call may be accessed by dialing 866.314.5050 for domestic callers and 617.213.8051 for international callers. The passcode for the call is 97800942. Please specify to the operator that you would like to join the "AVI BioPharma third quarter 2011 earnings call." The conference call will be webcast live under the events section of AVI's website at [www.avibio.com](http://www.avibio.com), and will be archived there following the call for 90 days. Please connect to AVI's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary. An audio replay will be available through November 10, 2011 by calling 888.286.8010 or 617.801.6888 and entering access code 42274933.





## **About AVI BioPharma**

AVI BioPharma is focused on the discovery and development of novel RNA-based therapeutics for rare and infectious diseases, as well as other select disease targets. Applying pioneering technologies developed and optimized by AVI, the Company is able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. Unlike other RNA-based approaches, AVI's technologies can be used to directly target both messenger RNA (mRNA) and precursor messenger RNA (pre-mRNA) to either down-regulate (inhibit) or up-regulate (promote) the expression of targeted genes or proteins. By leveraging its highly differentiated RNA-based technology platform, AVI has built a pipeline of potentially transformative therapeutic agents, including eteplirsen (the non-proprietary name for AVI-4658), which is in clinical development for the treatment of Duchenne muscular dystrophy, and multiple drug candidates that are in clinical development for the treatment of infectious diseases. For more information, visit [www.avibio.com](http://www.avibio.com).

## **Forward-Looking Statements and Information**

*In order to provide AVI's investors with an understanding of its current results and future prospects, this press release contains statements that are forward-looking. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements about the development of AVI's product candidates, AVI's estimates regarding its future revenue and expenses and expectations regarding future success, revenue and funding from government and other sources.*

*These forward-looking statements involve risks and uncertainties, many of which are beyond AVI's control. Known risk factors include, among others: clinical trials may not demonstrate safety and efficacy of any of AVI's drug candidates and/or AVI's antisense-based technology platform; development of any of AVI's drug candidates, including AVI-6002 or AVI-6003, may not result in funding from the U.S. government in the anticipated amounts or on a timely basis, if at all; and any of AVI's drug candidates may fail in development, may not receive required regulatory approvals, or be delayed to a point where they do not become commercially viable.*

*Any of the foregoing risks could materially and adversely affect AVI's business, results of operations and the trading price of AVI's common stock. For a detailed description of risks and uncertainties AVI faces, you are encouraged to review the official corporate documents filed with the Securities and Exchange Commission. AVI does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.*



**AVI BIOPHARMA, INC.**  
(A Development-Stage Company)  
**STATEMENTS OF OPERATIONS**  
(unaudited)  
(in thousands, except per share amounts)

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
Revenues from license fees, grants and research contracts	\$ 7,524	\$ 8,702	\$ 33,405	\$ 13,903
Operating expenses:				
Research and development	15,610	9,059	48,161	22,080
General and administrative	<u>3,185</u>	<u>3,440</u>	<u>12,171</u>	<u>11,017</u>
Operating loss	(11,271)	(3,797)	(26,927)	(19,194)
Other income (loss):				
Interest (expense) income and other, net	199	82	440	170
(Increase) decrease on warrant valuation	<u>7,052</u>	<u>(3,578)</u>	<u>25,579</u>	<u>(5,509)</u>
Net loss	\$ (4,020)	\$ (7,293)	\$ (908)	\$ (24,533)
Net loss per share—basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.07)</u>	<u>\$ (0.01)</u>	<u>\$ (0.22)</u>
Shares used in per share calculations—basic and diluted	<u>135,738</u>	<u>111,767</u>	<u>127,523</u>	<u>110,863</u>

**SELECTED BALANCE SHEET DATA**  
(unaudited)  
(in thousands)

	September 30, 2011	December 31, 2010
Cash and cash equivalents	\$ 46,356	\$ 33,589
Total current assets	51,945	37,838
Total assets	61,083	45,976
Total current liabilities	26,531	45,857
Total shareholders' equity (deficit)	31,752	(2,817)