

**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): May 2, 2011**

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**AVI BioPharma, Inc.**

(Exact name of registrant as specified in its charter)

**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 May 5, 2011, AVI BioPharma, Inc. (the "Company") announced via press release the Company's results for the three month period ended March 31, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

As previously disclosed in Amendment No. 1 to the Company's annual report on Form 10-K filed with the SEC on May 2, 2011, Dr. Graham Johnson, the Company's Senior Vice President of Preclinical Development and Research, will cease to be an employee of the Company effective May 13, 2011.

**Item 8.01 Other Events.**

On May 5, 2011, the Company received a letter from the U.S. Food and Drug Administration stating that the Company may proceed with its Phase 1 study of AVI-7100, the Company's lead product candidate for the treatment of influenza.

**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 May 5, 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: May 5, 2011

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EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated May 5, 2011.



AVI Media and Investor Contact:  
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**AVI BioPharma Announces First Quarter 2011 Financial Results**

- FDA Clears AVI-7100 Influenza Drug Candidate to Proceed with Phase 1 Study—
- Two New Drug Candidates Enter Phase 1 for Hemorrhagic Fever Viruses—
- Lead Duchenne Muscular Dystrophy Drug Candidate Advancing into U.S. Placebo Controlled Trial in June—
- Continued Strong Government Contract Revenues, Over \$14 Million in First Quarter—

**Bothell, WA — May 5, 2011** — AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based drugs, today reported financial results for the three months ending March 31, 2011.

“We have realized significant accomplishments this year in shaping a new vision for the company with new management and a clear strategy,” said Chris Garabedian, president and chief executive officer of AVI BioPharma. “We have advanced our Duchenne muscular dystrophy clinical program, continued to execute on our government-funded infectious disease programs, and are prioritizing our early research programs for both internal development and external business partnerships.”

**Financial Results**

For the first quarter of 2011, AVI reported an operating loss of \$5.5 million, compared with an operating loss of \$7.7 million in the first quarter of 2010. The reduction in the operating loss is primarily the result of a \$13.1 million increase in government research contract revenues, offset by an \$8.7 million increase in research and development expenses and a \$2.2 million increase in general and administrative costs. The increase in the government research contract

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revenues and the increase in research and development costs were primarily related to the Ebola, Marburg and H1N1 government contracts that were new in 2010.

Research and development expenses were \$14.8 million in the first quarter of 2011, compared to \$6.1 million in the first quarter of 2010, an increase of \$8.7 million. The increase was due primarily to increases in the research costs for the Ebola, Marburg and H1N1 contracts, partially offset by lower spending on the Duchenne muscular dystrophy (DMD) program and other research programs. General and administrative expenses in the first quarter were \$5.0 million, compared to \$2.8 million in the first quarter of 2010, an increase of \$2.2 million. The increase was attributed to higher compensation costs and employee related costs resulting from the increased headcount, accrued severance and stock compensation expense associated with the expected departure of a senior officer, legal expenses, and consulting costs.

Revenue for the first quarter of 2011 increased to \$14.3 million from \$1.2 million in the first quarter of 2010, an increase of \$13.1 million, as a result of a net increase in revenue from the Ebola, Marburg and H1N1 government research contracts.

Net income for the first quarter of 2011 was \$1.8 million, or \$0.02 per share, compared to a net loss for the first quarter of 2010 of \$0.6 million, or \$0.01 per share. The \$2.4 million increase in net income was primarily due to the reduced operating loss caused by higher revenue from the new Ebola, Marburg and H1N1 contracts and the change in the valuation of certain warrants described below.

In connection with prior equity financings, AVI issued warrants that are classified as liabilities and are adjusted to fair value on a quarterly basis impacting 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 first quarter of 2011, the warrant valuation decreased by \$7.3 million compared to a decrease in the warrant valuation of \$7.1 million in the first quarter of 2010.

AVI had cash and cash equivalents of \$23.3 million as of March 31, 2011, a decrease of \$10.3 million from December 31, 2010. This decrease was due primarily to the \$10.1 million of cash used in operations during the first quarter of 2011 and cash used for property and equipment and patent-related costs of approximately \$0.3 million, and was partially offset by cash inflows from the exercise of warrants of \$0.1 million. Accounts receivable increased \$10.4 million to \$13.6 million and accounts payable also increased \$5.2 million to \$6.5 million, both of these increases are the result of the increase in revenue from the Ebola, Marburg and H1N1 contracts.

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In April 2011, AVI sold 23.0 million shares of its common stock at the price of \$1.50 per share in an offering registered under the Securities Act. The offering generated gross proceeds of \$34.5 million.

### **2011 Recent Corporate Developments**

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

—Presented complete data from a Phase 1b/2 study of eteplirsen in DMD patients, as well as comparison of clinical and preclinical pharmacokinetic parameters of eteplirsen, at the 63rd Annual Meeting of the American Academy of Neurology.

—Published data from two new papers in the International Journal of Toxicology demonstrating that the exon-skipping DMD drug candidate eteplirsen was well tolerated in mice and monkeys at doses up to the maximum feasible doses of 960 and 320 mg/kg, respectively. No dose limiting toxicities were seen in either species. Further, a mechanistic toxicity evaluation revealed that no toxicity was associated with exon-skipping and the resulting dystrophin expression in a dystrophic animal, the *mdx* mouse.

—Received approval from the United States Adopted Names (USAN) Council of the nonproprietary name eteplirsen for AVI-4658, AVI's lead exon-skipping therapy for the treatment of DMD.

#### **Infectious Disease Programs**

—Received notice from the U.S. Food and Drug Administration that the clinical hold on AVI-7100, AVI's lead influenza drug candidate, was removed and that AVI may proceed with its Phase 1 study.

—Initiated Phase 1 clinical studies of AVI-6002 and AVI-6003, lead drug candidates for the treatment of Ebola virus and Marburg virus, respectively, in healthy volunteers. These studies are the first to evaluate the safety and tolerability of AVI's proprietary *PMOplus*<sup>TM</sup> chemistry in humans.

#### **Corporate Developments**

—Completed public offering of common stock generating \$34.5 million in gross proceeds to be used for general corporate purposes, including research and product development.

—Appointed Peter Linsley, Ph.D., an experienced scientist widely recognized for his groundbreaking RNA-focused research and work advancing scientific discoveries into clinical development, as senior vice president and chief scientific officer.

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**2011 Guidance**

For 2011, AVI confirms its previously provided guidance for revenue of approximately \$50 million to \$60 million and cash expenditures for operations, net of government funding and other collaborative efforts, to be approximately \$23 million to \$28 million. AVI believes it will continue to receive funding from government contracts and has assumed certain revenues 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 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 800.215.2410 for domestic callers and 617.597.5410 for international callers. The passcode for the call is 63971514 and please specify to the operator that you would like to join the "AVI BioPharma first 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.

**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 technology platform, AVI has built a pipeline of potentially transformative therapeutic agents, including a clinical stage Duchenne muscular dystrophy candidate and anti-infective candidates for influenza and hemorrhagic fever viruses. 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



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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, including the initiation of a Phase 2 study in June 2011 for eteplirsen, AVI’s estimates regarding its future revenues and expenses and expectations regarding future success, revenues 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 its antisense-based technology platform; development of any of AVI’s drug candidates, including AVI-6002, AVI-6003 or AVI-7100, may not result in funding from the TMT 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 its 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)  
(in thousands, except per share amounts)  
(unaudited)

	Three Months Ended	
	March 31,	
	2011	2010
Revenues, from grants and research contracts	\$ 14,296	\$ 1,205
Operating expenses:		
Research and development	14,801	6,096
General and administrative	5,026	2,844
Operating loss	(5,531)	(7,735)
Other income (loss):		
Interest income, and other net	90	42
Decrease on warrant valuation	7,274	7,109
Net income (loss)	\$ 1,833	\$ (584)
Net income (loss) per share—basic	\$ 0.02	\$ (0.01)
Net income (loss) per share—diluted	\$ 0.02	\$ (0.01)
Shares used in per share calculations—basic	112,482	110,429
Shares used in per share calculations—diluted	121,285	110,429

**BALANCE SHEET HIGHLIGHTS**  
(unaudited)  
(in thousands)

	March 31, 2011	December 31, 2010
Cash and cash equivalents	\$ 23,283	\$ 33,589
Total current assets	38,495	37,838
Total assets	47,031	45,976
Total current liabilities	43,220	45,857
Total shareholders' equity (deficit)	\$ 920	\$ (2,817)

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