## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): May 10, 2012

## 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)

Chec	k 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 followin
provi	sions (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))

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

On May 10, 2012, AVI BioPharma, Inc. (the "Company") announced via press release the Company's results for the three month period ended March 31, 2012. 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:

Exhibit Number	Description
99 1	Press release dated May 10, 2012

## **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 10, 2012

## EXHIBIT INDEX

Exhibit Number Description

99.1 Press release dated May 10, 2012.



AVI Investor and Media Contact: Erin Cox 425.354.5140 ecox@avibio.com

## AVI BioPharma Announces First Quarter 2012 Financial Results and Recent Corporate Developments

- Duchenne Muscular Dystrophy (DMD) and Infectious Disease Programs Continue to Advance in Clinical Development
- Strong Dataset Presented on AVI's Lead Drug Candidate Eteplirsen, Demonstrating Restoration of Dystrophin
- Long-Term Treatment Study with Eteplirsen Ongoing with 48-Week Dataset Expected Later This Year

**BOTHELL, WA, May 10, 2012** — AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based therapeutics, today reported financial results for the three months ended March 31, 2012, and provided an update of recent corporate developments.

"We have achieved a major milestone with our technology by demonstrating eteplirsen's ability to produce the essential protein, dystrophin, in DMD patients at levels that we believe should translate to clinically meaningful benefits," said Chris Garabedian, President and CEO of AVI. "This drug effect is further underscored by the strong safety profile we observed with eteplirsen at the highest doses and longest duration of treatment that have ever been conducted with our unique RNA-based drug chemistry."

#### **Financial Results**

For the first quarter of 2012, AVI reported an operating loss of \$6.9 million, compared with an operating loss of \$5.5 million in the first quarter of 2011. The increase in the operating loss is primarily due to a decrease of \$3.1 million in government research contract revenues, partially offset by a \$1.7 million decrease in general and administrative costs.

Revenue for the first quarter of 2012 decreased to \$11.2 million from \$14.3 million in the first quarter of 2011, a change of \$3.1 million. The lower revenue was attributable to a \$2.4 million decrease in revenue on the H1N1 contract due to its completion in June 2011 and a \$0.7 million decrease in revenue on the ongoing Ebola and Marburg U.S. government contract due to the variability of subcontracting activities.



Research and development expenses were \$14.8 million for both the first quarter of 2012 and the first quarter of 2011. During the current quarter as compared to the first quarter of the prior year, spending on DMD increased by \$1.8 million primarily due to the Phase IIb trials for eteplirsen and a \$0.4 million increase in spending on other proprietary research. These increases were offset by a \$1.2 million reduction in spending on the H1N1 U.S. government contract which was completed in June 2011, a \$0.6 million reduction in spending on the ongoing Ebola and Marburg U.S. government contract and a \$0.4 million reduction in personnel related costs.

General and administrative expenses were \$3.3 million in the first quarter of 2012 compared to \$5.0 million in the first quarter of the prior year. The \$1.7 million decrease is primarily due to a \$1.1 million decrease in personnel costs related to the December 2011 reorganization and an executive severance package recorded in the first quarter of 2011. Legal and professional services also decreased \$0.5 million compared to the first quarter of the prior year.

Net loss for the first quarter of 2012 was \$17.7 million, or \$0.13 per share, compared to net income for the first quarter of 2011 of \$1.8 million, or \$0.02 per share. The \$19.5 million change in net loss was primarily due to \$18.2 million in other expense associated with the change in the valuation of the Company's outstanding warrants as described below, and a \$1.3 million increase in operating losses.

In connection with equity financings in 2007 and 2009, the Company issued warrants that are classified as liabilities and are adjusted to fair value on a quarterly basis through other 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 2012, the warrant valuation increased by \$10.9 million compared to a decrease in the warrant valuation of \$7.3 million in the first quarter of 2011.

AVI had cash and cash equivalents of \$30.6 million as of March 31, 2012, a decrease of \$9.3 million from December 31, 2011. This decrease was due primarily to cash used in operations during the first quarter of 2012.



#### **Recent Corporate Developments**

Duchenne Muscular Dystrophy (DMD) Program

- Announced that treatment with eteplirsen met the primary efficacy endpoint in a randomized, double-blind, placebo-controlled Phase IIb study in boys with DMD. Eteplirsen administered once weekly at 30 mg/kg over 24 weeks resulted in a statistically significant ( $p \le 0.002$ ) increase in novel dystrophin (22.5% dystrophin-positive fibers as a percentage of normal) compared to no increase in the placebo group.
- Presented efficacy and safety data from the Phase IIb study examining 24 weeks of treatment with eteplirsen in boys with DMD at the 2012 American Academy of Neurology Meeting.

#### Infectious Disease Programs

— Presented single ascending dose data on AVI-6002 and AVI-6003, AVI's lead therapeutic candidates for the treatment of Ebola and Marburg, respectively, and efficacy data on AVI-7100, AVI's lead therapeutic drug for the treatment of influenza, at the 22nd Annual European Congress of Clinical Microbiology and Infectious Diseases (ECCMID). In February 2012, AVI announced that it received approval from the FDA to proceed with a single oligomer from AVI-6003, AVI-7288, as the lead product candidate against Marburg virus infection.

#### **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 800.659.2032 for domestic callers and 617.614.2712 for international callers. The passcode for the call is 33411604. Please specify to the operator that you would like to join the "AVI BioPharma first quarter 2012 earnings call." The conference call will be webcast live under the events section of AVI's website at 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 May 17, 2012 by calling 888.286.8010 or 617.801.6888 and entering access code 75539841.

#### 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, 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.

#### 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, the expected timing of results from the extension study of eteplirsen, the potential for the creation of novel dystrophin to lead to clinically meaningful benefits over a longer course of treatment with eteplirsen and 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 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) (in thousands, except per share amounts) (unaudited)

		Three Months Ended March 31,	
	2012	2011	
Revenues, from grants and research contracts	\$ 11,212	\$ 14,296	
Operating expenses:			
Research and development	14,805	14,801	
General and administrative	3,281	5,026	
Operating loss	(6,874)	(5,531)	
Other income (loss):			
Interest income and other, net	96	90	
Gain (loss) on change in warrant valuation	(10,926)	7,274	
Net income (loss)	<u>\$ (17,704</u> )	\$ 1,833	
Net income (loss) per share— basic	\$ (0.13)	\$ 0.02	
Net income (loss) per share— diluted	\$ (0.13)	\$ 0.02	
Shares used in per share calculations—basic	135,743	112,482	
Shares used in per share calculations— diluted	135,743	121,285	

# BALANCE SHEET HIGHLIGHTS (in thousands)

	March 31,	Detelliber 31,
	2012	2011
Cash and cash equivalents	\$30,573	\$ 39,904
Total current assets	37,632	45,184
Total assets	46,647	54,368
Total current liabilities	29,923	20,601
Total shareholders' equity	14,022	31,017