## 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): March 10, 2011

# 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)

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))

D 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 March 10, 2011, AVI BioPharma, Inc. (the "Company") announced via press release its results for the fourth quarter and year ended December 31, 2010. A copy of the Company's press release is attached hereto as Exhibit 99.1. The information in this Form 8-K 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 NumberDescription99.1Press release issued by AVI BioPharma, Inc., dated March 10, 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/ J. David Boyle II

J. David Boyle II Senior Vice President and Chief Financial Officer

Date: March 10, 2011

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EXHIBIT INDEX

### Exhibit Number

99.1

Description

Press release issued by AVI BioPharma, Inc., dated March 10, 2011.



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AVI Media Contact: David Schull Russo Partners 212.845.4271 David.schull@russopartnersllc.com

#### AVI BioPharma Announces Fourth Quarter and Full Year 2010 Financial Results

Financial Results and Corporate Update Conference Call Today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time)

BOTHELL, WA — March 10, 2011 — AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based drugs, today reported financial results for the three and 12 months ended December 31, 2010.

"Our key accomplishments in 2010 position AVI for significant progress this year," said Chris Garabedian, president and chief executive officer of AVI BioPharma. "These accomplishments include proof-of-concept data from our clinical study of AVI-4658 in Duchenne muscular dystrophy patients and the award of government contracts totaling more than \$300 million for our infectious disease programs. As we recently announced, we are moving forward with a strategy that can accelerate the initiation of a pivotal Phase 3 study for AVI-4658 by as much as one year ahead of our original schedule. Our objective is to initiate this study in the second half of next year. In addition, our anti-viral programs for Ebola, Marburg and influenza should enter Phase 1 clinical trials in the next couple of months. It is an exciting time to be at AVI, and we look forward to communicating our continued progress throughout the year."

#### **Financial Results**

For the fourth quarter of 2010, AVI reported an operating loss of \$1.7 million, compared with an operating loss of \$4.0 million in the fourth quarter of 2009. The decrease in the operating loss is the result of a \$10.4 million increase in government research contract revenues, offset by

a \$7.2 million increase in research and development expenses and a \$0.9 million increase in general and administrative costs. The increase in the government research contract 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 \$13.9 million in the fourth quarter of 2010, compared to \$6.6 million in the fourth quarter of 2009, an increase of \$7.3 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 program. General and administrative expenses in the fourth quarter were \$3.4 million, compared to \$2.5 million in the fourth quarter of 2009, an increase of \$0.9 million. The increase was attributed to higher compensation costs related to increased headcount, legal expenses and facilities costs related to AVI's new Bothell, Washington facility.

Revenue for the fourth quarter of 2010 increased to \$15.5 million from \$5.1 million in the fourth quarter of 2009 as a result of a net increase in revenue from the new Ebola, Marburg and H1N1 government research contracts.

For the year 2010, the operating loss was \$20.9 million, compared with an operating loss of \$15.5 million for the year ended 2009. The \$5.4 million increase in the operating loss was primarily the result of a \$11.6 million increase in research and development costs and a \$5.7 million increase in general and administrative costs, offset in part by a \$11.8 million increase in government research contract revenues and other revenue.

Research and development expenses were \$36.0 million for the year ended 2010, compared to \$24.4 million for the year ended 2009, an increase of \$11.6 million. The increase was due primarily to \$5.6 million in costs related to the July 2010 Ebola and Marburg government contract and \$4.2 million in costs related to the July 2010. Additionally, \$5.5 million is related to the increased production of therapeutic drug substance, a \$1.5 million increase in costs for the 2009 H1N1 government contract and a \$1.4 million increase in all other research and development costs offset by a \$4.3 million decline in spending related to the 2006 Ebola, Marburg and Junín government contracts and \$2.3 million reduction in Duchenne muscular dystrophy project costs.

General and administrative expenses for the year 2010 were \$14.4 million, compared to \$8.7 million for the year 2009, an increase of \$5.7 million. The increase was the result of a \$2.6 million charge related to the April 2010 departure of AVI's former chief executive officer. The increase was also attributable to higher compensation costs related to increased headcount,

legal expenses, a reduction of the fair value of property held for sale and facilities costs related to AVI's new Bothell, Washington facility.

Revenue for the year 2010 increased to \$29.4 million from \$17.6 million for the year 2009 as a result of a net increase in revenue from the new Ebola, Marburg and H1N1 government research contracts.

The net loss for the fourth quarter of 2010 was \$7.6 million, or \$0.07 per share, compared to a net income for the fourth quarter of 2009 of \$3.5 million, or \$0.03 per share. The \$11.1 million increase in the net loss was primarily due to the change in the valuation of certain warrants described below. The net loss for the year 2010 was \$32.2 million, or \$0.29 per share, compared to a net loss for year 2009 of \$25.2 million, or \$0.27 per share. The \$7.0 million increase in the net loss was primarily due to the valuation of certain warrants described below.

In connection with AVI's 2009 and prior equity financings, the Company issued warrants that are classified as non-cash liabilities. The amount of the warrant liability is primarily affected by changes in AVI's stock price between each financial reporting period and causes the warrant liability to fluctuate as the market price of AVI's stock fluctuates. In the fourth quarter of 2010, the warrant valuation increased to \$6.0 million relative to the third quarter 2010. For the year 2010, the warrant valuation at December 31, 2009.

AVI had cash and cash equivalents of \$33.6 million as of December 31, 2010, a decrease of \$14.7 million from December 31, 2009. This decrease was due primarily to the cash used in operations during the year 2010 of \$15.2 million and cash used for property and equipment and patent-related costs of approximately \$2.0 million, and payment of long-term debt of \$0.1 million offset by cash inflows from the exercise of stock options and warrants of \$2.6 million.

#### 2010 Fourth Quarter and Recent Corporate Developments

#### Duchenne Muscular Dystrophy (DMD) Program

—Initiated a plan to conduct key NDA-enabling activities concurrently for our Duchenne muscular dystrophy program, which will include a long-term in vivo toxicology study necessary for pivotal studies, GMP manufacturing scale-up plan and a six month Phase 2 clinical study of AVI-4658 at higher doses. With these components running in parallel, it is our objective to initiate a pivotal Phase 3 trial as early as the second half of 2012.



- Reported data from the completed Phase 1b/2 Study 28 of AVI-4658 in patients with Duchenne muscular dystrophy that demonstrated a broadly favorable safety and tolerability profile, including adverse events that were mostly mild to moderate, not dose related, and not probably related to study drug. Additional data highlights include demonstration of new dystrophin protein expression, generation of dystrophin positive-fibers up to 55% of normal, correct localization of dystrophin, reduction in key inflammatory markers, the absence of anti-dystrophin antibodies, and general stability in exploratory markers of clinical performance. Data from the study were presented at the 15th International Congress of the World Muscle Society and the 6th Annual Meeting of the Oligonucleotide Therapeutics Society.

—Awarded approximately \$1.2 million in U.S. Government cash grants for therapeutic development projects involving RNA-based drug candidates, including our drug candidate for the treatment of Duchenne muscular dystrophy. The grants were funded by the U.S. Government's Qualifying Therapeutic Discovery Project (QDTP) program.

#### Influenza Program

-Presented data from preclinical investigations that demonstrated the rapid response capability of AVI's influenza drug program at the 2010 Chemical and Biological Defense Science and Technology Conference and the 48th Annual Meeting of Infectious Diseases Society of America.

- Presented data from preclinical investigations of AVI-7100 for treatment of Influenza A at the 6th Annual Meeting of the Oligonucleotide Therapeutics Society.

#### Dengue Program

—Successfully completed a rapid response exercise in 11 days including designing and manufacturing a novel RNA-based drug candidate against dengue virus. This exercise was supported by the Transformational Medical Technologies (TMT) program from the U.S. Department of Defense Chemical and Biological Defense program through the Defense Threat Reduction Agency.

- Presented data from preclinical investigations of AVI-6006 in Dengue virus infected mouse and ferret models at the 48th Annual Meeting of Infectious Diseases Society of America.

Collaboration with the Karolinska Institutet

—Formed collaboration with the Karolinska Institutet to identify RNA-based therapeutic candidates for the treatment of extensively drug-resistant tuberculosis (XDR-TB). The drug candidates will target individual human host and bacterial genes, as well as combinations of PMO-based drug candidates that target both host and bacterial genes.

#### Corporate Developments

-Appointed Chris Garabedian, an experienced leader with expertise in building sustainable growth biopharmaceutical companies, as Chief Executive Officer and President.

-Appointed Effie Toshav, a skilled professional specializing in industry-specific legal, corporate development and strategic matters, as senior vice president and general counsel.

#### 2011 Guidance

For 2011, AVI provides 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**

The conference call may be accessed by dialing 800.435.1261 for domestic callers and 617.614.4076 for international callers. The passcode for the call is 94335816 and please specify to the operator that you would like to join the "AVI BioPharma fourth quarter and full year 2010 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 for at least 30 days there following the call. 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.

#### 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 about the development of AVI's product candidates, including NDA-enabling activities, the initiation of a Phase 2 clinical trial and the initiation of a pivotal Phase 3 study in the second half of 2012 for AVI-4658 and the initiation of Phase 1 clinical trials in 2011 for AVI's three leading anti-viral product candidates (AVI-6002, AVI-6003 and AVI-7100), 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-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 December 31,		Twelve Months Ended December 31,	
	2010	2009	2010	2009
Revenues from license fees, grants and research contracts	\$ 15,516	\$ 5,141	\$ 29,420	\$ 17,585
Operating expenses:				
Research and development	13,886	6,624	35,972	24,396
General and administrative	3,365	2,470	14,382	8,696
Operating loss	(1,735)	(3,953)	(20,934)	(15,507)
Other income (loss):				
Interest (expense) income and other, net	84	(312)	259	(454)
(Increase) decrease on warrant valuation	(5,993)	7,791	(11,502)	(9,198)
Net income (loss)	<u>\$ (7,644)</u>	\$ 3,526	<u>\$ (32,171</u> )	\$(25,159)
Net income (loss) per share—basic	\$ (0.07)	\$ 0.03	\$ (0.29)	<u>\$ (0.27)</u>
Net income (loss) per share—diluted	\$ (0.07)	\$ 0.03	\$ (0.29)	\$ (0.27)
Shares used in per share calculations—basic	112,328	110,266	111,233	93,090
Shares used in per share calculations—diluted	112,328	125,647	111,233	93,090

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

	As of December 31, 2010	December 31, December 31,	
Cash and cash equivalents	\$ 33,589	\$ 48,275	
Total current assets	37,838	51,310	
Total assets	45,976	60,027	
Total current liabilities	45,857	33,507	
Total shareholders' equity (deficit)	(2,817)	23,630	