# 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): March 16, 2010

# 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** (I.R.S. Employer Identification No.)

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

(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 16, 2010, AVI BioPharma, Inc. (the "Company") issued a press release announcing the Company's financial results for the fourth fiscal quarter and fiscal year ended December 31, 2009. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02, in Item 9.01 hereof and in Exhibit 99.1 shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

# Item 9.01. Financial Statements and Exhibits.

The following exhibit is being furnished (not filed) herewith:

99.1 Press release, dated March 16, 2010, entitled "AVI BioPharma Announces Fourth Quarter and Full Year 2009 Financial Results"

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### SIGNATURES

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 Bothell, State of Washington, on March 16, 2010.

AVI BioPharma, Inc.

By: /s/ Leslie Hudson, Ph.D.

Leslie Hudson, Ph.D. President and Chief Executive Officer (Principal Operating Officer)

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# EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release, dated March 16, 2010, entitled "AVI BioPharma Announces Fourth Quarter and Full Year 2009 Financial Results"

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### AVI BioPharma Announces Fourth Quarter and Full Year 2009 Financial Results

Financial Results and Corporate Update Conference Call Today at 8:30 a.m. Eastern time (5:30 a.m. Pacific)

**BOTHELL, WA** — **March 16, 2010** — AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based drugs, today reported financial results for the three and twelve months ending December 31, 2009.

"We've achieved significant progress over the past year. Our DMD program delivered the first clinical evidence of efficacy in two trials and our biodefense business, based on past successes and new data, garnered up to \$22.5 million in new government drug development contracts. We also significantly improved our R&D and business capabilities as part of our headquarters move to the greater Seattle area," stated Leslie Hudson, Ph.D., President and CEO of AVI BioPharma. "In 2010 we plan to advance and expand our DMD program guided by the outcome of the ongoing systemic trial of AVI-4658. We intend to leverage our biodefense successes and believe we may have the opportunity to develop an influenza therapeutic program."

Revenues for the fourth quarter of 2009 were \$5.1 million, compared to \$5.5 million in the fourth quarter of 2008. Revenues for the full year ended December 31, 2009 were \$17.6 million, compared to \$21.3 million in the full year ended December 31, 2008, reflecting decreases in research contract revenues of \$3.7 million.

The operating loss for the fourth quarter of 2009 was \$4.0 million compared to an operating loss of \$2.9 million from the same period in the prior year. The operating loss for the fourth quarter of 2009 was more than the loss from the fourth quarter of 2008 as the result of higher research and development costs associated with our Duchenne Muscular Dystrophy project.

The operating loss for the full year ended December 31, 2009 decreased to \$15.5 million from \$27.5 million for the prior year period. In 2008, operating loss included a charge of \$9.9 million for acquired in-process research and development associated with the acquisition of Ercole Biotech, Inc. The operating loss in 2009 also decreased compared to 2008 as a result of lower research and development and general and administrative expenses.

The net income for the fourth quarter of 2009 was \$3.5 million, or \$0.03 per share, compared with a net loss for the fourth quarter of 2008 of \$1.1 million, or \$(0.01) per share. The net income for the fourth quarter of 2009 includes a non-cash income for warrant liability of \$7.8 million compared to a gain from the same source of \$1.7 million during the fourth quarter of 2008. For the full year ended December 31, 2009, the Company reported a net loss of \$25.2 million, or \$(0.27) per share, compared with a net loss for the comparable period in 2008 of \$24.0 million, or \$(0.34) per share. The net loss for the full year ended December 31, 2009 includes a non-cash expense for warrant liability of \$9.2 million compared to a gain of \$3.2 million during the same period of 2008. These are non-cash liabilities; the Company does not expect to expend any cash to settle these liabilities. The increase on warrant valuation is a non-cash expense and is the result of the increase in the Company's stock price subsequent to the issuance of warrants as a part of the equity financings that closed in January and August of 2009. The increase on the warrant valuation will fluctuate as the market price of the Company's stock.

Research and development (R&D) expenses for the fourth quarter of 2009 increased to \$6.6 million from \$5.1 million during the fourth quarter of 2008. R&D expenses for the full year ended December 31, 2009 decreased to \$24.4 million from \$27.3 million in the prior year period. The increase in R&D expenses for the fourth quarter 2009 was due primarily to increases in the spending for the Duchene Muscular Dystrophy program. The decrease in R&D expenses for the full year ended December 31, 2009 was due primarily to decreases in government research contracting costs associated with the decline in government research contract revenue.

General and administrative (G&A) expenses for the fourth quarter of 2009 decreased to \$2.5 million, from \$3.3 million in the prior year's fourth quarter. G&A expenses in the year ended December 31, 2009 decreased to \$8.7 million from \$11.5 million in the prior-year period. The G&A expense decrease for the current year vs. the prior year time frame was due primarily to stock compensation expenses incurred in the prior-year quarter related to the Ercole acquisition, the resignation of former executive officers and relocation costs of new executive officers.

Net interest income and other expenses declined primarily due to declines in market rates of interest on the Company's interest-earning investments and the write off of valuations for patents, property and equipment.

We had cash, cash equivalents and short—term securities of \$48.4 million as of December 31, 2009, an increase of \$36.9 million from December 31, 2008. This increase was primarily due to two equity financings that raised aggregate net proceeds of \$47.8 million, partially offset by cash used in operations of \$8.8 million, property and equipment and patent-related costs of approximately \$2.0 million, and debt repayments of \$0.1 million.

# 2010 Guidance

For 2010, AVI provides guidance for expenditures for operations, net of government funding and other collaborative efforts, to be approximately \$23 million to \$27 million. The Company believes it will continue to receive funding from government and other sources to pursue the development of product candidates, and has assumed certain revenues from these awards in providing this guidance. If the Company does not continue to receive the funding from its current contracts, our guidance may change.

# Duchenne Muscular Dystrophy (DMD)

- AVI showed impressive levels of new dystrophin expression in DMD patients in a Phase 1 trial evaluating intramuscular injection of AVI-4658, AVI's lead drug candidate with potential to treat DMD by skipping exon 51.
- Announced positive data from the initial cohorts in Study 28, the Phase 1b/2 clinical trial evaluating systemic delivery of AVI-4658 for the treatment of patients with DMD. RNA exon skipping was seen in 3 of 3 patients with DMD following treatment with 2 or 4 mg/kg, including one patient with robust dystrophin protein expression.
- Completed dosing of all 19 DMD patients enrolled in the ongoing Study 28, with the final two cohorts, five and six, completing 12 weeks of dosing in 4 patients each at 10 mg/kg and 20 mg/kg, respectively with AVI-4658.
- Entered into or expanded DMD program agreements for up to \$7.2 million in non-dilutive funding to support and build upon proof-of-concept established in two clinical trials in 2009:
  - Amended the Charley's Fund, Inc. sponsored research agreement providing up to an additional \$3 million in sponsored research funding to support the development of AVI-5038, AVI's lead drug candidate to treat DMD by skipping exon 50.
  - Established a \$2.5 million contract with Children's National Medical Center of Washington, D.C., with funding from the US Department of Defense, to conduct preclinical studies supporting the development of AVI-4658 as a DMD treatment.
  - Entered into an agreement with Action Duchenne providing approximately \$1.2 million in funding to support AVI's DMD-related research, development and regulatory efforts.
  - Received grants totaling \$500,000 from CureDuchenne and the Foundation to Eradicated Duchenne to support continuing development of drug candidates to treat DMD.
- Received US and European Orphan Drug Designation for AVI-5038.

# **Biodefense** Program

 Based on successful research culminating in open INDs for our candidate drugs targeting Ebola and Marburg viruses, we submitted two proposals to the US Department of Defense (DOD) to develop FDA approvable medical countermeasures for Ebola and Marburg viruses in response to an RFP published in November 2009 by the DOD Transformational Medical Technologies Initiative to develop medical countermeasures (therapeutics) for the treatment of hemorrhagic fever viruses.

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- Expanded existing contract with the Defense Threat Reduction Agency (DTRA) to include up to \$5.9 million in additional research and development of RNA-based drugs targeting Ebola and Marburg viruses.
- Expanded the DTRA contract to include \$11.5 million of new funding for additional research and development of AVI's RNA-based Junín drug candidate.

# Influenza Therapeutic

Entered into a contract worth up to \$5.1 million with the DTRA for the development of RNA-based drugs targeting the H1N1 swine flu virus. In
partnership with the US government, we successfully conducted an exercise demonstrating the ability to rapidly respond to a real-world emerging
viral threat.

# Corporate

- Moved the AVI corporate headquarters to the greater Seattle area to build the management, clinical development and drug discovery capabilities by drawing upon the region's greater biotechnology sector relevant expertise:
  - Established a new biology and chemistry research group in Bothell, WA.
  - · Appointed Paul Medeiros as Chief Business Officer
  - · Appointed Dr. Steve Shrewsbury as Chief Medical Officer.
- Announced our understanding that our partner Cook Therapeutics decided to discontinue development of its cobalt-chromium stent coated with AVI-5126 because of an unexpectedly high rate of restenosis.
- Appointed Drs. Christopher Henney and Kathleen Behrens to AVI's board of directors.
- · Completed two offerings of common stock and warrants providing the company with approximately \$50 million in aggregate gross proceeds.

# **Conference Call**

A conference call to review the financial results and provide a corporate update will be held today, March 16, 2010, at 8:30 a.m. Eastern time (5:30 a.m. Pacific time). Dr. Leslie Hudson, AVI's President and Chief Executive Officer, and J. David Boyle II, AVI's Senior Vice President and Chief Financial Officer, will host the call.

The conference call may be accessed by dialing 866.578.5771 for domestic callers and 617.213.8055 for international callers. The passcode for the call is 39302987. Please specify to the operator that you would like to join the "AVI BioPharma fourth quarter and year end 2009 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. 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.

AVI BioPharma is focused on the discovery and development of RNA—based drugs utilizing proprietary derivatives of its antisense chemistry (morpholinomodified phosphorodiamidate oligomers or PMOs) that can be applied to a wide range of diseases and genetic disorders through several distinct mechanisms of action. Unlike other RNA therapeutic approaches, AVI's antisense technology has been used to directly target both messenger RNA (mRNA) and its precursor (pre-mRNA), allowing for both up and down-regulation of targeted genes and proteins. AVI's RNA—based drug programs are being evaluated for the treatment of Duchenne muscular dystrophy, including an ongoing systemic Phase 1b/2 clinical trial of exon skipping with AVI-4658. AVI's antiviral programs have demonstrated promising outcomes in Ebola Zaire and Marburg Musoke virus infections and may prove applicable to other viral targets such as Junín, influenza, HCV or Dengue viruses. For more information, visit 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.

[Tables to Follow]

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# <u>AVI BIOPHARMA, INC.</u>

(A Development-Stage Company)

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended December 31,				Twelve Months Ended December 31,				
		2009	_	2008		2009		2008	
Revenues from license fees, grants and research contracts	\$	5,141	\$	5,479	\$	17,585	\$	21,258	
Operating expenses:									
Research and development		6,624		5,070		24,396		27,331	
General and administrative		2,470		3,303		8,696		11,469	
Acquired in-process research and development		—						9,916	
Operating loss		(3,953)		(2,894)		(15,507)		(27,458)	
Other income (loss):									
Interest (expense) income and other, net		(312)		36		(454)		344	
(Increase) decrease on warrant valuation		7,791		1,718		(9,198)		3,161	
Net income (loss)	\$	3,526	\$	(1,140)	\$	(25,159)	\$	(23,953)	
Net income (loss) per share—basic	\$	0.03	\$	(0.01)	\$	(0.27)	\$	(0.34)	
Net income (loss) per share—diluted	\$	0.03	\$	(0.01)	\$	(0.27)	\$	(0.34)	
Shares used in per share calculations - basic		110,266		71,074		93,090		69,491	
Shares used in per share calculations - diluted		125,647		71,074		93,090		69,491	

### BALANCE SHEET HIGHLIGHTS (in thousands)

	December 31, 2009		December 31, 2008		
Cash, cash equivalents and short-term securities	\$ 48,446	\$	11,474		
Total current assets	51,310		17,044		
Total assets	60,027		25,536		
Total current liabilities	33,507		7,288		
Total shareholders' equity	\$ 23,630	\$	15,732		

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