

## **AVI BioPharma Announces First Quarter 2010 Financial Results**

May 10, 2010 4:04 PM ET

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

BOTHELL, WA, May 10, 2010 (MARKETWIRE via COMTEX) --AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based drugs, today reported financial results for the three months ending March 31, 2010.

Revenues for the first quarter of 2010 were \$1.2 million, down from \$3.1 million in the first quarter of 2009, reflecting a decrease in government research contracts revenues of \$1.9 million. The net loss for the first quarter of 2010 was \$0.6 million, or \$0.01 per share, compared with a net loss for the first quarter of 2009 of \$0.9 million, or \$0.01 per share. The operating loss increased to \$7.7 million in the first quarter of 2010 compared to \$3.6 million in the first quarter of 2009. The increase in the operating loss is the result of lower revenue, higher research and development expenses and higher general and administration expenses.

"We are excited by the possibilities represented in our current programs, including Duchenne muscular dystrophy, influenza, hemorrhagic fever and antibacterial programs, as well as the broader potential applications of our RNA-based therapeutic platform technologies," stated J. David Boyle II, AVI's interim President and Chief Executive Officer, and Chief Financial Officer. "We are very committed to the efficient operation and execution of our business and over the near to mid-term we will remain highly focused on progressing our programs, and I look forward to sharing that progress with you."

Research and development expenses increased to \$6.1 million in the first quarter of 2010 from \$4.5 million in the first quarter of 2009. The increase in research and development expenses was due primarily to increases in research and development costs related to the Duchenne muscular dystrophy project.

General and administrative expenses increased to \$2.8 million in the first quarter of 2010 from \$2.2 million in the first quarter of 2009. The increase in general and administrative expenses was due primarily to higher legal costs, rent for the new Bothell, Washington location and employee relocation expenses.

The decrease on warrant liability of \$7.1 million in 2010 was the result of the decline in the Company's stock price. In 2009, the warrant liability decreased \$2.6 million as the result of the decline in the Company's stock price subsequent to the issuance of warrants as a part of the equity financing that closed in January 2009. The decrease or (increase) on warrant liability fluctuates as the market price of the Company's stock fluctuates.

The net loss decreased to \$0.6 million in the first quarter of 2010 from \$0.9 million in 2009. The net loss decreased slightly primarily due to the increase in the operating loss offset by the decrease of the warrant liability, a non-cash gain that resulted from the fluctuation in the Company's stock price.

Cash, cash equivalents and short-term securities were \$41.6 million as of March 31, 2010, a decrease of \$6.8 million from December 31, 2009. This decrease was due primarily to the cash used in operations during the first quarter of 2010 and cash used for property and equipment and patent-related costs of approximately \$500,000.

### **2010 First Quarter and Recent Corporate Developments**

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

-- Published results and scientific findings of three GLP-compliant 12-week toxicity studies, a safety pharmacology battery and genotoxicity evaluations of AVI-4658, our lead PMO drug candidate being developed for the treatment of DMD, in the International Journal of Toxicology. The data demonstrated no drug related effects on health status, even when dosed at the maximum feasible dose either intravenously or subcutaneously, and there were no reports of injection site reactions. It was also reported that the genotoxicity evaluation of AVI-4658 revealed no genotoxic potential, even at very high concentrations. These results suggest AVI-4658 may have a wide therapeutic window for chronic dosing.

- Announced that AVI-5038, a preclinical drug candidate using our PPMO chemistry and being developed for DMD, received an orphan drug designation from the Committee for Orphan Medical Products of the European Medicines. AVI-5038 previously obtained Orphan Drug status in the U.S.
- Presented a poster at the 2010 American Academy of Neurology Annual Meeting, entitled AVI-5038: Initial Efficacy and Safety Evaluation in Cynomolgus Monkeys. The poster contained a preliminary summary of findings from an ongoing 12-week preclinical study in which cynomolgus monkeys were dosed intravenously with AVI-5038 at doses of 1.5, 6 and 15 mg/kgs. The poster notes toxicological findings observed following bolus intravenous administration at 6 and 15mg/kg. The preliminary results suggest that the toxicities seen in this study are dose dependent and primarily involve the kidney. Since the collection and analysis is ongoing, the data set is not yet sufficient to determine the ultimate impact these findings might have on the future development of AVI-5038.
- Received two \$250,000 grants, one from CureDuchenne and another from the Foundation to Eradicate Duchenne, to support continued research and development of our exon skipping drug candidates for the treatment of DMD. CureDuchenne and the Foundation to Eradicate Duchenne are US not-for-profit foundations fully dedicated to supporting the research and development of a cure for DMD.

## Influenza Program

- The Transformational Medical Technologies Initiative, or TMTI, a Department of Defense program intended to help protect against biological threats, announced that it successfully partnered with AVI on a "rapid response exercise" against the pandemic H1N1 virus, which is also known as Swine flu or Swine Origin Influenza Virus. TMTI stated that the exercise demonstrated, at a preclinical level, the ability to rapidly respond to a real world viral threat utilizing our RNA-based therapeutics platform, including the preclinical evaluation of RNA-based drug candidates. TMTI further noted that in a preclinical model evaluating our lead candidate against a fully virulent human pandemic H1N1 virus, we demonstrated a statistically significant reduction in virus level that exceeded the reduction using Tamiflu(R), a current standard of care drug.
- Secured increased funding of up to approximately \$4.0 million under our contract with the U.S. Defense Threat Reduction Agency. The increased funding supports, in cooperation with TMTI, continued preclinical development of our lead influenza drug candidate against H1N1, as well as expanded preclinical evaluation against H5N1 (avian flu) and drug resistant H1N1 and H3N2 flu strains. This is in addition to the \$4.1 million received under the initial contract terms and brings total funding for this agreement up to \$8.1 million.

## Hemorrhagic Fever Programs

- Based on successful research culminating in open INDs for our drug candidates 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.

## Antibacterial Program

- Published online in The Journal of Infectious Diseases new data demonstrating the potential utility of phosphorodiamidate morpholino oligomers (PMOs) as antimicrobial agents. The publication describes preclinical studies demonstrating the in vitro and in vivo efficacy of peptide-conjugated phosphorodiamidate morpholino oligomers (PPMOs) against the Burkholderia cepacia complex by targeting acpP, a protein known to be important for bacterial growth. Published in conjunction with the study is an editorial entitled New Horizons in Treating Burkholderia Species Infections which addresses these studies and the underlying PMO technology opportunity as antimicrobials.

## Corporate Developments

- Entered an agreement on April 20th with a group of shareholders in connection with a 13D they filed requesting a special meeting of shareholders. As part of the agreement, the AVI Board of Directors appointed J. David Boyle II Interim President and Chief Executive Officer. The interim CEO appointment follows Dr. Leslie Hudson's resignation as President, Chief Executive Officer and a director of the Company. The Board plans to initiate a search for CEO candidates, which will include both external and internal candidates.
- Anthony R. Chase joined the AVI Board and its nominating and corporate governance committee, and K. Michael Forrest has stepped down from the AVI Board. With these changes, AVI's Board is currently comprised of seven directors, all of whom are independent.
- Mr. Michael Casey and Dr. Christopher Henney informed the Board of their decisions not to stand for re-election at the 2010 Annual Meeting.

## 2010 Guidance

For 2010, AVI confirms 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.

## Upcoming Corporate Presentations

AVI BioPharma is planning to present at upcoming investment and industry conferences, including:

- Rodman & Renshaw Annual Global Investment Conference, May 16-18, London, UK
- Jeffries 2010 Global Life Sciences Conference, June 8-11, 2010, New York, New York
- BMO Capital Markets 10th Annual Focus on Healthcare Conference, August 5, New York, New York

## Conference Call

A conference call to review the financial results and provide a corporate update will be held today, May 10, 2010, at 5:00 p.m. Eastern time (2:00 p.m. Pacific time). J. David Boyle II, AVI's Interim President and Chief Executive Officer, and Chief Financial Officer, will host the call.

The conference call may be accessed by dialing 866.362.5158 for domestic callers and 617.597.5397 for international callers. The passcode for the call is 84089006. Please specify to the operator that you would like to join the "AVI BioPharma first quarter 2010 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. 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 RNA-based drugs utilizing proprietary derivatives of its antisense chemistry (morpholino-modified 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 Junin, influenza, HCV or Dengue viruses. For more information, visit [www.avibio.com](http://www.avibio.com).

"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]

#### AVI BIOPHARMA, INC. (A Development-Stage Company)

#### STATEMENTS OF OPERATIONS (unaudited)

(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2010	2009
Revenues, from grants and research contracts	\$ 1,205	\$ 3,150
Operating expenses:		
Research and development	6,096	4,495
General and administrative	2,844	2,220
Operating loss	(7,735)	(3,565)
Other income (loss):		
Interest income, and other net	42	16
(Increase) decrease on warrant valuation	7,109	2,622
Net loss	\$ (584)	\$ (927)
Net loss per share -- basic and diluted	\$ (0.01)	\$ (0.01)

Shares used in per share calculations	110,429	80,759
	= =====	=====

BALANCE SHEET HIGHLIGHTS  
(unaudited)  
(in thousands)

	March 31, 2010	December 31, 2009
	-----	-----
Cash, cash equivalents and short-term securities	\$ 41,610	\$ 48,446
Total current assets	44,149	51,310
Total assets	52,825	60,027
Total current liabilities	26,341	33,507
Total shareholders' equity	\$ 23,473	\$ 23,630

SOURCE: AVI BioPharma, Inc.