AVI BioPharma Announces Third Quarter 2009 Financial Results & Corporate Highlights

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AVI-4658 for Duchenne Muscular Dystrophy in Final Cohort and on Track for Interim Data; Cook's Global Therapeutics Has No Further Plans to Develop AVI-5126 in Drug Eluting Stent

For Immediate Release

BOTHELL, WA — November 9, 2009 — AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based drugs, today reported financial results for the three and nine months ending September 30, 2009. The Company will host a conference call today, Monday, November 9, at 9:30 a.m. Eastern time (6:30 a.m. Pacific) to review its financial results and corporate highlights (see below for details).

Revenues for the third quarter of 2009 were $6.3 million, compared to $5.2 million in the prior–year period, reflecting increases in research contract revenues of $1.1 million. Revenues for the first nine months of 2009 were $12.4 million, compared to $15.8 million in the first nine months of 2008, reflecting decreases in research contract revenues of $3.4 million.

The operating loss for the three months ended September 30, 2009 decreased to $2.9 million from an operating loss of $5.9 million from the same period in the prior year. The operating loss for the nine months ended September 30, 2009 decreased to $11.6 million from $24.6 million for the prior year period. The operating loss for the third quarter declined as the result of lower general and administrative costs associated with the resignation of former executive officers and relocation costs of new executive officers in 2008. Additionally, the operating loss reduction for the nine month period reflects the $9.9 million expense for acquired in-process research and development from the Ercole acquisition only in 2008 and lower spending in 2009 on research and development related primarily to government research contracts.

The net loss for the third quarter of 2009 was $8.1 million, or $(0.08) per share, compared with a net loss for the third quarter of 2008 of $6.0 million, or $(0.08) per share. The net loss for the third quarter of 2009 includes a non-cash expense for warrant valuation liability of $5.0 million compared to an expense from the same source of $0.2 million during the third quarter of 2008. For the nine months ending September 30, 2009, the Company reported a net loss of $28.7 million, or $(0.33) per share, compared with a net loss for the comparable period in 2008 of $22.8 million, or $(0.33) per share. The net loss for the nine months ending September 30, 2009 includes a non-cash expense for warrant valuation liability of $17.0 million compared to a gain of $1.4 million during the same period of 2008. The increase on warrant valuation is a non-cash expense and results from 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 or decrease on the warrant valuation will fluctuate as the market price of the Company’s stock fluctuates. The warrant valuation liability is a non-cash liability and the Company is not required to expend any cash to settle this warrant valuation liability.

Research and development (R&D) expenses for the third quarter of 2009 decreased to $7.5 million from $7.7 million during the third quarter of 2008. R&D expenses for the nine months ending September 30, 2009 decreased to $17.8 million from $22.3 million in the prior-year period. The decrease in R&D expenses for the three and nine month periods ending September 30, 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 third quarter of 2009 decreased to $1.8 million, from $3.4 million in the comparable prior year period. G&A expenses in the nine months ending September 30, 2009 decreased to $6.2 million from $8.2 million in the prior-year period. The G&A expense decrease for the current year compared to the prior year periods is due primarily to stock compensation expenses incurred in the prior-year periods related to the Ercole acquisition and the resignation of former executive officers and relocation costs of new executive officers.

AVI had cash, cash equivalents and short–term securities of $50.4 million as of September 30, 2009, an increase of $38.9 million from December 31, 2008. This increase was primarily due to two equity financings that raised net proceeds of $47.8 million, partially offset by cash used in operations of $7.7 million, property and equipment and patent-related costs of approximately $1.0

million, and all other cash usage of $0.2 million.

“We continue to make good progress in recruitment and dose escalation in our ongoing systemic trial in Duchenne muscular dystrophy and are on course for intermediate data by years’ end,” said Leslie Hudson, Ph.D., President and Chief Executive Officer. “With regard to AVI-5126, we believe that Cook’s Global Therapeutics Company has no further plans for development of the drug-eluting stent utilizing AVI-5126.”

Third Quarter and Recent Corporate Highlights & Updates:

Cook’s Global Therapeutics Trial

- We believe that further clinical development of a next-generation drug-eluting stent using AVI-5126, which is licensed to Global Therapeutics, a Cook Medical Company, has been discontinued because of an unexpectedly high rate of restenosis. An ongoing, prospective, open label, multi-center feasibility trial of the stent being conducted in Germany by Cook is expected to be closed out within several weeks. Recruiting of patients was terminated in the third quarter and Cook Medical is currently following up patients who have not yet reached the final assessment point at 6 months post treatment. Once follow up and analysis have been completed, AVI will have access to the clinical data.

Duchenne Muscular Dystrophy

- The ongoing open-label, systemic Phase 1b/2 clinical trial of exon skipping AVI-4658 in patients with Duchenne muscular dystrophy is currently on course for intermediate data analysis and release during the fourth quarter of this year. Data to be assessed include *in vitro* response of patients to drug, RNA-based analysis and protein expression data.
- Results and scientific findings of a Phase 1 clinical trial assessing the "proof of concept" and safety of AVI-4658 in patients with DMD were published in the journal, *Lancet Neurology*. These findings, which show that treatment with AVI-4658 was safe and effective in inducing dystrophin expression, suggest that AVI-4658 could have promise as a drug for the treatment of DMD.
- Full data from the completed Phase 1 clinical trial of AVI-4658 in patients with DMD was presented at the 14th Annual International Congress of the World Muscle Society in Geneva, Switzerland. The Company also presented preliminary safety data from AVI's current systemic Phase 1b/2 clinical trial of AVI-4658 in patients with DMD at the same meeting. This presentation highlighted the study's early findings, which showed AVI-4658 to be well tolerated in patients in the first two completed dosing cohorts and the study's three ongoing dosing cohorts, where there have been no confirmed, drug-related adverse events or safety issues.
- An update on preliminary safety data from the ongoing systemic Phase 1b/2 clinical trial of the exon skipping drug AVI-4658 in patients with Duchenne muscular dystrophy (DMD) was presented at the 7th Annual Action Duchenne Conference in London, UK. The most recent data from the ongoing Phase 1b/2 trial at two MDEX sites in the UK demonstrate that AVI-4658 was well tolerated by DMD patients in a dose escalation study that has now started its sixth and final cohort (20 mg/kg).
- Research findings were published in *Molecular Therapy* demonstrating dramatic effects of exon skipping peptide-linked phosphorodiamidate morpholino oligomer (PPMO) in the prevention and treatment of severely affected, dystrophin and utrophin-deficient mice, preventing severe deterioration of the treated animals and extending their lifespan.

BioDefense, Immunology & Anti-infectives

- An expanded contract funding of approximately $11.5 million was received from the Defense Threat Reduction Agency’s (DTRA) Transformational Medical Technologies Initiative (TMTI) to support development of the Investigational New Drug data package for its candidate drug, AVI-7012, to treat Junin virus infection. To date, the United States Department of Defense has contracted with AVI for work potentially worth up to $45.4 million for the development of AVI’s RNA-based drug candidates to treat Ebola, Marburg and Junin virus infections (AVI-6002, AVI-6003 and AVI-7012, respectively).
- The Company currently has a total of $61.7 million of contracted development studies. As of September 30, 2009, $44 million has been billed, of which $38.3 million has been received in cash and $5.7 million is in accounts receivable. The Company has $17.7 in development contracts remaining that have not yet been completed and have not been billed. The Company expects to complete the remaining contract activity and receive the contracted revenue in 2010 and early 2011.
- Research work is being performed under AVI’s contract with the U.S. Defense Threat Reduction Agency (DTRA) for development of RNA-based candidate drugs targeting H1N1 swine flu. The Company is proceeding with mouse and ferret studies to select lead drug candidates.

- Data regarding the Company's antisense technology for productive control of the immune response in hemorrhagic virus infections, including Ebola and Marburg virus, was presented at the 49th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in San Francisco. These preclinical studies demonstrated that AVI's specific peptide conjugated phosphorodiamidate morpholino oligomers (PPMO) targeting innate and adaptive immune responses can diminish hemorrhagic viral pathogenesis and dramatically increase host survival rates in mouse lethal challenge studies. Such studies demonstrate the potential of the Company's RNA-based therapeutics to control the immune response in hemorrhagic virus infections, including Ebola and Marburg virus.

Research

- Research demonstrating the ability of a PPMO therapy to prevent the onset of cardiomyopathy in a mouse model of DMD was published in the journal *Cardiovascular Research* . The paper was authored by researchers at the University of North Carolina at Chapel Hill and AVI.

Corporate

- AVI's corporate headquarters and much of its R&D team was moved to the greater Seattle area. Activities in Corvallis are centered on biodefense and drug supply through outsourced manufacturing as well as the technical development of manufacturing processes. In the Seattle area location, chemistry and biology labs are in operation and research teams in place.
- Closed a public offering of 24,295,775 shares of common stock and warrants to purchase an additional 9,718,310 shares of common stock for gross proceeds of approximately $34.5 million.

Guidance:

For 2009, AVI confirms its guidance for expenditures for operations, net of government funding and other collaborative efforts, to be approximately $10 to $12 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, this might have a negative impact on this guidance.

Conference Call

AVI management will hold a conference call to report second quarter 2009 financial results on Monday, November 9, 2009, at 9:30 a.m. Eastern time (6:30 a.m. Pacific time).

Individuals interested in listening to the live conference call may do so by dialing 877-591-4956 toll free within the United States and Canada, or 719-325-4775 for international callers.

A replay of the call will be available by dialing 888-203-1112 toll free within the U.S. and Canada or 719-457-0820 for international callers. The passcode for the replay is 4369547. In addition, a recording of the call will be available within approximately 24 hours at www.avibio.com.

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 as well as for the treatment of cardiovascular restenosis through our partner Global Therapeutics, a Cook Group Company. 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 influenza, HCV or Dengue viruses. For more information, visit www.avibio.com.

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