AVI BioPharma Announces First Quarter Financial Results

5/9/07

PORTLAND, Ore.--(BUSINESS WIRE)--May 9, 2007--AVI BioPharma, Inc. (Nasdaq:AVII) today reported financial results for the three months ended March 31, 2007.

For the first quarter of 2007, AVI reported a net loss of $9.7 million, or $0.18 per share, compared with a net loss of $9.1 million, or $0.18 per share, for the first quarter of 2006. Revenues for the first quarter of 2007 were $536,000, compared with $66,000 for the first quarter of 2006, reflecting increases in research contracts revenues of $485,000 and license fees of $31,000, partially offset by decreases in grants revenues of $46,000.

Research and development (R&D) expenses were $6.3 million in the first quarter of 2007, compared with $6.8 million in the first quarter of 2006. This decrease was due primarily to decreases in employee costs of $940,000, of which $430,000 was related to the acceleration of the vesting of certain stock options in the first quarter of 2006, decreases in SFAS 123R expenses of $140,000, and salaries and bonuses of $360,000, partially offset by increases in chemical and lab supply costs of $390,000, government-contract related equipment expenses of $350,000, and professional consultant costs of $160,000. The remaining research and development decrease was due to net decreases in clinical trial related expenses of $500,000, partially offset by increases in leasehold and patent amortization expenses of $50,000 and facility costs of $40,000.

General and administrative (G&A) expenses were $4.3 million in the first quarter of 2007, compared with $2.8 million in the first quarter of 2006. This increase was due primarily to increases in employee costs of $1.2 million of which $1.6 million (including $562,500 in cash compensation and $1.1 million in SFAS 123R expenses) was related to the Separation and Release Agreement with the company's former Chief Executive Officer, partially offset by decreases in SFAS 123R expenses of $130,000 and salaries and bonuses of $330,000. General and administrative expenses also included increases in legal expenses of $230,000 and accounting expenses of $50,000.

AVI had cash, cash equivalents and short-term securities of $27.0 million as of March 31, 2007, a decrease of $6.1 million from December 31, 2006. This decrease was due primarily to $5.5 million used in operations and approximately $610,000 used for purchases of property and equipment and patent-related costs.

"We have high expectations that novel drugs based on AVI's NEUGENE(R) technology and ESPRIT (Exon Skipping Pre-RNA Interference Technology) therapeutics will be able to significantly improve patients' lives. While continuing to make progress in our R&D activities, we are re-evaluating our clinical and pre-clinical programs with the goal of allocating our focus and resources to those that hold the greatest potential for near-term market opportunities," said K. Michael Forrest, interim chief executive officer of AVI.

Product Pipeline Update

Technology Overview

AVI has developed proprietary third-generation NEUGENE antisense compounds that are designed to bind to specific disease-causing gene sequences to disable or inactivate the disease process. AVI believes its NEUGENE antisense agents are more stable, specific, efficacious and safer than second-generation antisense compounds in clinical development by others. AVI also believes that its NEUGENE-based ESPRIT therapeutics will allow for fine genetic surgery at the RNA processing level that may enable the deletion of disease-causing genetic sequences or the skipping of mutated sequences, allowing the expression of functional proteins in certain diseases.

AVI's clinical development is primarily focused on three disease categories, cardiovascular disease infectious disease and genetic disorders. The company will initially apply its ESPRIT therapeutic approach to genetic disorders, including a collaborative program in muscular dystrophy. The results of this research may potentially apply to diseases with an immunologic component, such as diabetes or inflammatory disorders. In addition, AVI is investigating certain other important clinical conditions that it believes are particularly well-suited to treatment with NEUGENE-based drugs.

Cardiovascular Disease Program

Resten-NG(R) (AVI-4126) is a NEUGENE antisense drug for treating cardiovascular restenosis, the re-narrowing of a coronary artery following angioplasty. Resten-NG inhibits the expression of the c-myc gene, which the company believes plays a key role in the development of the pathology leading to restenosis. In a completed Phase II study, AVI demonstrated that Resten-NG prevented restenosis at the site of balloon angioplasty as measured by angiography and intravascular ultrasound at six months. In March 2006 AVI announced a development and commercialization agreement with Cook Group Inc., in which Cook Group licensed AVI-4126 for the down-regulation of c-myc gene expression in vascular diseases. This agreement covers device delivery of Resten-NG as well as Resten-MP(TM), the microparticle formulation of AVI-4126, for treating cardiovascular restenosis. As part of this agreement, Cook Group has assumed control of the APPRAISAL Phase II clinical study, in which Resten-MP is being evaluated in the prevention of restenosis when delivered intravenously in conjunction with the placement of one or more bare-metal stents. In preclinical studies, Resten-MP was as effective in preventing restenosis as was AVI-4126 delivered by catheters or stents.

In October 2006 AVI announced the initiation of a clinical program to assess the safety and effectiveness of Resten-CP(TM) for the treatment of coronary vascular disease. Resten-CP is AVI-4126 incorporating a peptide to enhance delivery to the saphenous vein ex vivo before use in coronary artery bypass graft (CABG) surgery. This is a 600-patient randomized, double blind, placebo-controlled trial incorporating Phase Ib through Phase III components. The Phase Ib stage of the trial is underway in Europe and a decision on continuation into the Phase II/III stages of the study will be made after evaluation of the first 110 enrolled patients.

Infectious Disease Program

AVI's infectious disease program encompasses research on more than 50 different viruses representing most viral families and involves collaborations with investigators worldwide. Results from these studies have enhanced AVI's potential ability to design effective agents for emerging as well as for engineered pathogens. AVI's antiviral research program has produced antisense drugs shown to be active in preclinical studies against a wide range of RNA viruses, including hepatitis C virus (HCV), seasonal influenza A virus, West Nile virus, dengue virus, SARS coronavirus, Ebola virus and Marburg virus. AVI has published confirmation through independent laboratories of NEUGENE antisense efficacy in in vitro experiments against multiple strains of seasonal influenza, as well as the H5N1 sub-strain, a potential worldwide public health threat. AVI intends to test this compound for potential efficacy against the H5N1 sub-strain in animal models.

In June 2005 the company announced the acceptance by the U.S. FDA of an IND application for the treatment of HCV using the company's NEUGENE compound AVI-4065. Following disappointing results from two small Phase 1 studies in HCV patients in which less-than-expected reductions in viral titer were observed, AVI has developed a high dose-escalating treatment protocol designed to exceed blood level concentrations of the drug achieved in the earlier studies. The goal of this study, which will be conducted in Europe, is to achieve a clinically significant reduction in viral load. The company has completed GMP manufacturing of AVI-4065 for the planned high dose treatment protocol and is currently awaiting approval from the Ministry of Health in the Ukraine to commence the study.

To potentially address the large commercial seasonal influenza market, AVI has developed NEUGENE antisense drug candidates that target genetic regions of the influenza A virus that are highly conserved between the six viral subtypes that cause human disease. These include three viral subtypes that caused pandemics in the 20th Century -- the 1918 Spanish flu (H1N1), the 1957 Asian flu (H2N2) and the 1968 Hong Kong flu (H3N2) -- and three subtypes of avian flu that have been reported to cause disease in humans (H5N1, H7N7 and H9N2). Collaborators confirmed, based on in vitro experiments, that a single NEUGENE drug was active against most of these influenza subtypes, including the emerging H5N1 avian strain.

Subsequently, in experiments sponsored by AVI and conducted at Tulane University School of Medicine and the United States Army Medical Research Institute for Infectious Diseases (USAMRIID), mice were pre-treated with antisense phosphorodiamidate morpholino oligomers (PMOs), and then infected with two different strains of influenza A (H3N2 and H1N1). Treated mice showed significantly reduced clinical signs (weight loss) and increased survival compared to control-treated and untreated mice. In addition, PMO-treated mice showed significantly reduced viral titer (to below limit of detection) in comparison to untreated mice.

Histological examination of the lungs showed that treated mice had reduced pathology when examined for infiltrating cells or alveolar damage. Based on these encouraging preclinical data, AVI intends to explore potential partnership arrangements with companies that are active in the marketing of seasonal influenza vaccines. AVI also intends to undertake additional animal testing of its compounds to determine their potential efficacy in the treatment of experimental infections caused by the H5N1 subtype, the strain that is feared could cause another pandemic flu outbreak.

Duchenne Muscular Dystrophy

In February 2006 AVI announced publication of an article in Nature Medicine indicating that AVI's ESPRIT technology may hold significant potential to bypass faulty dystrophin gene expression in patients with muscular dystrophy. In December 2006 the company announced the initiation of a clinical program with AVI-4658 for the treatment of Duchenne muscular dystrophy (DMD). The first phase of the clinical program has been designed as a dose-escalating trial to be conducted in collaboration with MDEX Consortium in the U.K. The trial is expected to commence shortly after approval of the CTX (an IND equivalent), which is currently under review by the UK health authorities.

Bio-Defense Program

AVI has an active collaborative program with the Department of Defense (DoD) in the area of bio-threats and emerging diseases. In 2005 and early 2006, AVI received $4.6 million for ongoing programs in drug development for the highly lethal Ebola and Marburg viruses, and countermeasures for ricin and anthrax toxins.

In January 2006 AVI announced that the final version of the 2006 defense appropriations act had been approved, which included an allocation of $11.0 million to fund AVI's ongoing defense-related programs. Net of government administrative costs, it is anticipated that AVI will receive up to $9.8 million under this allocation. AVI's NEUGENE technology is expected to be used to continue developing therapeutic agents against Ebola, Marburg and dengue viruses, as well as to continue developing countermeasures for anthrax exposure and antidotes for ricin toxin. AVI has received signed contracts for three of the projects, with total government expenditures of $7.1 million. AVI continues to work with the government to define the scope of work to be performed on the fourth project, dengue viruses. AVI expects that funding under these contracts will be received over the next 12 months as it seeks reimbursement for its research under the contracts, and such funding is not reflected in AVI's 2007 first quarter financial statements.

In December 2006 AVI announced the execution of a two-year $28 million research contract with the Defense Threat Reduction Agency (DTRA), an agency of the DoD, to fund AVI's development of therapeutic agents to treat the effects of Ebola, Marburg and Junin hemorrhagic viruses. In the first quarter of 2007, AVI received $485,000 under this contract.

Conference Call

AVI BioPharma has scheduled an investor conference call regarding this announcement, and the company's current and planned business activities, to be held May 9th beginning at 11:00 a.m. Eastern time.

Individuals interested in listening to the conference call may do so by dialing (888) 803-8271 within the U.S. and Canada, or (706) 634-2467 for international callers. A telephone replay of the conference call will be available for 48 hours beginning within two hours of the conclusion of the call, by dialing (800) 642-1687 for domestic callers, or (706) 645-9291 for international callers, and entering reservation number 5409988.

The live conference call also will be available to private investors via the Internet at www.avibio.com. A replay of the call will be available on the company's Web site for 14 days following the completion of the call.

About AVI BioPharma

AVI BioPharma develops therapeutic products for the treatment of life-threatening diseases using third-generation NEUGENE antisense drugs and ESPRIT exon skipping technology. AVI's lead NEUGENE antisense compound is designed to target cell proliferation disorders, including cardiovascular restenosis. In addition to targeting specific genes in the body, AVI's antiviral program uses NEUGENE antisense compounds to combat disease by targeting single-stranded RNA viruses, including West Nile virus, hepatitis C virus, dengue virus, Ebola virus and influenza A virus. AVI's

NEUGENE-based ESPRIT technology will initially be applied to potential treatments for Duchenne muscular dystrophy. More information about AVI is available on the company's Web site at 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.

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

STATEMENTS OF OPERATIONS
(unaudited)

	Three months ended March 31,	
	2007	2006
Revenues, from license fees, grants and research contracts	$ 536,042	$ 65,962
Operating expenses:		
Research and development	6,317,641	6,763,245
General and administrative	4,303,885	2,821,726
	10,621,526	9,584,971
Other income:		
Interest income, net	362,509	457,859
Net loss	$ (9,722,975)	$ (9,061,150)
Net loss per share -- basic and diluted	$ (0.18)	$ (0.18)
Shares used in per share calculations	53,241,730	51,715,050

BALANCE SHEET HIGHLIGHTS
(unaudited)

	March 31, 2007	December 31, 2006
Cash, cash equivalents and short-term securities	$ 27,046,111	$ 33,152,132
Total current assets	28,307,380	33,939,913
Total assets	35,307,047	40,862,746
Total current liabilities	4,346,755	3,150,845
Total shareholders' equity	$ 30,960,292	$ 37,711,901

CONTACT: Company Contact:
AVI BioPharma, Inc.
Michael Hubbard, 503-227-0554
hubbard@avibio.com
or
Investor Contacts:
Lippert/Heilshorn & Associates, Inc.
Jody Cain or Brandi Floberg, 310-691-7100

jcain@lhai.com
bfloberg@lhai.com
or
Press Contact:
Waggener Edstrom Worldwide
Bioscience and Healthcare Practice
Jenny Moede, 503-443-7000
jmoede@waggeneredstrom.com

SOURCE: AVI BioPharma, Inc.