AVI BioPharma Reports Third Quarter Financial Results

11/8/06

PORTLAND, Ore.--(BUSINESS WIRE)--Nov. 8, 2006--AVI BioPharma, Inc. (Nasdaq:AVII) today reported financial results for the three and nine months ended September 30, 2006.

The net loss for the third quarter of 2006 was $6.8 million, or $0.13 per share, compared with a net loss for the third quarter of 2005 of $1.7 million, or $0.04 per share. Results for the third quarter of 2006 include stock-based compensation expenses of $1.0 million recognized in accordance with SFAS 123R. Results for the third quarter of 2005 do not include SFAS 123R compensation expenses since the adoption occurred beginning January 1, 2006. Revenues for the 2006 third quarter were $13,000, down from $3.3 million in the prior-year quarter, reflecting lower research contract revenues. Revenues for the 2005 third quarter were primarily due to the recognition of $3.2 million in research contract revenue from the receipt in 2005 of $3.4 million in government funding for work on viral disease research projects.

Research and development (R&D) expenses for the quarter increased to $5.9 million from $4.1 million in the prior year, and general and administrative (G&A) expenses increased to $1.3 million from $1.1 million in the prior year. The increase in R&D expenses was due to an additional $690,000 in employee costs, including $645,000 related to SFAS 123R, and to higher clinical costs of $980,000 from the expansion of clinical programs in hepatitis C virus (HCV) and coronary artery bypass grafting (CABG). The remaining increase in R&D expenses also reflects $120,000 in contracting costs for the production of GMP subunits, which are used by AVI to manufacture compounds for future clinical trials. The increase in G&A expenses was due primarily to an additional $300,000 in employee costs, including $360,000 related to SFAS 123R, partially offset by decreases in employee costs of $125,000 from the transition of nine employees in AVI's Colorado facility to Cook Group Inc. in April 2006, subsequent to AVI's licensing transaction with Cook.

For the nine months ended September 30, 2006, AVI BioPharma reported a net loss of $22.7 million, or $0.43 per share, compared with a net loss for the comparable period in 2005 of $12.1 million, or $0.28 per share. Results for the nine months ended September 30, 2006 include stock-based compensation expense of $3.9 million, of which $3.1 million is related to SFAS 123R and $830,000 is related to the acceleration of the vesting of certain stock options. Results for the nine months ended September 30, 2005 do not include SFAS 123R compensation expense. Revenues for the nine months ended September 30, 2006 were $98,000, down from $3.4 million in the prior-year period, reflecting lower research contract revenues. Revenues for the nine months ended September 30, 2005 were primarily due to the recognition of $3.2 million in research contract revenue from the receipt in 2005 of $3.4 million in government funding for work on viral disease research projects.

R&D expenses for the nine months ended September 30, 2006 increased to $18.6 million from $12.2 million in the prior-year period, and G&A expenses increased to $5.7 million from $3.8 million. The increase in R&D expenses was due primarily to an additional $2.4 million in employee costs, including $1.8 million related to SFAS 123R, $430,000 related to the acceleration of the vesting of certain stock options, and to higher clinical costs of $1.9 million from the expansion of clinical programs in HCV and CABG. The increase in R&D expenses also reflects $500,000 in AVI common stock issued to Chiron Corporation as the first milestone payment under a license agreement granting AVI a nonexclusive license to Chiron's patents and patent applications for the research, development and commercialization of antisense therapeutics against HCV, and $1.1 million in contracting costs for the production of GMP subunits. The increase in G&A expenses was due primarily to an additional $1.8 million in employee costs, including $1.3 million related to SFAS 123R and $400,000 related to the acceleration of the vesting of certain stock options.

AVI had cash, cash equivalents and short-term securities of $38.4 million as of September 30, 2006, a decrease of $8.6 million from December 31, 2005. This decrease was due primarily to $15.5 million used in operations and approximately $1.2 million used for purchases of property and equipment and patent-related costs, offset by the receipt of $5.0 million in net proceeds from a stock purchase agreement with Cook and $3.1 million from the exercise of warrants and options and sales under the company's employee stock purchase plan during the nine months ended September 30, 2006.

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. AVI's NEUGENE(R) technology will 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 continues to work with the government to define the scope of the work to be performed on these programs. This additional funding for 2006 has not been received and has not been reflected in AVI's 2006 third quarter financial statements.

"As planned we have initiated our clinical program for the treatment of coronary vascular disease with AVI-5126, or Resten-CP(TM), which combines our third-generation antisense drug AVI-4126 with our proprietary CytoPorter(TM) delivery peptide," said Denis R. Burger, Ph.D., chief executive officer of AVI BioPharma. "We are taking a cost-effective and efficient approach to Resten-CP's clinical development. These studies are being conducted at clinical cardiovascular surgery sites in the Ukraine and Poland as the first step in our program. Based on anticipated efficacy results from these studies, which are expected in late 2007, we expect to broaden our program with a goal to commercialize Resten-CP for CABG in all major global markets within five years.

"We are actively enrolling patients in our modified HCV clinical trial with plans to discuss preliminary results in the first half of 2007, and continue making progress with activities to enter the clinic with our Exon Skipping Pre-RNA Interference Technology, or ESPRIT, therapeutics in Duchenne muscular dystrophy. Based on strong preclinical data that indicate the ability of our NEUGENE compounds to target multiple strains of influenza and animal studies that are in progress, we plan to file an Investigational New Drug (IND) application for the treatment of avian influenza," added Dr. Burger.

Product Pipeline Update

Technology Overview

AVI has developed proprietary third-generation NEUGENE antisense technology, which is characterized by a novel synthetic backbone. NEUGENE antisense compounds are designed to bind to specific disease-causing gene sequences to disable or inactivate the disease process. AVI believes that this chemistry allows NEUGENE antisense agents to be more stable, specific, efficacious and safer than second-generation antisense compounds in clinical development by others.

AVI's clinical development is focused on two disease categories: cardiovascular disease and infectious disease. In addition, AVI applies its technology to certain other clinical applications that it believes are particularly amenable to antisense drug development, namely genetic disorders, inflammatory diseases and oncology.

In September 2005 the company announced a new application of its proprietary NEUGENE technology, called ESPRIT (Exon Skipping Pre-RNA Interference Technology). ESPRIT therapeutics allow for fine genetic surgery at the RNA processing level that enables the deletion of disease-causing genetic sequences or the skipping of functional sequences that are over-expressed or harmful in certain diseases. In February 2006 the company 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. The company is applying the ESPRIT therapeutic approach in genetic disorders, including a potential collaborative program in muscular dystrophy, as well as to diseases with an immunologic component, such as diabetes and multiple sclerosis.

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 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 ongoing 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 for the treatment of coronary vascular disease. Resten-CP is a new-generation of AVI-4126 that incorporates the company's proprietary transporter tail CytoPorter to enhance delivery to the saphenous vein ex vivo before use in bypass surgery. The first step planned in this program is to assess the therapeutic benefit of exposing an excised saphenous vein to Resten-CP immediately before connecting it to the coronary artery circulation of patients undergoing CABG procedures. In October 2006 AVI also initiated pivotal studies in the Ukraine and Poland. Based on anticipated efficacy results from these trials expected in late 2007, AVI expects to initiate a worldwide clinical program to bring Resten-CP to all major markets within five years.

Infectious Disease Program

AVI's infectious disease program is extensive, 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 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 HCV, 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 preclinical experiments against multiple strains of influenza, including avian influenza strain H5N1, a potential worldwide public health threat.

AVI plans to focus its antiviral drug development program on infectious diseases that represent large market opportunities. In June 2005 the company announced the acceptance by the U.S. Food and Drug Administration (FDA) of an IND application for the treatment of HCV using the company's NEUGENE compound AVI-4065. In September 2005 AVI announced the initiation of an HCV clinical trial to assess the safety, tolerability, pharmacokinetics and viral response to treatment with AVI-4065 in healthy volunteers and patients with chronic active HCV. The company reported favorable safety, tolerability and pharmacokinetic results in January 2006 from the first phase of its HCV program. Based on preliminary data in the second phase of the HCV study presented in May 2006, the clinical trial protocol was modified to allow for extended treatment duration with AVI-4065 to enhance the pharmacokinetics and potentially enhance viral and clinical response in HCV patients. In July 2006 AVI began patient enrollment to fill an extended treatment cohort in this study.

To potentially address the large seasonal influenza commercial 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 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 have confirmed that a single NEUGENE drug was effective in preclinical studies against most influenza subtypes, including the emerging H5N1 avian strain. Based on animal studies in progress, AVI plans to file an IND application for its NEUGENE drug for avian flu that is also efficacious against the far more common influenza A viruses, which kill an average of 35,000 Americans every year.

The company is collaborating with the Centers for Disease Control and Prevention (CDC) in its dengue virus program, and expects dengue fever/dengue hemorrhagic fever to be the next viral program to move into clinical development.

Bio-Defense Program

AVI has an active collaborative program with the Department of Defense 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 the final version of the 2006 defense appropriations act was approved, which included an allocation of $11.0 million to fund AVI's ongoing defense-related programs. AVI continues to work with the government to define the scope of the work to be performed on these programs. This additional funding has not been received and has not been reflected in AVI's 2006 third quarter financial statements.

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 November 15th 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 9155986.

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. AVI's lead NEUGENE antisense compound is designed to target cell proliferation disorders, including cardiovascular restenosis, cancer and polycystic kidney disease. 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 has introduced a NEUGENE-based exon-skipping technology called ESPRIT therapy. 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 September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenues, from license fees, grants and research contracts	$13,252	$3,281,805	$97,772	$3,366,314
Operating expenses:				
Research and development	5,938,867	4,147,201	18,624,041	12,204,260
General and administrative	1,347,114	1,052,244	5,684,551	3,773,303
	7,285,981	5,199,445	24,308,592	15,977,563
Other income:				
Interest income, net	492,083	225,169	1,466,995	486,957
Net loss	$(6,780,646)	$(1,692,471)	$(22,743,825)	$(12,124,292)
Net loss per share-- basic and diluted	$(0.13)	$(0.04)	$(0.43)	$(0.28)
Shares used in per share calculations	52,964,049	44,184,293	52,546,293	43,608,789

BALANCE SHEET HIGHLIGHTS
(unaudited)

	September 30, 2006	December 31, 2005
Cash, cash equivalents and short-term securities	$ 38,425,020	$ 47,051,082
Total current assets	39,289,335	48,653,394
Total assets	46,542,091	56,407,982
Total current liabilities	2,182,879	2,747,973
Total shareholders' equity	$ 44,359,212	$ 53,660,009

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