AVI BioPharma Announces Second Quarter Financial Results

8/8/07

PORTLAND, Ore., Aug 08, 2007 (BUSINESS WIRE) -- AVI BioPharma, Inc. (Nasdaq:AVII) today reported financial results for the three and six months ended June 30, 2007.

The net loss for the second quarter of 2007 was $8.5 million, or $0.16 per share, compared with a net loss for the second quarter of 2006 of $6.9 million, or $0.13 per share. Revenues for the 2007 second quarter were $2.4 million, up from $19,000 in the prior-year quarter, reflecting increases in research contracts revenues of $2.4 million and license fees of $31,000, partially offset by decreases in grants revenues of $8,000.

Research and development (R&D) expenses for the quarter increased to $9.2 million from $5.9 million last year, and general and administrative (G&A) expenses increased to $2 million from $1.5 million in the prior year. The increase in R&D expenses was due to higher clinical costs of $1.4 million from the expansion of clinical programs. The increase in R&D expenses also reflects $1.8 million in expenses for government research contracts. The increase in G&A expenses was due primarily to increases in legal expenses of $315,000 and compensation costs of $225,000, partially offset by decreases in SFAS 123R expenses of $75,000.

For the six months ended June 30, 2007, AVI BioPharma reported a net loss of $18.3 million, or $0.34 per share, compared with a net loss for the comparable period in 2006 of $16.0 million, or $0.31 per share. Revenues for the first half of 2007 were $2.9 million, up from $85,000 in the first half of 2006, reflecting increases in research contracts revenues of $2.9 million and license fees of $63,000, partially offset by decreases in grants revenues of $55,000.

R&D expenses for the first six months of 2007 increased to $15.5 million from $12.7 million in the prior-year period, and G&A expenses increased to $6.3 million from $4.3 million. The increase in R&D expenses was due to higher net clinical costs of $700,000, and $170,000 in contracting costs for the production of GMP subunits. The increase in R&D expenses also reflects $2.1 million in expenses for government research contracts. In addition, R&D expenses include increases in chemical and lab supply costs of $390,000, professional consultant costs of $240,000, and leasehold and patent amortization expenses of $50,000. These R&D increases were partially offset by decreases in employee costs of $980,000, of which $430,000 was related to the acceleration of the vesting of certain stock options in the first quarter of 2006 and decreases in SFAS 123R expenses of $290,000 and salaries and bonuses of $250,000. The increase in G&A expenses was due primarily to increases in compensation costs of $1.4 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 $200,000. G&A expenses also included increases in legal expenses of $545,000 and accounting expenses of $60,000.

AVI had cash, cash equivalents and short-term securities of $19.3 million as of June 30, 2007, a decrease of $13.8 million from December 31, 2006. This decrease was due primarily to $12.7 million used in operations and $1.1 million used for purchases of property and equipment and patent-related costs.

"We have over the years explored numerous promising development programs based on the versatility of our next-generation NEUGENE(R) antisense technology and, following a re-evaluation of our programs, have identified those we believe have the greatest near-term commercialization potential," said K. Michael Forrest, interim chief executive officer of AVI. "Our current plans are to advance the clinical development of NEUGENE drug candidates targeting specific cardiovascular conditions; use our new exon-skipping pre-RNA interference technology, or ESPRIT, for the treatment of selected genetic diseases with the first indication as Duchenne muscular dystrophy, or DMD; to pursue opportunities provided under our relationships with the Department of Defense to develop products that are potentially effective against lethal biological weapons; and,to continue preclinical work developing an effective compound in combating an outbreak of pandemic influenza caused by the H5N1 strain of avian flu.

"We have decided to discontinue our current hepatitis C (HCV) clinical development program. We are redirecting and tightly concentrating our drug discovery activities on programs designed to improve the potency, delivery systems, efficacy and safety of our compounds, including those for potential use in HCV," he added. "Discontinuation of the HCV clinical program is expected to allow additional resources to be used in support of our cardiovascular and DMD development programs."

Product Pipeline Update

Technology Overview

AVI has developed proprietary next-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's NEUGENE-based ESPRIT therapeutics function at the RNA processing level enabling the deletion of disease-causing genetic sequences or the skipping of mutated sequences, potentially allowing the expression of functional proteins in certain diseases.

Cardiovascular Disease Program

AVI-4126 and AVI-5126 are NEUGENE antisense drugs for treating cardiovascular restenosis, the re-narrowing of a coronary artery following angioplasty. These drugs inhibit 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 AVI-4126 prevented restenosis at the site of balloon angioplasty as measured by angiography at six months. In March 2006, AVI announced a development and commercialization agreement with Cook Group Inc., in which Cook Group licensed NEUGENES for the down-regulation of c-myc gene expression in certain vascular diseases. As part of this agreement, Cook Group has assumed control of the APPRAISAL Phase II clinical study, in which Resten-MP (AVI-4126 delivered with microparticles) is being evaluated in the prevention of restenosis when delivered intravenously in conjunction with the placement of one or more bare-metal stents. In July

2007, Global Therapeutics, a Cook Medical company, announced that it had completed six-month follow-up on patients enrolled in the APPRAISAL Phase II study. In July 2007, Global Therapeutics also reported plans to initiate a clinical study for the inhibition of restenosis in patients following angioplasty using a bare metal, cobalt chromium stent, a drug delivery catheter and AVI-5126.

In October 2006, AVI announced its intention to initiate a clinical program to assess the safety and effectiveness of AVI-5126 in coronary artery bypass graft surgery (CABG). AVI-5126 is a combination of AVI-4126 and a delivery peptide, and will be applied to the saphenous vein graft ex vivo before engraftment. This is a 600-patient randomized, double blind, placebo-controlled trial incorporating Phase Ib through Phase III components. The Phase Ib/II stage of the trial is underway in the Ukraine, with additional sites soon to come on line in Poland. Enrollment of the first 110 patients is expected by the first quarter of 2008. AVI has established a drug safety monitoring committee comprised of independent third parties to periodically evaluate safety data. No safety issues have been reported to date.

Infectious Disease Program

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.

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. AVI has announced plans to begin a clinical trial with cross-licensing and development partner Ercole Biotech, Inc. with AVI-4658 for the systemic treatment of DMD.

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 virus. AVI expects that funding under these signed contracts will be received over the next 12 months. In the second quarter of 2007, AVI recognized $1.1 million in research contract revenue under this contract.

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 half of 2007, AVI received $1.7 million 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 August 8 beginning at 11:00 a.m. Eastern time (8:00 a.m. Pacific 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 7205349.

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 dengue virus, Ebola virus and H5N1 avian influenza 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 June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Revenues, from license fees, grants and research contracts	$ 2,351,424	$ 18,558	$ 2,887,466	$84,520
Operating expenses:				
Research and development	9,160,816	5,921,929	15,478,457	12,685,174
General and administrative	2,030,796	1,515,711	6,334,681	4,337,437
	11,191,612	7,437,640	21,813,138	17,022,611
Other income:				
Interest income, net	303,568	517,053	666,077	974,912
Net loss	$(8,536,620)	$(6,902,029)	$(18,259,595)	$(15,963,179)
Net loss per share-- basic and diluted	$ (0.16)	$ (0.13)	$ (0.34)	$ (0.31)
Shares used in per share calculations	53,560,360	52,946,054	53,381,256	52,333,952

BALANCE SHEET HIGHLIGHTS

(unaudited)

	June 30, 2007	December 31, 2006
Cash, cash equivalents and short-term securities	$ 19,320,301	$ 33,152,132
Total current assets	21,215,260	33,939,913
Total assets	31,208,514	40,862,746
Total current liabilities	4,886,894	3,150,845
Total shareholders' equity	$ 24,214,945	$ 37,711,901

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