

AVI BioPharma Announces Third Quarter Financial Results

11/6/07

PORTLAND, Ore.--(BUSINESS WIRE)--Nov. 6, 2007--AVI BioPharma, Inc. (Nasdaq:AVII) today reported financial results for the three and nine months ended September 30, 2007.

"We are making tangible progress against well-defined programs that we believe hold significant near-term commercialization potential," said K. Michael Forrest, interim chief executive officer of AVI. Key achievements during the first nine months of 2007 include:

- -- Initiation of a 600-patient Phase 2 clinical trial by AVI using AVI-5126 for the prevention of restenosis in saphenous veins following their engraftment in coronary artery bypass surgery (CABG) procedures;
- -- Progress by AVI's partner Cook Medical in the evaluation of AVI-4126 and AVI-5126 as candidates for the prevention of restenosis in patients following placement of bare metal stents during angioplasty procedures;
- -- Accelerated evaluation and development of ESPRIT (Exon Skipping Pre-RNA Interference Technology) for the treatment of serious medical conditions, including Duchenne muscular dystrophy (DMD);
- -- Receipt of a \$2.4 million grant from Charley's Fund for development of an ESPRIT product targeted at exon 50 mutations in DMD patients;
- -- Receipt of Orphan Drug designation from the U.S. Food and Drug Administration (FDA) for an ESPRIT product targeted at exon 51 mutations in DMD patients;
- -- Approval by the Medicines and Healthcare products Regulatory Agency (MHRA), the health authority in the United Kingdom, to commence an intramuscular clinical study with AVI-4658 in DMD boys afflicted with an exon 51 mutation. Patient screening in this study is now underway;
- -- Confirmation of \$35.0 million in contracts with the U.S.

 Department of Defense (DoD) for development of

 NEUGENE(R)-based products for the prevention and treatment of
 life-threatening conditions caused by bioterrorist agents;
- -- Announcement of preclinical results demonstrating the ability of NEUGENE drugs to provide up to 100% protection against lethal challenges with Ebola and Marburg viruses in non-human primates;
- -- Enhancement of AVI's corporate governance through the appointment of two new, highly capable directors to AVI's board. These appointments were brought about through collaborative discussions between shareholder representatives and management.

Financial Results

The net loss for the third quarter of 2007 was \$7.0 million, or \$0.13 per share, compared with a net loss for the third quarter of 2006 of \$6.3 million, or \$0.12 per share. Revenues for the 2007 third quarter were \$2.9 million, up from \$13,000 in the prior-year quarter, reflecting increases in research contracts revenues of \$2.9 million and license fees of \$31,000, partially offset by decreases in grants revenues of \$2,000.

Research and development (R&D) expenses for the quarter increased to \$9.9 million from \$5.9 million last year, and general and administrative (G&A) expenses increased to \$1.5 million from \$1.3 million in the prior year. The increase in R&D expenses reflects \$2.1 million in expenses for government research contracts and \$1.9 million in contracting costs for the production of GMP subunits. The increase in R&D expenses also reflects \$470,000 in consultant fees. These R&D increases were partially offset by decreases in net clinical expenses of \$510,000. The increase in G&A expenses was due primarily to higher compensation costs of \$165,000, legal expenses of \$55,000 and accounting costs of \$20,000, partially offset by decreases in SFAS 123R expenses of \$65,000.

For the nine months ended September 30, 2007, AVI BioPharma reported a net loss of \$23.0 million, or \$0.43 per share, compared with a net loss for the comparable period in 2006 of \$22.6 million, or \$0.43 per share. Revenues for the nine months ended September 30, 2007 were \$5.8 million, up from \$98,000 for the comparable period in 2006, reflecting increases in research contracts revenues of \$5.7 million and license fees of \$94,000, partially offset by decreases in grants revenues of \$57,000.

R&D expenses for the nine months ended September 30, 2007 increased to \$25.4 million from \$18.6 million in the prior-year period, and G&A expenses increased to \$7.9 million from \$5.7 million. The increase in R&D expenses reflects \$4.2 million in expenses for government research contracts and \$2.0 million in contracting costs for the production of GMP subunits. The increase in R&D expenses also includes increases in professional consultant costs of \$710,000, in chemical and lab supply costs of \$350,000, in net clinical expenses of \$190,000, and in leasehold and patent amortization expenses of \$90,000. These R&D increases were partially offset by decreases in employee costs of \$1.1 million, 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 \$440,000 and salaries and bonuses of \$200,000. The increase in G&A expenses was due primarily to increases in compensation costs of \$1.8 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 \$265,000. G&A expenses also included increases in legal expenses of \$600,000 and accounting expenses of \$80,000.

AVI had cash, cash equivalents and short-term securities of \$14.0 million as of September 30, 2007, a decrease of \$19.1 million from December 31, 2006. This decrease was due primarily to \$17.3 million used in operations and \$1.8 million used for purchases of property and equipment and patent-related costs.

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.

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 (or avian flu), 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 initiation of a clinical program with AVI-4658 for the treatment of DMD. The first phase of the clinical program has been designed as a proof-of-concept dose-escalating trial to be conducted in collaboration with MDEX Consortium in the U.K. In October 2007 research teams at the Imperial College of London, in collaboration with MDEX Consortium, received approval from the Medicines and Healthcare products Regulatory Agency (MHRA) in the U.K. to begin screening patients for this clinical trial. AVI has also 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. In November 2007 the FDA Office of Orphan Products Development granted orphan drug designation to AVI-4658 for the system treatment of DMD. In October 2007 AVI announced that the company had been awarded a \$2.45 million grant from Charley's Fund, Inc., a nonprofit organization that funds DMD-specific drug development and discovery initiatives, for the development of an ESPRIT compound by AVI and Ercole Biotech to skip exon 50.

Bio-Defense Program

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 has received signed contracts for \$9.8 million, which represents the full allocation, net of government administrative costs. 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 expects that funding under these signed contracts will be completed over the next 12 months. In the first nine months of 2007, AVI recognized \$2.1 million in research contract revenue under this contract.

In December 2006 AVI announced the execution of a two-year \$28.0 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 nine months of 2007, AVI recognized \$3.6 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 November 6 beginning at 10:00 a.m. Eastern time (7:00 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 20823763. 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 Nine Months Ended
September 30, September 30,

2007 2006 2007 2006

	September 307		beptember 307	
	2007	2006	2007	2006
Revenues, from license fees, grants and research contracts	\$ 2,911,406	\$ 13,252	\$ 5,798,872	\$ 97,772
Operating expenses: Research and				
development General and	9,880,480	5,938,867	25,358,937	18,624,041
administrative	1,544,512	1,347,114	7,879,193	5,684,551
	11,424,992	7,285,981	33,238,130	24,308,592
Other income: Interest				
income, net Gain on warrant	182,320	492,083	848,397	1,466,995

liability	1,296,322	529,136	3,550,330	135,453
Net loss	\$(7,034,944)	\$(6,251,510)	\$(23,040,531)	\$(22,608,372)
Net loss per share basic and diluted	\$ (0.13)	\$ (0.12) \$	\$ (0.43) \$	\$ (0.43)
Shares used in per share calculations	53,693,693	52,964,049	53,500,250	52,546,293

BALANCE SHEET HIGHLIGHTS

(unaudited)

 Cash, cash equivalents and short-term securities
 \$ 14,049,759 \$ 33,152,132

 Total current assets
 16,754,113
 33,939,913

 Total current liabilities
 9,550,330
 8,343,421

 Total shareholders' equity
 \$ 15,225,708 \$ 32,519,325

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