

AVI BioPharma Announces 2006 Fourth Quarter and Full Year Financial Results

3/15/07

PORTLAND, Ore.--(BUSINESS WIRE)--March 15, 2007--AVI BioPharma, Inc. (NASDAQ:AVII) today reported financial results for the three and 12 months ended December 31, 2006.

The net loss for the fourth quarter of 2006 was \$8.3 million, or \$0.16 per share, compared with a net loss for the fourth quarter of 2005 of \$4.6 million, or \$0.10 per share. Results for the fourth quarter of 2006 include non-cash stock-based compensation expenses of \$935,000 recognized in accordance with SFAS 123R. Results for the fourth quarter of 2005 do not include SFAS 123R compensation expenses because SFAS 123R is effective beginning January 1, 2006. Revenues for the three months ended December 31, 2006 were \$18,000, down from \$1.4 million in the prior year period, reflecting lower research contract revenues. Revenues for the three months ended December 31, 2005 were primarily the result of the recognition of \$1.4 million in research contract revenue from government funding for work on viral disease research projects.

Research and development (R&D) expenses for the fourth quarter of 2006 increased to \$6.7 million from \$4.9 million in the prior year period, and general and administrative (G&A) expenses increased to \$2.1 million from \$1.4 million in the prior year period. The increase in R&D expenses was due to an additional \$725,000 in employee costs, including \$585,000 related to SFAS 123R. The increase in R&D expenses also reflects \$675,000 in AVI common stock issued to Ercole Biotech, Inc. under the terms of a stock purchase agreement, and \$575,000 in contracting costs for the production of GMP subunits, which are used by the Company to manufacture compounds for future clinical trials. The increase in G&A expenses was due primarily to an additional \$650,000 in employee costs, including \$350,000 related to SFAS 123R.

For the 12 months ended December 31, 2006 AVI reported a net loss of \$31.1 million, or \$0.59 per share, compared with a net loss in the comparable period in 2005 of \$16.7 million, or \$0.37 per share. Results for 2006 include non-cash stock-based compensation expense of \$4.9 million, of which \$4.0 million is related to SFAS 123R and \$830,000 is related to the acceleration of the vesting of certain stock options. Results for 2005 do not include SFAS 123R compensation expense. Revenues in 2006 were \$115,000, down from \$4.8 million in 2005, reflecting lower research contract revenues. Revenues for 2005 were primarily the result of the recognition of \$4.6 million in research contract revenues from government funding, as described above.

R&D expenses during 2006 increased to \$25.3 million from \$17.1 million in the prior year, and G&A expenses increased to \$7.8 million from \$5.2 million. The increase in R&D expenses was due primarily to an additional \$3.1 million in employee costs, including \$2.4 million related to SFAS 123R, \$430,000 related to the acceleration of the vesting of certain stock options, and to higher clinical costs of \$2.2 million from the expansion of clinical programs in hepatitis C virus (HCV) and in coronary artery bypass grafting (CABG). Approximately \$1.7 million of this increase was due to contracting costs for the production of GMP subunits. The increase in R&D expense also reflects \$675,000 in AVI common stock issued to Ercole Biotech, Inc. as described above and \$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. The increase in G&A expenses was due primarily to an additional \$2.4 million in employee costs, including \$1.6 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 \$33.2 million as of December 31, 2006, a decrease of \$13.9 million from December 31, 2005. This decrease was due primarily to \$20.6 million used in operations and approximately \$1.5 million used for purchases of equipment and patent-related costs, offset by the receipt of \$5.0 million in net proceeds from a stock purchase agreement with Cook Group Inc., and \$3.2 million from the exercise of warrants and options and sales under the company's employee stock purchase plan.

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(R) 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 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 is not reflected in AVI's 2006 financial results.

"Active clinical programs are currently underway with our NEUGENE compounds in coronary vascular disease and HCV, and with our novel Exon Skipping Pre-RNA Interference Technology, or ESPRIT, in Duchenne muscular dystrophy," said Denis R. Burger, Ph.D., chief executive officer of AVI BioPharma.

"We believe important milestones with our coronary vascular disease program will be met in the coming months," he added. "Cook Group, licensee of AVI-4126 for the treatment of vascular disease, has discussed plans to present core laboratory data from the fully enrolled APPRAISAL Phase II study with Resten-MP at the EuroPCR meeting to be held in late May. We also hope to announce interim safety data as part of the Phase Ib/II portion of our CABG trial around mid-year and we are on track with our stated milestone of reporting data from the first 110 patients enrolled in this trial late this year or early next year. CABG is a commonly performed surgery for blocked coronary arteries and our work in this arena is truly exciting. Our NEUGENE drug has already been shown to be efficacious in a Phase II clinical trial for cardiovascular restenosis, which is believed to be caused by the same mechanism of action as vein graft failure in CABG procedures. At this time, we know of no other drugs approved or in development for this indication, limiting potential competition in the near horizon."

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 primarily 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 well-suited to antisense drug development, such as genetic disorders and inflammatory diseases.

In September 2005 the company announced a new application of its proprietary NEUGENE technology, called ESPRIT (Exon Skipping Pre-RNA Interference Technology). The company believes that 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 functional sequences that are over-expressed or harmful in certain diseases. The company is applying the 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 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 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 a new-generation of AVI-4126 that incorporates the company's proprietary transporter tail CytoPorter(R) to enhance delivery to the saphenous vein ex vivo before use in bypass surgery. This is a pivotal 600-patient randomized, double blind, placebo-controlled trial incorporating Phase Ib through Phase III components. The Phase Ib stage of the trial is underway and a decision on continuation into the pivotal stages (Phase II/III) of the study will be made after evaluation of the first 110 enrolled patients. An additional pivotal study in the United States may also be initiated for U.S. market approval.

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 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 continue 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 (PK) and viral response to 14 days of treatment with AVI-4065 in healthy volunteers and then in patients with chronic active HCV. The company reported favorable safety, tolerability and PK results among healthy volunteers in January 2006. Preliminary data on HCV patients were presented in May 2006. The PK in HCV patients was significantly different from that of healthy volunteers, which was not anticipated. The blood concentration of the drug in HCV patients was only one-third of that predicted to be required for a clinically significant reduction in viral load. Consistent with this observation, no clinically significant reduction in viral load was observed.

Based on these data, two additional studies were proposed using AVI-4065: an extended treatment duration protocol, and a high dose treatment protocol. Preliminary data from the protocol extending treatment duration to 28 days have not shown a significant benefit on improving PK or reducing viral load, although the study is ongoing. AVI has plans to conduct a high dose escalating treatment protocol designed to exceed the predicted blood concentration with the goal of achieving a clinically significant reduction in viral load. AVI plans to complete this study and anticipates reporting safety, PK, and viral response data from the study before the end of this year. The company recently completed GMP manufacturing of AVI-4065 for the planned high dose treatment protocol.

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 have confirmed that a single NEUGENE drug was effective in preclinical studies against most of these 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. Net of government administrative costs, it is anticipated that AVI will receive up to \$9.8 million under this allocation. 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 is not reflected in AVI's 2006 financial results.

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 Department of Defense, to fund AVI's development of therapeutic agents to treat the effects of Ebola, Marburg and Junin hemorrhagic viruses. AVI expects to receive revenue from this contract beginning in 2007.

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 clinical program is starting with a proof-of-concept, dose-escalating trial conducted in collaboration with MDEX Consortium in the U.K.

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 March 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 1518112.

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)

(unaudiccu)

	Three Months Ended December 31,				Year Ended December 31,			
					2006			
Revenues, from license fees, grants and research								
<pre>contracts Operating expenses: Research and</pre>	\$ 17,519	\$	1,417,446	\$	115,291	\$	4,783,760	
development General and	6,721,547		4,913,490		25,345,588		17,117,750	
administrative	2,068,201		1,409,066		7,752,752		5,182,369	
	 8,789,748	_	6,322,556	_	33,098,340	_	22,300,119	
Other income (loss): Interest								
income, net	 443,042	_	353,538 	_	1,910,037	_	840,495	

Net loss	\$(8	,329,187)	\$(4,	551,572)	\$(31	,073,012)	\$(16	,675,864)
Net loss per	===:	======	====	======	====	======	=====	:======
share basic and diluted	\$	(0.16)	\$	(0.10)	\$	(0.59)	\$	(0.37)
Shares used in	===:	======	====	======	====	======	=====	:======
per share calculations	53	,000,236	47,	838,357	52	,660,711	44,	,655,008
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BALANCE SHEET HIGHLIGHTS (unaudited)

December 31, 2006 2005

Cash, cash equivalents and short-term securities \$ 33,152,132 \$ 47,051,082

Total current assets 33,939,913 48,653,394

Total assets 40,862,746 56,407,982

Total current liabilities 3,150,845 2,747,973

Total shareholders' equity \$ 37,711,901 \$ 53,660,009

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SOURCE: AVI BioPharma, Inc.