AVI BioPharma Announces Third Quarter 2010 Financial Results

November 9, 2010 4:02 PM ET

Financial Results and Corporate Update Conference Call Today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time)

BOTHELL, WA, Nov 09, 2010 (MARKETWIRE via COMTEX) --

AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based therapeutics, today reported financial results for the three and nine months ended September 30, 2010.

For the third quarter of 2010, AVI reported an operating loss of $3.8 million, compared with an operating loss of $2.9 million in the third quarter of 2009. The increase in the operating loss is the result of a $1.6 million increase in research and development expenses and a $1.6 million increase in general and administrative costs, offset in part by a $2.3 million increase in government research contract revenues.

Research and development expenses were $9.1 million in the third quarter of 2010, compared to $7.5 million in the third quarter of 2009, an increase of $1.6 million. The increase was due primarily to increases in the research costs for the H1N1 program and higher compensation and employee costs for additional research and development staff. General and administrative expenses in the third quarter were $3.4 million, compared to $1.8 million in the third quarter of 2009, an increase of $1.6 million. The increase was attributed to higher compensation costs, legal expenses, a reduction in the fair value of property held for sale and facilities costs related to AVI's new Bothell, Washington facility.

Revenue for the third quarter of 2010 increased to $8.7 million from $6.4 million in the third quarter of 2009 as a result of a net increase in revenue from the new H1N1, Ebola and Marburg government research contracts.

In the first nine months of 2010, the operating loss was $19.2 million, compared with an operating loss of $11.5 million in the first nine months of 2009. The $7.7 million increase in the operating loss was primarily the result of a $4.8 million increase in general and administrative costs and a $4.3 million increase in research and development costs, offset in part by a $1.4 million increase in government research contract revenues.

Research and development expenses were $22.1 million in the first nine months of 2010, compared to $17.8 million in the first nine months of 2009, an increase of $4.3 million. The increase was due primarily to $2.0 million in research costs for the H1N1 and Junin projects, $1.4 million in costs for active investigational therapeutic components, and $0.9 million in increased compensation and employee costs from the addition of new staff. General and administrative expenses in the first nine months of 2010 were $11.0 million, compared to $6.2 million in the first nine months of 2009, an increase of $4.8 million. The increase was primarily the result of a $2.6 million one-time charge related to the April 2010 departure of AVI's former chief executive officer. The increase was also attributable to higher compensation costs, legal expenses, a reduction of the fair value of property held for sale and facilities costs related to AVI's new Bothell, Washington facility.

Revenue for the first nine months of 2010 increased to $13.9 million from $12.4 million in the first nine months of 2009 as a result of a net increase in revenue from government research contracts.

The net loss for the third quarter of 2010 was $7.3 million, or $0.07 per share, compared to a net loss for the third quarter of 2009 of $8.1 million, or $0.08 per share. The $0.8 million decrease was primarily due to the increase in the operating loss offset by a change in the valuation of certain warrants described below. The net loss for the first nine months of 2010 was $24.5 million, or $0.22 per share, compared to a net loss for the first nine months of 2009 of $28.7 million, or $0.33 per share. The $4.2 million decrease was primarily due to the increase in the operating loss offset by the valuation of certain warrants described below.

In connection with AVI's 2009 and prior equity financings, the Company issued warrants that are classified as non-cash liabilities. The amount of the warrant liability is primarily affected by changes in AVI's stock price between each financial reporting period and causes the warrant liability to fluctuate as the market price of AVI's stock fluctuates. In the third quarter of 2010, the warrant valuation increased by $3.6 million relative to the second quarter 2010. In the first nine months of 2010, the warrant valuation increased by $5.5 million relative to the valuation at December 31, 2009.

AVI had cash and cash equivalents of $36.0 million as of September 30, 2010, a decrease of $12.3 million from December 31, 2009. This decrease was due primarily to the cash used in operations during the first nine months of 2010 and cash used for property and equipment and patent-related costs of approximately $1.5 million, offset by cash inflows from the exercise of stock options and warrants of $2.5 million.

"Over the past few months, I believe the execution of our business strategy and progress in our development programs has led to a growing appreciation within our industry and the scientific community of our RNA-based therapeutics programs employing our intrinsically charge-neutral PMO-based chemistries," said J. David Boyle II, AVI's interim President and Chief Executive Officer, and Chief Financial Officer. "This appreciation and interest is leading to greater visibility in the industry and active dialogues with potential pharma partners and drug development collaborators. As we move through the fourth quarter of 2010 and into 2011, we expect our ongoing business development efforts, program development efforts and strategic focus will yield both expanded partnership and program opportunities."

2010 Third Quarter and Recent Corporate Developments

Duchenne Muscular Dystrophy (DMD) Program

-- Reported data from the completed Phase 1b/2 Study 28 of AVI-4658 in patients with Duchenne muscular dystrophy that demonstrated a broadly favorable safety and tolerability profile, including adverse events that were mostly mild to moderate, not dose related, and not probably related to study drug. Additional data highlights include substantial new dystrophin expression and dystrophin positive-fibers up to 55%, correct localization of dystrophin, reduction in key inflammatory markers, the absence of anti-dystrophin antibodies, and general stability in exploratory markers of clinical performance. The results support the rapid progression of the candidate into a Phase 2 study later this year.

-- Presented data from the completed Phase 1b/2 Study 28, as well as additional data from the AVI-4658 preclinical program, that demonstrated the unique potential for AVI's exon skipping technology at the 15th International Congress of the World Muscle Society. Two presentations were delivered by Stephen B. Shrewsbury, M.D., Senior Vice President and Chief Medical Officer at AVI. One presentation was delivered by Dr. Francesco Muntoni, Professor of Pediatric Neurology and Head of the Dubowitz Neuromuscular Centre at the UCL Institute of Child Health, London, England.

-- Presented data from Study 28 patients supporting the potential for AVI-4658 in treatment of patients with Duchenne muscular dystrophy at the 6th Annual Meeting of the Oligonucleotide Therapeutics Society. The presentation was delivered by Ryszard Kole, Ph.D., Senior Vice President at AVI and an AVI Distinguished Scientist.

-- Presented highlights of the biopsy data from Study 28, the recently completed Phase 1b/2 clinical trial of AVI-4658, at the XII International Congress on Neuromuscular Diseases. The presentations were delivered by Stephen B. Shrewsbury, M.D., and Dr. Francesco Muntoni.

-- Submitted to the U.S. Food and Drug Administration (FDA) a series of three 12-week Good Laboratory Practice studies of AVI-4658, one conducted in primates and two in mice at maximum feasible doses, that led to the Investigational New Drug application (IND) for clinical studies in the U.S. to be opened.

-- Published data in International Journal of Toxicology that demonstrated AVI-4658 was well tolerated in primates when injected at up to Maximum Feasible Dose (320mg/kg) and resulted in no adverse pulmonary, cardiovascular or neurological effects. In addition, a standard battery of genotoxicity studies were published demonstrating that AVI-4658 had no mutagenic potential.

Influenza Program

-- Announced results from two preclinical studies of the therapeutic potential of AVI-7100 against a fully virulent pandemic H1N1 virus that were highlighted by statistically significant reductions in average viral titer versus a saline control and a control with Tamiflu(R) of up to 3.9 log in a relevant ferret model. The studies were supported by the Transformational Medical Technologies (TMT) program of the U.S. Department of Defense, which is funding an accelerated IND enabling program and Phase 1 trial of AVI-7100.

-- Presented data from preclinical investigations that identify AVI-7100 as a lead candidate with a broad safety margin and demonstrated efficacy in influenza models challenged by H3N2 and H1N1 at the 48th Annual Meeting of Infectious Diseases

Society of America. Patrick Iversen, Ph.D., Senior Vice President of Research and Innovation at AVI, presented the data in a poster session.

-- Presented data from preclinical investigations of AVI-7100 for treatment of Influenza A at the 6th Annual Meeting of the Oligonucleotide Therapeutics Society. Peter Sazani, Ph.D., Executive Director, Preclinical Development at AVI, presented the data in a poster session.

-- Presented data from a preclinical evaluation of AVI-7100 in a pandemic flu ferret model at the 50th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) Annual Meeting. Patrick Iversen, Ph.D., presented the data in a poster session.

Hemorrhagic Fever Programs

-- Published data in Nature Medicine that demonstrated AVI-6002 and AVI-6003, the respective lead therapeutic candidates against Ebola and Marburg viruses, provide post-exposure efficacy in non-human primates. Treatment of Ebola virus-infected primates with AVI-6002 led to 60% survival, and treatment of Marburg-infected primates with AVI-6003 conferred 100% survival.

-- Entered into a new contract for up to approximately $291 million through the TMT program for the advanced development of AVI's hemorrhagic fever virus therapeutic candidates, AVI-6002 and AVI-6003, for Ebola and Marburg viruses, respectively. If TMT exercises all four segments comprising the contract, activities undertaken by AVI would include all clinical and licensure activities necessary to obtain FDA regulatory approval of each therapeutic candidate and would provide for a total funding award to AVI of up to approximately $291 million over a period of approximately six years.

-- In December 2006 we entered into a two year research contract with the Defense Threat Reduction Agency (DTRA) of the Department of Defense to fund development of our RNA-based therapeutic candidates for Ebola, Marburg and Junin hemorrhagic viruses. In November 2010, the Company and DTRA agreed that the key activities under this contract had been completed and that further activities under this contract would cease and this contract would be deemed concluded. As of September 30, 2010, AVI has recognized revenue of $38.2 million with respect to this contract and expects to complete all activities under this contract in 2010.

Dengue Program

-- Presented data from preclinical investigations of AVI-6006 in Dengue virus infected mouse and ferret models at the 48th Annual Meeting of Infectious Diseases Society of America. Patrick Iversen, Ph.D., presented the data in a poster session.

-- Presented data from a preclinical evaluation of AVI-6006 in a Dengue virus infected mouse model at the 50th ICAAC Annual Meeting. Patrick Iversen, Ph.D., presented the data in a poster session.

Antibacterial Program

-- Granted key claims by the U.S. Patent and Trademark Office for phosphorodiamidate morpholino oligomers (PMOs) as antibacterial agents that cover the use of peptide-conjugated phosphorodiamidate morpholino oligomers (PPMOs) to target the acyl carrier protein (AcpP), a gene considered essential for bacterial growth in both gram positive and gram negative bacteria.

Corporate Developments

-- Appointed Graham Johnson, a 30-year biotech veteran with experience in the design, discovery and development of novel therapeutics, including an extensive background in infectious diseases and neuroscience, as Senior Vice President, Preclinical Development and Research. Appointed Patrick Iversen, Ph.D., Senior Vice President of Research and Innovation, and Ryszard Kole, Ph.D., Senior Vice President and an AVI Distinguished Scientist.

-- Announced the award of five cash grants to AVI totaling approximately $1.2 million under the U.S. Government's Qualifying Therapeutic Discovery Project program. AVI was awarded grants for each of the five project applications submitted for the company's Duchenne muscular dystrophy program and four infectious disease programs.

2010 Guidance

For 2010, AVI confirms guidance for expenditures for operations, net of government funding and other collaborative efforts, to be approximately $21 million to $25 million. AVI believes it will continue to receive funding from government and other sources to pursue the development of product candidates and has assumed certain revenues from these awards in providing this guidance. If AVI does not continue to receive the funding from its current contracts, its guidance may change.

Upcoming Corporate Presentations

AVI is planning to present at upcoming investment and industry conferences, including: -- Maxim Group Growth Conference, November 18, 2010, New York, New York

Conference Call

A conference call to review the financial results and provide a corporate update will be held today, November 9, 2010, at 5:00 p.m. Eastern time (2:00 p.m. Pacific time). J. David Boyle II, AVI's Interim President and Chief Executive Officer, and Chief Financial Officer, and Stephen B. Shrewsbury, AVI's Senior Vice President and Chief Medical Officer, will host the call. The conference call may be accessed by dialing 800.573.4842 for domestic callers and 617.224.4327 for international callers. The passcode for the call is 29591329 and please specify to the operator that you would like to join the "AVI BioPharma third quarter 2010 earnings call." The conference call will be webcast live under the events section of AVI's website at www.avibio.com, and will be archived there following the call. Please connect to AVI's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

About AVI BioPharma

AVI BioPharma is focused on the discovery and development of novel RNA-based therapeutics for rare and infectious diseases, as well as other select disease targets. Applying pioneering technologies developed and optimized by AVI, the Company is able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. Unlike other RNA-based approaches, our technologies can be used to directly target both messenger RNA (mRNA) and precursor messenger RNA (pre-mRNA) to either down-regulate (inhibit) or up-regulate (promote) the expression of targeted genes or proteins. By leveraging its highly differentiated RNA antisense-based technology platform, AVI has built a pipeline of potentially transformative therapeutic agents, including a clinical stage Duchenne muscular dystrophy candidate and anti-infective candidates for influenza and hemorrhagic fever viruses. For more information, visit www.avibio.com.

Forward-Looking Statements and Information

In order to provide AVIs investors with an understanding of its current results and future prospects, this press release contains statements that are forward-looking. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements about the development of AVI's product candidates, including preclinical development, filing of an IND application, completion of a Phase 1 human safety clinical trial, clinical development and FDA approval, expectations regarding funding from government and other sources and expectations regarding partnering opportunities and other strategic transactions.

These forward-looking statements involve risks and uncertainties, many of which are beyond AVI's control. Known risk factors include, among others: development of any of AVI 7100, AVI 6002 or AVI 6003 may not result in funding from the TMT in the anticipated amounts or on a timely basis, if at all; clinical trials may not demonstrate safety and efficacy of any of AVI's drug candidates and/or its antisense-based technology platform; any of AVI's drug candidates may fail in development, may not receive required regulatory approvals, or be delayed to a point where they do not become commercially viable; and AVI may not be able to secure partnering or other strategic transactions with respect to the development of its product candidates on favorable terms or at all.

Any of the foregoing risks could materially and adversely affect AVI's business, results of operations and the trading price of its common stock. For a detailed description of risks and uncertainties AVI faces, you are encouraged to review the official corporate documents filed with the Securities and Exchange Commission. AVI does not undertake any obligation to publicly

update its forward-looking statements based on events or circumstances after the date hereof.

AVI BIOPHARMA, INC.
(A Development-Stage Company)
SUMMARY STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues from license fees, grants and research contracts	$ 8,702	$ 6,353	$ 13,903	$ 12,448
Operating expenses:				
Research and development	9,059	7,473	22,080	17,770
General and administrative	3,440	1,800	11,017	6,226
Operating loss	(3,797)	(2,920)	(19,194)	(11,548)
Other non-operating (loss) income:				
Interest (expense) income and other, net	82	(132)	170	(147)
(Increase) decrease on warrant valuation	(3,578)	(5,038)	(5,509)	(16,989)
Net loss	$ (7,293)	$ (8,090)	$ (24,533)	$ (28,684)
Net loss per share-- basic and diluted	$ (0.07)	$ (0.08)	$ (0.22)	$ (0.33)
Shares used in per share calculations	111,767	95,261	110,863	87,493

BALANCE SHEET HIGHLIGHTS
(unaudited)
(in thousands)

	September 30, 2010	December 31, 2009
Cash and cash equivalents	$ 35,967	$ 48,275
Total current assets	42,314	51,310
Total assets	50,860	60,027
Total current liabilities	43,765	33,507
Total shareholders' equity	$ 4,163	$ 23,630

SOURCE: AVI BioPharma, Inc.