

AVI BioPharma Announces Second Quarter 2011 Financial Results and Recent Corporate Developments

August 4, 2011 4:01 PM ET

BOTHELL, WA, Aug 04, 2011 (MARKETWIRE via COMTEX) --

AVI BioPharma, Inc. (NASDAQ: AVII)

-- Duchenne Muscular Dystrophy (DMD) Phase II Study of Eteplirsen Enrolling and to Begin Dosing This Month

-- Three Infectious Disease Candidates Progressing in Phase I Safety Studies and Have Completed Initial Dosing Cohorts

-- Strong Cash Position With \$54.2 Million as of June 30, 2011; Guidance for Cash Expenditures Revised to \$28 to \$33 Million for 2011

AVI BioPharma, Inc. (NASDAQ: AVII), a developer of RNA-based drugs, today reported financial results for the three and six months ended June 30, 2011, and provided an update of recent corporate developments.

"We now have four products advancing in clinical development, including safety studies for our three infectious disease candidates and a placebo-controlled Phase II study with eteplirsen, which is about to initiate dosing in DMD patients," said Chris Garabedian, President and CEO of AVI. "These clinical-stage products represent several variations of our morpholino drug chemistries and illustrate the progress and promise of our unique RNA-based technology."

Financial Results

For the second quarter of 2011 AVI reported an operating loss of \$10.1 million compared with an operating loss of \$7.7 million in the second quarter of 2010. The increase in the operating loss was primarily the result of increased second quarter research and development expenses of \$10.9 million offset by increased revenues of \$7.6 million and a \$0.7 million decrease in general and administrative expenses. Research and development expenses increased primarily as the result of higher costs associated with the July 2010 Ebola and Marburg government contract and increased research and development costs for AVI's Duchenne muscular dystrophy (DMD) development program.

Research and development expenses were \$17.8 million in the second quarter of 2011, compared to \$6.9 million in the second quarter of 2010, an increase of \$10.9 million, due primarily to a \$6.0 million increase in spending related to the July 2010 Ebola and Marburg government contract, a \$5.1 million increase in DMD-related program costs, and \$0.9 million in spending for the H1N1 contracts and other research and development costs, which were partially offset by a \$1.1 million decrease in spending on AVI's 2006 government contracts.

General and administrative expenses in the second quarter of 2011 were \$4.0 million, compared to \$4.7 million in the second quarter of 2010, a decrease of \$0.7 million. The decrease in general and administrative expenses was the result of a \$2.6 million decrease in severance related costs for the former chief executive officer that we incurred in the second quarter of 2010, but that we did not continue to incur in the second quarter of 2011. This decrease was partially offset by an increase of \$1.4 million in salaries, severance and employee related costs from increased staff, \$0.4 million in higher costs for professional and legal services, and \$0.1 million in increased costs for facilities.

Revenue for the second quarter of 2011 increased to \$11.6 million from \$4.0 million in the second quarter of 2010 as a result of the increased revenue associated with the July 2010 Ebola and Marburg government contract.

In the first half of 2011, the operating loss was \$15.7 million, compared with an operating loss of \$15.4 million in the first half of 2010. The increase in the operating loss was the result of higher costs for research and development of \$19.6 million and increased general and administrative costs of \$1.4 million, offset by increased revenues of \$20.7 million.

Research and development expenses were \$32.6 million in the first half of 2011, compared to \$13.0 million in the first half of 2010, an increase of \$19.6 million, due primarily to a \$14.9 million increase in spending related to the July 2010 Ebola and Marburg government contract, a \$4.5 million increase in DMD-related program costs, \$1.8 million in spending for the H1N1

contracts and other research and development costs, which were partially offset by a \$1.6 million decrease in spending on AVI's 2006 government contracts.

General and administrative expenses in the first half of 2011 were \$9.0 million, compared to \$7.6 million in the first half of 2010, an increase of \$1.4 million. The increase is primarily due to \$3.2 million in salaries, severance and employee related costs from increased staff, \$0.7 million in higher costs for professional and legal services, and \$0.1 million in increased costs for facilities. The increase in general and administrative expenses was partially offset by a \$2.6 million decrease in severance related costs for the former chief executive officer that we incurred in the first half of 2010, but that we did not continue to incur in the first half of 2011.

Revenue for the first half of 2011 increased to \$25.9 million from \$5.2 million in the first half of 2010 primarily as a result of the increased revenue associated with the July 2010 Ebola and Marburg government contract.

The net income for the second quarter of 2011 was \$1.3 million, or \$0.01 per share, compared to a net loss for the second quarter of 2010 of \$16.7 million, or \$0.15 per share. The \$18.0 million increase was primarily due to change in the valuation of certain warrants described below offset by the increase in the operating loss. The net income for the first half of 2011 was \$3.1 million, or \$0.03 per share, compared to a net loss for the first half of 2010 of \$17.2 million, or \$0.16 per share. The \$20.3 million increase was primarily due to the change in the valuation of certain warrants described below.

In connection with prior equity financings, AVI issued warrants that are classified as liabilities and are adjusted to fair value on a quarterly basis impacting net income (loss). The amount of the warrant liability is primarily affected by changes in AVI's stock price during each financial reporting period which causes the warrant liability to fluctuate as the market price of AVI's stock fluctuates. In the second quarter of 2011, the warrant valuation decreased by \$11.3 million compared to an increase in the warrant valuation of \$9.0 million in the second quarter of 2010. In the first half of 2011, the warrant valuation decreased by \$18.5 million compared to an increase in the warrant valuation of \$1.9 million in the first half of 2010.

AVI had cash and cash equivalents of \$54.2 million as of June 30, 2011, an increase of \$20.6 million from December 31, 2010. This increase was due primarily to the cash raised in the April 2011 equity financing, which raised net proceeds of approximately \$32.1 million, and the proceeds from the exercise of warrant and stock options of \$0.2 million, partially offset by cash used in operations during the first half of 2011 of \$10.5 million and cash used for property and equipment and patent-related costs of approximately \$1.2 million.

Recent Corporate Developments

Duchenne Muscular Dystrophy (DMD) Program

-- Data published in The Lancet from a Phase Ib/II clinical trial of eteplirsen showed that the therapeutic was well tolerated, with no clear drug-related serious adverse events; eteplirsen induced exon 51 skipping in all cohorts, and novel dystrophin protein expression was observed in a dose-dependent manner.

-- Received approval from the institutional review board to initiate the Phase II trial of eteplirsen in DMD patients, positioning AVI to initiate the study in August 2011.

Infectious Disease Programs

-- Initiated AVI's third clinical trial this year with a Phase I initiation for AVI-7100, AVI's lead influenza drug candidate, in healthy volunteers.

-- Responded to the U.S. Department of Defense's RFP seeking the full clinical development of AVI's influenza drug candidate; an update on the status of the RFP process will be provided on this afternoon's conference call (details below).

-- Successfully completed in 18 days the first simultaneous rapid-response exercise against both bacterial and viral targets, which included designing and manufacturing novel RNA-based drug candidates with the Naval Medical Research Center.

-- Presented data from AVI's RNA-based hemorrhagic fever and infectious disease programs at the 21st European Congress of Clinical Microbiology and Infectious Diseases.

Other Developments

-- Issued a broad composition of matter patent for PMOplus(TM) chemistry platform by the U.S. Patent and Trademark Office titled "Oligonucleotide Analogs Having Cationic Intersubunit Linkages."

-- Appointed Ed Kaye, M.D., a recognized industry leader in the development of therapeutics for the treatment of rare genetic diseases and pediatric neurological diseases, as Chief Medical Officer.

2011 Guidance

For 2011, AVI confirms guidance for revenue of approximately \$50 million to \$60 million. The guidance for projected cash expenditures for operations, net of government funding and other collaborative efforts, has been adjusted to a range of approximately \$28 to \$33 million, an increase from previously provided guidance of \$23 to \$28 million.

The increase in projected cash burn compared to previously provided guidance is primarily the result of manufacturing scale-up costs that will be incurred in the later part of 2011 (earlier than originally anticipated) to support the accelerated development plan for eteplirsen and our broader DMD program; development costs associated with the Phase I safety study of AVI-7100; costs associated with transitioning executive management departures and hiring; and increased research costs for expanding the application of our PMO chemistries. AVI believes it will continue to receive funding from government contracts 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.

Conference Call

AVI BioPharma will hold a financial results and corporate update conference call today at 5:00 p.m., Eastern Time (2:00 p.m., Pacific Time). The conference call may be accessed by dialing 866.713.8565 for domestic callers and 617.597.5324 for international callers. The passcode for the call is 86734094. Please specify to the operator that you would like to join the "AVI BioPharma second quarter 2011 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 for 90 days. 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, AVI's 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-based technology platform, AVI has built a pipeline of potentially transformative therapeutic agents, including eteplirsen, which is in clinical development for the treatment of Duchenne muscular dystrophy, and multiple drug candidates that are in clinical development for the treatment of infectious diseases. For more information, visit www.avibio.com.

Forward-Looking Statements and Information

In order to provide AVI's 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 the initiation of a Phase II study in August 2011 for eteplirsen, AVI's estimates regarding its future revenues and expenses and expectations regarding future success, revenues and funding from government and other sources.

These forward-looking statements involve risks and uncertainties, many of which are beyond AVI's control. Known risk factors include, among others: clinical trials may not demonstrate safety and efficacy of any of AVI's drug candidates and/or AVI's

antisense-based technology platform; development of any of AVI's drug candidates, including AVI-6002, AVI-6003 or AVI-7100, may not result in funding from the U.S. Government in the anticipated amounts or on a timely basis, if at all; and 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.

Any of the foregoing risks could materially and adversely affect AVI's business, results of operations and the trading price of AVI's 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)
(unaudited)
(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenues from license fees, grants and research contracts	\$ 11,585	\$ 3,997	\$ 25,881	\$ 5,201
Operating expenses:				
Research and development	17,750	6,931	32,551	13,020
General and administrative	3,960	4,733	8,986	7,577
Operating loss	(10,125)	(7,667)	(15,656)	(15,396)
Other income (loss):				
Interest (expense) income and other, net	151	51	241	87
(Increase) decrease on warrant valuation	11,253	(9,040)	18,527	(1,931)
Net income (loss)	\$ 1,279	\$ (16,656)	\$ 3,112	\$ (17,240)
	=====	=====	=====	=====
	=====	=====	=====	=====
Net income (loss) per share -- basic	\$ 0.01	\$ (0.15)	\$ 0.03	\$ (0.16)
	=====	=====	=====	=====
Net income (loss) per share -- diluted	\$ 0.01	\$ (0.15)	\$ 0.02	\$ (0.16)
	=====	=====	=====	=====
Shares used in per share calculations -- basic	134,090	110,383	123,346	110,404
	=====	=====	=====	=====
Shares used in per share calculations -- diluted	138,916	110,383	130,018	110,404
	=====	=====	=====	=====

BALANCE SHEET HIGHLIGHTS
(unaudited)
(in thousands)

	June 30, 2011	December 31, 2010
	-----	-----
Cash and cash equivalents	\$ 54,188	\$ 33,589
Total current assets	66,023	37,838
Total assets	74,933	45,976
Total current liabilities	36,938	45,857
Total shareholders' equity (deficit)	\$ 35,149	\$ (2,817)

AVI Investor and Media Contact:

David Schull

Russo Partners

858.717.2310

or 212.845.4271

Email Contact

SOURCE: AVI BioPharma, Inc.

<http://www2.marketwire.com/mw/emailprcntct?id=709C90CEB621FFF4>