



AVI BioPharma Announces Approval to Conduct Systemic Trial for Duchenne Muscular Dystrophy and Second Quarter 2008 Financial Results

8/11/08

Corporate Highlights on RNA-based Therapeutics; new additions to the leadership team

For Immediate Release

[\[Financial Tables\]](#)

CORVALLIS, OR — August 11, 2008 — AVI BioPharma, Inc. (NASDAQ: AVII) today reported financial results for the three and six months ending June 30, 2008. The Company also reported that it has received approval from the Medicine and Healthcare Product Regulatory Agency (MHRA) to conduct its systemic trial of AVI-4658 in the treatment of Duchenne Muscular Dystrophy in the United Kingdom and also updated the new additions to its senior management team.

"As we continue AVI's transformation from an antisense pioneer into an RNA-based drug discovery and development company, we are excited to report on our recent progress and ongoing activities toward achieving both our short term and long term goals," said Dr. Leslie Hudson, Chief Executive Officer of AVI BioPharma. He continued, "Over the past twelve months, we have significantly enriched the pharmaceutical utility of our core phosphorodiamidate morpholino (PMO) technology through the addition of several new derivative chemistries that could improve the bioavailability, potency and therapeutic index of the original chemical series. Overall our antisense-based chemistries significantly expand the field of RNA-based therapeutics by not only competitively inhibiting mRNA translation, but by also directing the processing of pre-mRNA to provide potential therapeutic benefit in an important range of diseases. We believe these unique capabilities, which are not encompassed by the technology portfolio and intellectual property estate of our competitors, position AVI to secure a leading role in the future successes of RNA-based drug development."

Dr. Hudson concluded, "We have just begun to feel the impact of our newly acquired intellectual property, the recent advances in our core chemistry, the new product focus brought to our pipeline, the additions to our leadership team and the fiscal measures employed to extend our current financial runway. We believe that there are partnership opportunities for a company that can go beyond simple inhibition of mRNA – we believe we are such a company, but we now have to demonstrate this to capture the full value from our technology and intellectual property. With the ongoing and increasing interest in RNA-based therapeutics by both the pharmaceutical and biotech sectors, we believe our renewed activity and focus on business development, coupled with our preclinical and clinical advances, are happening at an opportune time."

Financial Results

Revenues

Revenues for the second quarter of 2008 were \$5 million, up from \$2.4 million in the prior-year period, reflecting increases in research contracts revenues of \$2.6 million. Revenues for the first half of 2008 were \$10.6 million, up from \$2.9 million in the first half of 2007, reflecting increases in research contracts revenues of \$7.7 million.

Net Loss

The net loss for the second quarter of 2008 was \$1.8 million, or \$0.02 per share, compared with a net loss for the second quarter of 2007 of \$7.8 million, or \$0.15 per share. For the six months ended June 30, 2008, the Company reported a net loss of \$16.8 million, or \$0.25 per share, compared with a net loss for the comparable period in 2007 of \$16.0 million, or \$0.30 per share.

Cash, Cash Equivalents and Marketable Securities

The Company had cash, cash equivalents and short-term securities of \$18.8 million as of June 30, 2008, a decrease of \$6.3 million from December 31, 2007. This decrease was due primarily to \$5.6 million used in operations and \$603,000 used for purchases of property and equipment and patent-related costs. This decrease includes approximately \$900,000 paid to Ercole for its use in retiring certain of its debts prior to closing of the Ercole acquisition.

Research and Development (R&D) Expenses

Research and Development (R&D) expenses for the second quarter of 2008 decreased to \$8.2 million from \$9.2 million during the second quarter of 2007. The decrease in R&D expenses was due to decreases in government research contract expenses of \$1.75 million, decreases in contract manufacturing costs of \$330,000 and decreases in amortization of leaseholds of \$135,000. These amounts were partially offset by increases in professional consultant costs of \$300,000, increases in purchases of government contract-related equipment of \$290,000, increases in net clinical expenses of \$230,000, severance payments to certain former Ercole employees of \$216,000 and increases in employee costs of \$140,000.

R&D expenses for the first six months of 2008 increased to \$15.6 million from \$15.5 million in the prior-year period. During this period the Company completed an asset acquisition of Ercole Biotechnology, Inc ("Ercole"), resulting in additional expenses of \$9.9 million relating to acquired in-process research and development. The R&D expenses also reflect increases of \$770,000 in compensation costs, \$617,000 in severance payments to certain Ercole employees, \$570,000 in net clinical expenses and \$65,000 in purchases of government-contract related equipment. These amounts were offset by decreases of \$950,000 in government research contract expense, \$300,000 in contract manufacturing costs, \$270,000 in amortization of leaseholds, \$250,000 in chemical costs and \$125,000 in professional consultant costs.

General and Administrative (G&A) Expenses

G&A expenses for the second quarter of 2008 decreased to \$1.7 million from \$2 million in the prior year's second quarter. The decrease in G&A expenses was due primarily to decreases in legal expenses of \$215,000, employee costs of \$52,000 and public and investor relations costs of \$51,000. G&A expenses in the first six months of 2008 decreased to \$3.7 million from \$6.3 million in the prior-year period. The G&A expense decrease was due primarily to a \$2.2 million decrease in employee costs, of which \$1.6 million was related to the Separation and Release Agreement with the Company's former Chief Executive Officer during the first quarter of 2007, as well as a \$600,000 decrease in SFAS 123R expenses. G&A expenses also included a \$360,000 decrease in legal expenses and a \$76,000 decrease in public and investor relations costs.

Second Quarter and Recent Corporate Highlights

In the second quarter 2008, the Company announced that J. David Boyle II will become Senior Vice President and Chief Financial Officer of AVI effective August 18, 2008. Mr. Boyle — previously Vice President of Finance and Chief Financial Officer of XOMA Ltd. — brings extensive operational and international financial and business experience to AVI.

In August, Shirley J. Leow joined AVI as Vice President of Clinical Operations and Project Management. Ms. Leow's responsibilities will include the coordination of AVI's preclinical and clinical collaborations on DMD. Her overall domain ownership of the DMD program as it advances through the clinic, will greatly improve the Company's capability to handle the current demands from its third party collaborators as well as to capitalize on future funding opportunities from both public and private sources. Ms. Leow brings more than 35 years experience in the biotech and pharmaceutical industries. Prior to joining AVI, she served in key clinical and program management leadership positions in Xanthus Pharmaceuticals, Wyeth, Navigant Biotechnologies and Pharmacia.

In June, the Company announced the addition of Ryszard Kole, Ph.D., to head up its discovery research programs as Senior Vice President of Discovery Research after a successful career as a tenured professor and researcher at the University of North Carolina and as the founder of Ercole Biotechnologies, Inc. In AVI, Dr. Kole's discovery research goals encompass further improvements to RNA-based chemistries as well as their application to the Company's major programs in Duchenne Muscular Dystrophy (DMD) and anti-viral therapies. These include further improvements in AVI's proprietary PPMO (peptide conjugated PMOs) and PMO+ (positively charged PMOs) chemistries, which build upon the strong fundamental properties of PMOs, AVI's first generation oligomers.

This change allowed Patrick Iversen, Ph.D. to move to a newly created role as Senior Vice President of Strategic Alliances and thus enhance the Company's ability to form broad strategic alliances and high-value partnerships. This is a key bridge between AVI's internal R&D teams and its external partner network and has significantly strengthened the Company's business development capabilities and opportunities. Dr. Iversen will continue to head up AVI's ongoing and successful collaboration with USAMRIID, as well as other external collaborative efforts that will provide the Company with potential commercial opportunities, including development partnerships, licensing or program spin-offs.

During the second quarter, the Company announced that it reduced staffing levels by approximately 15% to support a more focused approach to product development and discovery research. The Company believes that this reduction, combined with selective re-hiring, will save an estimated \$875,000 for the remainder of 2008 and an estimated \$1.6 million in 2009.

Product Pipeline and Discovery Research Updates

Duchenne Muscular Dystrophy (DMD)

The MHRA in the UK has given clearance for the Company to move forward with a Company-sponsored systemic clinical trial of AVI-4658 in the therapy of DMD in ambulatory patients. Additionally, there is an open ethics extension, which has allowed identification and screening of subjects for this trial prior to receiving Gene Therapy Advisory Committee (GTAC) approval. The Company anticipates receiving GTAC response to the proposed study such that the study could commence during the fourth quarter of this year. In addition, the MHRA has agreed that the on-going IM study of AVI-4658 in non-ambulatory patients may proceed directly to the top dose with an increased cohort size.

AVI has continued to demonstrate its scientific leadership in the application of exon skipping to DMD through the publication of preclinical results of a study demonstrating the ability of AVI's new class of drug candidates — termed PPMO-B — to induce sustained expression of dystrophin in the *mdx* mouse model of DMD. Treatment with this new class of AVI compound resulted in the sustained production of functional dystrophin in numerous tissues, including the heart, diaphragm and skeletal muscles. These are key organs for the treatment of the disease. The paper, published the peer-reviewed journal, *Molecular Therapy*, is titled "Sustained Dystrophin Expression Induced by Peptide-Conjugated Morpholino Oligomers in the Muscles of *mdx* Mice", by Natee Jearawiriyapaisarn, Hong Moulton, Brian Buckley, Jennifer Roberts, Peter Sazani, Suthat Fucharoen, Patrick Iversen and Ryszard Kole.

See: www.nature.com/mt/journal/vaop/ncurrent/abs/mt2008120a.html.

In addition, a number of Company and collaborator oral presentations, as well as posters, utilizing AVI technology were presented at the 11th Annual Meeting of the American Society of Gene Therapy in Boston. As a presentation to peers of the published data on DMD and TNF receptor referenced above, in July Dr. Kole was invited to present both sets of data at the Gordon Conference held at Colby College in Maine.

Cardiovascular Restenosis

The Company announced that its partner, Global Therapeutics — the cardiology unit of Cook Medical — had received CE Mark approval for a new cobalt chromium bare metal stent. The device, the Global Therapeutics GTX Coronary Stent System, is also the platform for a new drug-eluting stent (DES) utilizing AVI-5126, developed by AVI and licensed by Cook Medical. AVI-5126 is a more potent compound from the new PPMO drug class and has replaced the original PMO-based c-myc inhibitor AVI-4126. The new GTX DES system encompasses several technical advances in stent design as well as a potential breakthrough approach to reducing restenosis through the targeting of its cause (up regulation of *c-myc*) as opposed to its effect (inflammation). Cook Medical has indicated that the clinical trial to test the efficacy of AVI-5126 in inhibiting restenosis is expected to begin in Europe during the fourth quarter of 2008.

Biodefense Program: Ebola Zaire and Marburg Musoke Viruses

The Company's antiviral focus has been principally on efforts with the Department of Defense and in cooperation with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). Dr. Iversen made the opening presentation of the Pre-Conference Symposium to the 6th Annual Biodefense Vaccines & Therapeutics Meeting (June 9–11, 2008 in Washington, D.C.) at which he highlighted the Company's progress in the development of its therapeutic drugs against agents on the bioterrorism list, in particular Ebola Zaire and Marburg Musoke viruses.

The Company had announced earlier in the second quarter that treatment of non-human primates with either the antisense drug AVI-6002, or with AVI-6003, resulted in a reproducible and high rate of survival in the face of an otherwise lethal infection with Ebola or Marburg virus, respectively. Treatment of mice with AVI compounds designed for the treatment of Dengue virus infection have also resulted in reproducible and high rates of survival in the face of otherwise lethal infections. The Company's Dengue virus program is currently being supported through a separate government agreement and the program is in the designated class of diseases which are potentially eligible for the FDA's new Priority Review Voucher Program, which is scheduled to go into effect in September of 2008. The Company has filed pre-INDs with the FDA on its drugs to treat Ebola Zaire and Marburg Musoke and is completing its response to FDA feedback on the proposed toxicology program before proceeding to formal IND submissions.

Finally, Dr. Iversen presented at the TIDES Oligonucleotide and Peptide Technology and Product Development meeting in Las Vegas on May 20, 2008. The title of his presentation was "Manipulating the Immune Response with Cell Penetrating Peptide Conjugated Phosphorodiamidate Morpholino Oligomers" and featured the targeting of genes, such as interleukin-10 (IL-10), involved in the host immune response, with AVI's proprietary Phosphorodiamidate Morpholino Oligomers and arginine-rich peptides. IL-10 is considered a key regulator of immune response to infection from viruses, bacteria and other organisms.

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 on August 11, 2008 beginning at 9:30 a.m. Eastern time (6:30 a.m. Pacific time).

Individuals interested in listening to the live conference call may do so by dialing 877.704.5378 toll free within the United States and Canada, or 913.312.1268 for international callers.

Following the conference call, a recording of the call will be available for download (MP3) on the company's website: www.avibio.com.

About AVI BioPharma

AVI BioPharma is focused on the discovery and development of RNA-based drugs using the company's expanded portfolio of proprietary antisense compounds (PMOs). The company's technology applications leverage distinct mechanisms of action in a range of genetic diseases, genetic disorders and the genetic code of disease-causing organisms. The emerging field of directed alternative RNA splicing represents AVI's newest and most exciting application based on the company's core antisense technology. Functional attributes of this approach could include correcting genetic defects (RNA mutations; which AVI believes could produce promising treatments for Duchenne muscular dystrophy), coding for novel soluble receptors (an exciting and novel approach which could have application in the treatment of inflammatory diseases such as rheumatoid arthritis), and the reduction in activity of immune modulators in disease states (currently being applied to IL-10). AVI's RNA-based drug programs also include blocking mRNA translation. In AVI's biodefense program, this application has been successful against the single-stranded RNA viruses Ebola Zaire and Marburg Musoke in non-human primates and could have value against other viral targets such as HCV, Dengue, Junin, influenza and RSV viruses. This application also will be evaluated in the clinic for the treatment of cardiovascular restenosis by our partner, Cook Medical. More information about AVI is available at 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.

[Tables to Follow]

AVI BIOPHARMA, INC.
(A Development-Stage Company)

STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Revenues, from license fees, grants & research contracts	\$4,982,963	\$2,351,424	\$10,607,580	\$2,887,466
Operating expenses:				
Research and development	8,164,698	9,160,816	15,637,509	15,478,457
General and administrative	1,696,796	2,030,796	3,679,475	6,334,681
Acquired in-process				
Research and development	-	-	9,916,271	-
	9,861,494	11,191,612	29,233,255	21,813,138
Other income:				
Interest income, net	80,450	303,568	247,802	666,077

Gain (loss) on warrant liability	3,047,459	755,317	1,612,775	2,254,008
Net loss	\$(1,750,622)	\$(7,781,303)	\$(16,765,098)	\$(16,005,587)
Net loss per share — basic and diluted	\$(0.02)	\$(0.15)	\$(0.25)	\$(0.30)
Shares used in per share calculations	70,985,520	53,560,360	68,153,753	53,381,256

BALANCE SHEET HIGHLIGHTS

(unaudited)

	June 30, 2008	December 31, 2007
Cash, cash equivalents and short-term securities	\$18,786,092	\$25,074,413
Total current assets		22,546,479
Total assets	32,578,172	38,637,930
Total current liabilities	8,826,906	9,752,329
Total shareholders' equity	\$21,243,010	\$26,381,748
		28,711,451