AVI Biopharma 2006 Third Quarter Financial Results Conference Call Transcript

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Moderator: Denis Burger

November 15, 2006 8:00 a.m. Pacific Time

Operator: Ladies and gentlemen, welcome to the AVI BioPharma 2006 Third Quarter Financial Results conference call. At this time all participants are in a listen–only mode. Following management's prepared remarks we will hold a Q&A session. At that time professional investors may ask a question. To ask a question please press Star followed by 1 on your touchtone phone. If anyone has difficulty hearing the conference please press Star 0 for operator assistance.

As a reminder this conference is being recorded Wednesday, November 15, 2006. I would now like to turn the conference over to Ms. Jody Cain. Please go ahead ma'am.

Jody Cain: This is Jody Cain with Lippert Heilshorn & Associates. Thank you for participating in today's call. Joining me from AVI BioPharma are Denis Burger, Chairman and Chief Executive Officer; Alan Timmins, President and Chief Operating Officer; and Mark Webber, Chief Financial Officer.

Last Wednesday AVI BioPharma released financial results for the 2006 third quarter. If you have not received this news release or you would like to be added to the company's distribution list please call Lippert Heilshorn in Los Angeles at (310) 691–7100 and speak with Cheryl Park. This call is also being broadcast live over the Internet at www.avibio.com and a replay of the call will be available on the company's web site for the next two weeks.

Before we begin I would like to note that comments made by management during this conference call will include forward–looking statements within the meaning of federal securities laws. These forward–looking statements involve material risks and uncertainties. For a discussion of risk factors I encourage you to review the AVI BioPharma annual report on Form 10–K and subsequent reports as filed with the SEC.

Furthermore the content of this call contains time sensitive information that is accurate only as of the date of the live broadcast, November 15, 2006. The company undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this conference call. With that said I'd now like to turn the call over to Denis Burger. Denis?

Denis Burger: Thank you Jody and thank you all for joining us today. As you might have noted, we issued our third quarter financial results last week and we're holding our conference call today. The reason for this timing is that we are under accelerated filer rules for our quarterly results and had a third quarter deadline of November 9; however, business travel commitments prohibited us from holding our conference call until today.

Today's prepared remarks will focus on our cardiovascular programs. To provide you with a bit of a preview, our year end call in March will focus on our ESPRIT or Exon skipping technology.

The third quarter and recent weeks have been a productive period for AVI. We are currently conducting a pivotal clinical study with AVI–5126 or Resten–CP in coronary artery bypass patients. We are taking a cost effective, efficient, quality approach to the clinical development of Resten–CP. We expect preliminary results from this study late next year.

The ability to demonstrate efficacy in this study will be the first step in our plan to introduce Resten–CP as a coronary artery bypass graft or CABG treatment in all major markets within the following five years.

CABG surgery is one of the most commonly performed procedures in the United States and our third generation NeuGene antisense technology has demonstrated in a Phase II trial the ability to regulate a gene that could reduce the incidence of vein graft failure. Resten–CP as the treatment of CABG represents an important opportunity for AVI and Alan Timmins will provide additional background on this program later in today's call.

With those opening remarks I'll ask Mark Webber to review our recent financial performance. Mark?

Mark Webber: Thanks Denis. Today I'd like to review our 2006 third quarter financial results and our cash position and then I'll affirm our 2006 financial guidance.

Revenues from license fees, grants, and research contracts in the third quarter of 2006 were $13,000 compared with revenues of $3.2 million reported in the third quarter of 2005. Revenues last year were due primarily to recognition of $3.2 million in research contract revenue from government funding.

Operating expenses for the 2006 third quarter were $7.3 million compared with $5.2 million in the prior year. This increase was due primarily to higher R&D expenses including additional employee costs of $690,000 of which $645,000 was from stock–based compensation expense due to SFAS 123R; $980,000 due to expanded clinical programs in Hepatitis–C and CABG; and $120,000 was due to contracting costs for the production of GMP subunits, which we use to manufacture compounds for future clinical trials.

General and administrative expenses increased to $1.2 million in the third quarter of 2006 from $1.1 million in the third quarter of 2005. This G&A increase was due primarily to higher employee costs of $300,000 including $360,000 in stock–based compensation expense due to SFAS 123R offset by decreases in employee costs of $125,000 following the transition of nine employees at our Colorado facility to Cook Group in April, 2006.

We reported a net loss for the third quarter of 2006 of $6.8 million or 13 cents per share, which compares with a net loss of $1.7 million or 4 cents per share for the third quarter of 2005. Our 2006 third quarter results included stock–based compensation expense of $1 million.

For the nine months of 2006 revenues were approximately $98,000, down from $3.4 million in the prior year period. Higher revenues in the 2005 period again reflect the recognition of $3.2 million in research contract revenues and higher grant revenues.

Operating expenses for the nine months of 2006 were $24.3 million compared with $16 million in the nine months of 2005. This increase was due to higher R&D costs of approximately $18.6 million in the 2006 period compared with $12.2 million in the 2005 period primarily as a result of an additional $2.4 million in employee costs. These costs include $1.8 million in stock–based compensation expense due to SFAS 123R and $430,000 related to the acceleration of the vesting of certain stock options.

The increase in R&D expenses also reflects $1.9 million from the expansion of Hepatitis–C and CABG clinical programs; $500,000 of AVI common stock issued to Chiron Corporation as the first milestone payment under a license agreement that grants AVI a non–exclusive license to Chiron's patent and patent applications for the research, development, and commercialization of antisense therapeutics against HCV; and $1.1 million in contracting costs for the production of GMP subunits.

General and administrative expenses increased to $5.7 million for the nine months of 2006 from $3.8 million in the comparable period a year ago. This year's increase was due primarily to an additional $1.8 million in employee costs including $1.2 million in stock–based compensation expense due to SFAS 123R and $400,000 related to the acceleration of the vesting of certain stock options.

Our net loss for the nine months of 2006 was $22.7 million or 43 cents per share. This compares with a net loss for the nine months of 2005 of $12.1 million or 28 cents per share. The results for the 2006 period include stock–based compensation expense of $3.9 million of which $3.1 million was due to SFAS 123R and $830,000 was related to the acceleration of the vesting of certain stock options.

Reviewing our balance sheet, we reported cash, cash equivalents, and short term securities of $38.4 million as of September 30, 2006 -- a decrease of $8.6 million from December 31, 2005. This decrease was due primarily to $15.5 million used in operations and $1.2 million used for the purchase of property and equipment and patent–related costs.

This was offset by the receipt of $5 million in net proceeds from a stock purchase agreement with Cook Group and $3.1 million for an exercise of warrants and options and sales under the company's employee stock purchase plan.

Additionally in January, 2006 we were informed that in accordance with the final version of the 2006 Defense Appropriation Act approved by President Bush, AVI will be allocated $11 million to fund our ongoing defense–related programs including Ebola, Marburg, and dengue viruses as well as anthrax and ricin toxins. These funds have yet to be received and are not reflected in our third quarter financial statements.

In reviewing our 2006 financial guidance, we continue to expect cash burn for 2006 to be in the range of $15 million to $20 million. With that overview I would like now to turn the call over to Alan Timmins.

Alan Timmins: Thanks Mark, and let me add my welcome to those of you joining us this morning on the call and on the Internet. Today I want to focus on our recently announced program to evaluate the safety and efficacy of Resten–CP for the treatment of coronary vascular disease.

As Denis mentioned, coronary artery bypass grafting or CABG is among the most common surgeries with approximately 350,000 CABG procedures performed in the U.S. and about 800,000 performed worldwide each year.

Coronary arteries are the small blood vessels that supply the heart muscle with oxygen and nutrients. Fats and cholesterol can accumulate inside these small arteries and the arteries can gradually become clogged. CABG surgery creates new routes around narrowed and blocked arteries allowing sufficient blood flow to deliver oxygen and nutrients to the heart.

Often the surgery uses the saphenous vein from the patient's leg as the bypass graft. This vein is located on the inside of the leg running from the ankle to the groin. The saphenous vein normally does about 10% of the work of circulating blood from the leg to the heart and can be removed without harming the patient.

Although bypass surgery is effective in restoring blood flow, 30% to 50% of vein grafts eventually become blocked or otherwise fail. Indeed within the first year after a CABG procedure an estimated 15% to 30% of saphenous vein grafts fail. In addition vein graft failure significantly increases the risk of recurrent angina, late myocardia infarction, and the need for a repeat CABG on the same vessels.

Resten–CP represents a novel additive approach to CABG procedures that could reduce the recurrence of vein graft failure. Our decision to pursue clinical development is based on positive results from animal studies and a Phase II clinical trial with AVI–4126 for Resten–NG. Resten–NG targets the c–myc gene that regulates the many downstream genes that produce the pathology of self proliferation disorders including cardiovascular restenosis.

Pre–clinical studies have shown that silencing c–myc just at the time of injury may be sufficient to prevent late term consequences of intimal hyperplasia, the self proliferation considered to be the primary cause of vessel obstruction after CABG and intracoronary artery stent placement.

We have shown in a previous Phase II clinical study that Resten–NG reduced the restenosis rate after balloon angioplasty and stent placement by approximately 75%. Resten–CP has the same NeuGene component as Resten–NG. In addition it incorporates our proprietary CytoPorter delivery peptide, a transporter tail to enhance drug delivery to the saphenous vein ex vivo before use in bypass surgery.

Remember that this vein is only available for exposure to the drug for approximately 20 minutes. This delivery tool dramatically enhances the uptake of the drug into the vein graft in this short time period. Our CABG trial is the first clinical use of this delivery strategy.

The Phase Ib/II portion of the study has been initiated and enrollment is expected to commence by the end of the year. This is a pivotal multi–center, double–blinded, randomized and placebo controlled study that's powered for safety and superiority. It will include up to 600 patients in several well respected, high volume cardiovascular study sites including three centers in the Ukraine and 12 centers in Poland and it will be performed under ICH guidelines.

The control group will have the removed saphenous vein immersed in saline while the experimental group will have removed veins immersed in a Resten–CP solution before connection to the vein graft into the coronary artery circulation. As Denis discussed, we expect these studies to produce results from the initial patient groups by late 2007 and based on favorable efficacy data we'll then initiate a broader clinical program with the goal of commercializing Resten–CP in all major markets within five years.

There will be periodic safety evaluations for patients participating in the study including assessment of major adverse events which include death, myocardial attacks, or emergency need for a repeat CABG as well as 4–D coronary artery CAT scans. After a safety evaluation of the first 110 patients the study can become a pivotal program.

Patients will be under study surveillance for one year after the CABG procedure. During this period they will be evaluated systematically by standard coronary angiography criteria which includes blockage of the saphenous vein graft of 75% or more as measured by quantitative coronary artery angiography. With that overview of our Resten–CP program I'd like to turn the call back to Denis.

Denis Burger: Thanks Alan. Before we take your questions let me review some of our milestones. First in our cardiovascular program we have focused our internal efforts exclusively on our CABG program. We expect initial results from the first 110 patients in this trial late next year or early in 2008.

This represents a program that AVI plans to maintain in–house rather than to license out. It represents a market that can be addressed without a massive sales force since every bypass site is well known. If successful this procedure would become the standard of care and routinely used in all procedures. We believe that there are no competing drug development programs for this indication at this time.

As announced last March, the AVI–5126 cardiovascular program has been licensed to the Cook Group. Cook presented promising preliminary observations in the APPRAISAL study at last month's Transcatheter Cardiovascular Therapeutics conference.

The APPRAISAL study is designed to evaluate Resten–MP or AVI–4126 delivered intravenously via microparticle technology in conjunction with the placement of one or more bare–metal stents. Cook expects to present independently reviewed core lab data at the EuroPCR conference in May of next year.

Turning briefly to our infectious disease program, we are focusing commercial development on HCV, influenza, and dengue virus diseases. In our clinical trial with AVI–4065 in HCV we plan to report data from our modified cohorts in the first quarter of 2007.

In our influenza program we are taking steps to support our planned filing of an IND. Our NeuGene technology allows for the targeting of regions of the viral genetic code that are common to all influenza A subtypes. This suggests that a single new gene drug could provide effectiveness against most influenza strains including avian influenza and the more common seasonal influenza.

We are currently completing dose escalation studies in animals against both H1N1 which is one of the seasonal flu strains, and H5N1, which is the current avian flu threat. Positive data from these studies is required to support an IND filing. Additionally we expect to finish pre–clinical work with the dengue virus program later this year. This is expected to be the next viral program to move into clinical development.

Finally, with our NeuGene–based Exon skipping technology, or ESPRIT program, we expect to begin a clinical trial for the treatment of patients with muscular dystrophy early in next year in the U.K. and potentially later next year in the U.S.

Some of you most likely noted that we filed a $75 million shelf registration statement with the SEC a few weeks ago. Although shelf registrations have become an important tool for biotech companies to conduct future financings, we have no current plans to contact a financing. An active shelf registration provides us with flexibility in making the most advantageous financing decisions for AVI and our shareholders.

As you might have noticed we have not yet realized any of the $11 million allocation from the Department of Defense. Since our allocation exceeded a $5 million threshold, additional justifications and auditing has been required which has delayed the recognition of these funds compared to last year. We expect these funds to be recognized in our financials as early as this quarter and throughout 2007. We are also still in line for additional grant funding from DTRA as previously mentioned.

With that update at this time I'd like to open the call to questions. Operator?

Operator: Ladies and gentlemen, for professional investors who wish to ask a question, you will need to press Star then the number 1 on your telephone. You will hear a prompt to acknowledge your request. If your question has been answered and you wish to withdraw your polling request you may do so by pressing the Star then the number 2. If you are using a speakerphone please pick up your handset before entering your request. One moment please for the first question.

Your first question comes from Dennis Stanek with RBC Dain Rauscher.

Dennis Stanek: Good morning gentlemen.

Denis Burger: Good morning.

Dennis Stanek: A question -- looking out forward, have you folks applied for any new available grants on avian flu; If so, how many and for what amount?

Alan Timmins: We are actively looking at all grant opportunities. Specifically we don't have any applications pending with the government on avian flu at this time but those programs continue to come up along with other infectious disease requests by the government.

Dennis Stanek: Okay, with respect to your CABG trial, tell me why I should have confidence in your predictions on what you discussed a short while ago or any other clinical trials based on the handling of your HCV trial or your incomplete West Nile trial or any other products that have been abandoned such as pancreatic cancer or Avicine? Tell me why.

Denis Burger: Well first of all with the program on CABG the drug component that's used has already successfully completed a Phase II clinical trial and showed efficacy in Phase II in patients in cardiovascular restenosis. What we're doing in this trial is adding a delivery component that accelerates the delivery over the short time period we have available to the saphenous vein. And in pre–clinical studies we've shown that has been efficacious.

In terms of previous studies, it is unfortunate we haven't been able to enroll as many West Nile patients as planned because West Nile just hasn't been the emerging disease as expected a few years ago. In terms of commercial development of HCV we believe those programs after our initial studies will eventually be effective.

Dennis Stanek: Okay thank you.

Denis Burger: Thank you for the question.

Dennis Stanek: Thank you.

Operator: Your next question comes from Ren Benjamin with Rodman Renshaw.

Ling: Hi, this is actually Ling on behalf of Ren. Thank you for taking my question. My first question is regarding your CABG program. You mentioned, you know, that the first portion, the Phase I/II portion of the trial will involve 100 patients.

Can you tell me when do you expect to complete your enrollment? And also can you maybe give me a benchmark or more color on how do you think, you know, the safety is fine after you look at the first 100 patients.

Denis Burger: Yeah actually there are several early looks at the patients and the first ten patients are evaluated for safety, then additional patients are enrolled. We expect to have three month evaluations for safety and early efficacy on 110 patients at approximately the end of next year.

Ling: Do you expect to finish that three month evaluation by year end '07, right?

Denis Burger: That is correct.

Ling: Okay, and — all right, okay, my next question is regarding the HCV program and AVI has already initiated the trial with the modified protocol In this protocol what would be the dose range you are going to use?

Denis Burger: We have two modifications that we planned. One has been undertaken and is finishing and the second is planned to be initiated before the end of the year. The first is an extension of the treatment phase from 14 to 28 days and the second is an increase in dose which is a significant increased dose, somewhere between five and 10 times the dose that was previously administered.

And I can't tell you the precise dose escalation because we haven't finished our negotiations with the FDA in that regard.

Ling: Do you expect to initiate the second trial by year end?

Denis Burger: We do.

Ling: Okay, and also can you give me the timing on your filing for the R&D application for the avian flu program?

Denis Burger: We have always maintained that we'd like to file that IND this year in 2006. We also have also indicated that to be able to do that we have to have positive dose escalation studies in two different animal species with both H1N1 and H5N1 viruses.

The animal studies have been in progress since about March of this year from several different laboratories and our filing is dependent on a full evaluation of all the animal studies. So I can't tell you that it will take place by the end of this year or some time early next year.

Ling: Okay, thank you for taking my questions.

Denis Burger: Thanks.

Operator: Once again ladies and gentlemen, for professional investors who wish to ask a question, please press Star then the number 1 on your telephone.

Denis Burger: Well without further questions I'd like to thank you all for joining us and we look forward to a good close to this year and some exciting results early next year. From AVI, thank you very much.

Operator: Ladies and gentlemen that concludes your conference call for today. We thank you for your participation and ask that you please disconnect your lines.

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