AVI BioPharma Incorporated 2006 Second Quarter Financial Results Conference Call Transcript

8/10/06

Moderator: Denis Burger

August 8, 2006 8:00 a.m. Pacific Time

Operator: Welcome to the AVI BioPharma 2006 Second Quarter Financial Results conference call.

At this time, all participants are in a listen–only mode. Following management's prepared remarks, we'll hold a Q&A session. 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 August 8, 2006.

I would now like to turn the conference over to Jody Cain. Please go ahead, Ms. Cain.

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.

This morning AVI BioPharma released financial results for the 2006 second quarter. If you've not received this news release or 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 www.avibio.com and a replay of the call will be available on the company's Website for the next two weeks.

Before we begin, I'd 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 today's conference call contains time–sensitive information that is accurate only as of the date of the live broadcast, August 8, 2006. The company undertakes no obligation to revise or update any statements to reflect the events or circumstances after the date of this conference call.

With that said, I'd like to turn the call over to Denis Burger. Denis?

Denis Burger: Thank you, Jody, and thank you all for joining us today. I will start today's call with a few comments on the recent events, Mark Webber will summarize our financial results, and Alan Timmins will discuss several of our programs in greater detail. I will conclude with a review of key near–term activities and milestones and we'll then take your questions.

In our hepatitis C clinical program, after reporting preliminary data at the prestigious ICAR virology meetings treating HCV patients with our antisense compound, AVI–4065, we have modified the 14–day treatment protocol extending the duration of treatment. We are currently enrolling patients in a 28–day treatment cohort.

This represents one of several variables available to us to evaluate our promising antisense drug, AVI–4065. This current modification to the trial protocol is designed to optimize the pharmacokinetics and potential efficacy of the drug.

In addition to extending the number of days patients receive AVI–4065, we have a variety of modifications available to us to achieve our objective of developing a viable HCV therapy. These include increasing the dose, enhancing the delivery, fine–tuning the target, enhancing target affinity, and exploring combinations of antisense agents — or combinations of antisense agents with other drugs.

The fact that we were able to consider a broad range of potential modifications is a testament to the safety of our NeuGene compounds, which have been tested in more than 325 subjects with no serious drug–related adverse events. In our HCV trial with AVI–4065 to date, no tolerability issues have been observed during treatment or follow–up.

We expect to report pharmacokinetic, clinical and viral response, and any genetic variation data from the initial two cohorts of the 14–day treatment groups at the end of this current quarter.

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 second quarter financial results and our cash position and then I'll affirm our 2006 financial guidance.

Our revenues from license fees, grants, and research contracts in the second quarter of 2006 were $19,000, compared with revenues of $39,000 reported in the second quarter of 2005. This decrease was due to lower grant revenues, partially offset by higher research contract revenues.

Operating expenses in the 2006 second quarter were $7.4 million, compared with $5.2 million in the comparable 2005 quarter. This increase was due primarily to higher R&D expenses, including additional employee costs of $650,000 of which $640,000 was from non–cash, stock–based compensation expense due to the adoption of SFAS 123R; $600,000 was due to contracting costs for the production of GMP subunits, which are used to manufacture compounds for future clinical trials; and the balance of the increase was from higher clinical costs of $750,000 from the expansion of clinical programs in hepatitis C and coronary artery bypass grafting.

General and administrative expenses increased to $1.5 million in the second quarter of 2006 from $1.2 million in the second quarter of 2005. This

increase in G&A was due primarily to higher employee costs of $260,000, including $370,000 in non–cash, stock–based compensation, partially offset by decreases in employee costs of $130,000 when nine employees at our Colorado facility joined Cook Group in April 2006.

We reported a net loss for the second quarter of 2006 of $6.9 million, or 13 cents per share, which compared to the net loss of $4.9 million, or 11 cents per share, for the second quarter of 2005. Our 2006 second quarter results included non–cash, stock–based compensation expense of $1 million. For both the first half of 2006 and 2005, revenues were about $85,000.

Operating expenses in the first half of 2006 were $17 million, compared with $10.8 million in the first half of 2005. This increase was due to higher R&D costs of approximately $12.7 million in the 2006 period, compared with $8.1 million in the 2005 period, primarily as a result of an additional $1.7 million in employee costs. These costs include $1.2 million in non–cash, stock–based compensation expense due to the adoption of SFAS 123R and $430,000 of non–cash expenses related to the acceleration of divesting of certain stock options.

The increase in R&D also reflects higher clinical costs of $950,000 from the expansion of clinical programs in hepatitis C and coronary artery bypass grafting; $500,000 in non–cash expense for 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 patents and patent applications for the research, development and commercialization of antisense therapeutics against hepatitis C virus, and $1 million in contracting costs for the production of GMP subunits. The remaining increase was due to higher consulting costs of $320,000.

General and administrative expenses increased to $4.2 million in the first six months of 2006 from $2.7 million in the comparable period a year ago. This year's increase was due primarily to an additional $1.5 million in employee costs, including $930,000 in non–cash, stock–based compensation expense due to the adoption of SFAS 123R, and $400,000 of non–cash expenses related to the acceleration of divesting of certain stock options.

Our net loss for the first half of 2006 was $16 million, or 31 cents per share. This compared with a net loss in the first half of 2005 of $10.4 million, or 24 cents per share. Results for the first half of 2006 included non–cash, stock–based compensation expense of $2.9 million, of which $2.1 million was due to the adoption of SFAS 123R and $830,000 was related to the acceleration of divesting of certain stock options.

Reviewing our balance sheet, we reported cash, cash equivalents, and short–term securities of $44.5 million as of June 30, 2006, a decrease of $2.6 million from December 31, 2005. I want to emphasize that the net cash burn for the first half of this year was only $2.6 million.

This decrease was due primarily to $9.9 million use in operations and $750,000 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 the exercise of warrants and options and sales under the company's employee stock purchase plan during the first half of 2006.

Additionally, in January of 2006, we were informed that in accordance with the final version of the 2006 Defense Appropriations Act approved by President Bush, AVI would 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 second quarter financial statements.

Today we are affirming our financial guidance for 2006. We expect cash burn for 2006 to be in the range of $15 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. First, I'd like to discuss our hepatitis C program in greater detail.

Our Phase II trial with AVI–4065 is designed to assess the safety, powerability, pharmacokinetics and viral and clinical response in patients with active chronic HCV, a disease of the liver. We decided to extend the treatment duration from our original protocol of 14 days with the addition of a new cohort of patients treated twice daily for 28 days.

As Denis discussed, our decision to revise the protocol was based on PK results from the first few HCV patients treated for a 14–day period. AVI–4065 has a relatively long elimination half–life. Based on its mechanism of action, which is an irreversible binding to the viral genome preventing viral protein synthesis, a slow steady liver–loading with test drug was expected in patients with high level of viral target in the liver. This correspondingly predicts a slow steady decrease in viral load over the drug–loading period.

Pharmacokinetic analysis of the first few HCV patients treated was consistent with this prediction, which is encouraging for ongoing drug development.

Based on the rate of drug–loading in the initial trial patients, the maximal tissue concentration of drug should be reached in approximately 28 to 56 days. This indicates an extension of treatment duration from the 14–day period is required to reach maximum drug concentration and reduction of viral load in the liver. Extending the treatment period would be expected to further reduce viral load in responding patients and may ultimately decrease viral load in those patients who are not initial responders.

We expect to announce the clinical and viral response data from the HCV patients treated for 14 days around the end of the third quarter of 2006.

Treatment of HCV represents a major opportunity for AVI. According to the World Health Organization, approximately 170 million people worldwide are chronically infected with HCV. It's the most common chronic blood–born infection in the developed world and is the leading cause of liver transplants in the United States.

The Centers for Disease Control and Prevention estimate that approximately 3.9 million Americans have been infected with HCV, of whom 2.7 million are chronically infected.

The current HCV treatment is 24 weeks to 48 weeks of therapy with pegylated interferon alpha and ribavirin, and is successful in less than half the patients infected with genotype 1 HCV, the most common form of the virus in the U.S. Furthermore, this treatment has numerous side effects, some of them severe, which makes it difficult for nearly half of the patients to tolerate the recommended dosages and durations of treatment.

Turning to our cardiovascular program, we have finished preclinical studies for coronary artery bypass grafting, or CABG, with Resten–CP, which is AVI–5126. This drug is AVI–4126 with CytoPorter, or CP, attached to enhance delivery to the saphenous vein ex vivo before it's used in bypass surgery.

Based on positive results from animal studies and Phase II clinical trial results with AVI–4126 in targeting the c–myc gene, which is believed to

regulate many downstream genes that produce the pathology of restenosis, we expect to move into Phase II clinical trials in CABG later this year.

About 350,000 CABG surgeries are performed annually in the United States. This surgery creates new routes around narrowed and blocked arteries to allow sufficient blood flow to deliver oxygen and nutrients to the heart muscles.

With our out–license program for device delivery of AVI–4126, our licensee, Cook Group, is reporting progress with the Resten–MP APRAISAL clinical trial for the treatment of restenosis. Resten–MP is AVI–4126 with a proprietary microbubble technology to allow for systemic delivery.

The primary therapeutic endpoint of the study is the reduction in luminal diameter known as late loss from the time of intervention to follow–up at six months, as measured by quantitative angiography and intravascular ultrasound. Reduction in late loss is the standard indicator cardiologists use to gage long–term stent efficacy.

This trial is being conducted at three clinical sites in Germany in collaboration with Harvard Clinical Research Institute, an internationally recognized specialist in the management of coronary artery disease and stent clinical trials.

Cook has announced plans to provide an update of the APRAISAL clinical trial at the prestigious Transcatheter Cardiovascular Therapeutics, or TCT meeting this October.

Last week, we announced that we had been granted two additional patents that strengthen our intellectual property for both our licensed and our internal cardiovascular programs. The first of these patents covers broad use of AVI-4126 to treat any vascular injury alone or in combination with a stent, through January of 2020. The second covers the delivery of any antisense drugs via microbubbles to damaged vascular tissues until October of 2017.

In May, we were granted a patent covering the use of our NeuGene compounds to target bacterial cell division and cell cycle genes for the development of a new class of antibiotics, we call NeuBiotics. This new class of antibiotics holds the potential to treat a variety of infections caused by emerging strains of antibiotic–resistant gram–positive bacteria.

With that overview, I'd like to turn the call back to Denis.

Denis Burger: Thanks, Alan. Let me close with a review of our milestones. First, in our cardiovascular program, as Alan mentioned, we have focused our internal cardiovascular efforts exclusively on our CABG program, which we expect to move into clinical trials later this year.

Next, in our infectious disease program, we are focusing commercial development on HCV, influenza, and dengue virus diseases. As discussed in our HCV program, we are enrolling patients in a new cohort and we expect to report clinical and viral data from the HCV patients treated for 14 days around the end of the third quarter.

In our influenza program, we are taking steps to support our planned filing of an IND later this year. 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 NeuGene drug could prove effective against most influenza strains, including avian influenza and the more common seasonal influenza.

We are currently completing dose escalation studies as well as 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 preclinical 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 later this year. Currently, we are working with a consortium that includes pharmaceutical companies, including GlaxoSmithKline, as well as academic institutions and foundations with an interest in muscular dystrophy.

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

Operator: Ladies and gentlemen, if you wish to register for a question for today's question and answer session, you will need to press star, then the number 1 on your telephone. You will hear a prompt to acknowledge your request. If your request 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 while we wait for the first question.

Denis Burger: While we are waiting for the first question, I'd like to add a further comment on the multiple opportunities we envision with our ESPRIT technology. Results in an animal model that were presented at the Federation of Clinical Immunology Society's Annual Meeting in June demonstrated the effectiveness of this technology in delaying the onset of diabetes and reversing the diabetes after onset. This data validates applications of ESPRIT technology in regulating the immune response in autoimmune diseases.

Okay, operator, we're ready for the first question.

Operator: Your first question comes from the line of Ren Benjamin with Rodman and Renshaw.

Ren Benjamin: Hi, good morning, and thanks for taking the question.

Denis Burger: Good morning, Ren.

Ren Benjamin: How are you? Can you give us — a couple questions on the HCV program. How come you guys chose to evaluate the therapeutic for an additional 28 days and not 56 days?

Denis Burger: We didn't choose 28 and not 56, but we're going to do the 28–day program first. That doesn't mean it will carry all the way through before we consider the additional 56–day study, but it was easier involvement with the FDA to initiate the 28–day program before completing the 14–day study and having all the data available.

Ren Benjamin: Did you have to do any additional preclinical studies to satisfy the FDA before initiating the 28–day study?

Denis Burger: No. The 28–day study is now ongoing and patients have been enrolled and treated.

Ren Benjamin: Okay. You had mentioned several prominent modifications that you can pursue if, you know, the 28–day or the 56–day trials, you know, tell you that further modifications are necessary. What do you think are the most promising modifications that you may pursue after those trials and will you pursue it after you see the data or might you start tinkering around with those modifications before you see the data?

Denis Burger: Well, those are very good questions and I'd like to make the point that with our technology, we often make modifications to clinical trials' preclinical development programs. It turns out with HCV there aren't predictive models, animal models for the human chronic infection so you end up doing the modifications actually in the clinical studies.

If I can give you an example with our Ebola program, the first time out of the box in mice, we didn't have significantly different results than we did with the first time out of the box in the HCV program in the trial at 14 days that we reported preliminary data on. But we were able, by looking at subtle target variations, by changing dose and regimen, to bring that program to the point where it was efficacious in three different species, including primates.

So we have a history with this technology of iterative program; most of the time it's in the research lab, but this time it's actually in the clinic. Now to specifically address your question, I would think the two most prominent next studies that we're considering is an increase in dose, and also the potential combination of more than one antisense target.

Ren Benjamin: Okay. With the data that's expected at the end of the third quarter, are we expecting data from all the patients? So is this - is it the final data from the trial?

Denis Burger: We're expected to release the data from everyone that was treated in the first study. It won't be final in that the program actually has follow–up to three months. So we won't have analysis of the three–month data but we'll certainly have all of the relevant data that indicates the potential pharmacokinetic efficacy, viral variation that's relevant to continuing an iterative clinical program.

Ren Benjamin: And will this be announced at a conference or more of a press release; how will you do that?

Denis Burger: At this point, it will be around the end of the third quarter, at the end of this quarter, in a press release.

Ren Benjamin: Okay. Changing gears slightly to the funds and appropriations. You have some appropriations of approximately $11 million that have yet to be received. Does that need to be received in 2006 and so are you expecting it within the next two quarters or can that, you know, go on to 2007 when you bill the government?

Alan Timmins: It can go on; it's merely a matter of first reaching an agreement on exactly what the objectives of the experimentation are, then going — then meeting those objectives, then billing the government, and then of course, the last, longest, and most difficult is billing and then receiving the funds from the government. So it can move over into the next year.

And remember though, when we say 2006, also, when you work with the government, you're working on the government's fiscal year, which is a September 30 year–end. So much as our $4.6 million last year moved into this government fiscal year, so too can this $11 million move into the next government fiscal year.

Ren Benjamin: Okay. And my final question is there was a call for therapeutics to treat the avian flu I believe, and please correct me if I'm wrong, back earlier this year. And they're looking for — to allocate some of the avian flu money for novel therapeutics that are under development. And I believe September is when — sometime in September is when you were supposed to hear back from the government as to which companies may actually obtain funding. Have you applied for this allocation and are you expecting any funding in September?

Denis Burger: One thing about the government's applications and timelines is that they all change. And although we're in contact with the relevant parties that are involved in helping Human Services budget and the NIH portion of that, we don't expect that they're going to meet the September deadline; we expect we'll hear something by the end of the year.

Ren Benjamin: But you guys did apply for appropriations?

Denis Burger: We're on the list of companies that are participating in that. I'm hedging on the wording because there hasn't been a formal grant budget application associated with it as yet. So — and this is the nebulous area of how the government runs those programs. And I would expect that you'll hear more on that in formal applications as we get into the fourth quarter of this calendar year.

Ren Benjamin: Okay. Thank you very much.

Alan Timmins: Thank you.

Operator: Once again, if you do have a question, please press star, 1 on your telephone keypad at this time.

Your next question comes from the line of David Sandler with BFC Securities.

David Sandler: Hi. Good morning.

Denis Burger: Good morning, David.

David Sandler: In your recent press release about relating to the cardiovascular patents, it noted in the release that there were comments both by Joe Horn and by an investigator that they were very encouraged by the early results. I wondered if this referred to the actual results regarding late loss for early participants in the trial?

Denis Burger: It does. Now since Cook is running the program, we don't have first–hand information on a patient–by–patient rundown of how the six–month IVUS or angiography has come out but we have heard from them and they put those comments in the release based on clinical findings from six–month data. But they're very cautious in that they're not going to reveal much more than that until they give an update at the October TCT

Meeting as Alan mentioned.

David Sandler: Another question for you, is the — do you expect any participation in the West Nile Virus trial this year or is that trial now more abundant?

Denis Burger: The only thing that we're doing in regards to West Nile is further documenting whether our drug crosses the blood–brain barrier and can be found in cerebral spinal fluid. And we're doing some additional studies with that in patients — in subjects, normal subjects, but we're not involved in trying to recruit patients in West Nile disease, it's just proved too difficult, too rare, and too much of a small market opportunity.

David Sandler: Would you accept patients if they requested treatment?

Denis Burger: Probably not; we don't have an active protocol at this time to do that and we're using our clinical supply of drugs to answer the very important question of whether or not and to the quantication of the drug crossing the blood–brain barrier, which has a great opportunity for us to move forward into brain targets if it proves to be the case. We certainly had indications that it was the case in our West Nile study in that when we were in — not only did we test the drug in spinal fluid but as we increased the dose, we saw a dose escalation of the drug in the spinal fluid. Targets in the brain could be for Alzheimer's disease, for pain, for a whole variety of important indications where — cancer is an example where it's very difficult to get drugs to that site. So it's an important study but it's not relevant to treating West Nile infections.

David Sandler: How long do you think it will be until you get a conclusive determination from this study, whether the crossing the blood–brain barrier is a feature of the drug?

Denis Burger: This is active and ongoing and we've finished treating one cohort of patients; so I would expect by the end of the year.

David Sandler: Thank you.

Operator: There are no further questions at this time. Please proceed with your presentation or any closing remarks.

Denis Burger: Well, in closing, I'd like to thank you all for participating in this call. AVI is very excited about the clinical development programs that we have in progress and ongoing and the ones that are likely to start a little later this year. Thank you very much for your participation. Good–bye.

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.

END