AVI BioPharma Incorporated Second Quarter 2007 Results Conference Call Transcript

8/13/07

Lippert Heilshorn & Associates

Moderator: Mike Forrest

August 8, 2007, 8:00 a.m. Pacific Time

Operator: Welcome to the AVI BioPharma Second Quarter 2007 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 this conference, please press star–0 for operator assistance.

As a reminder, this conference is being recorded August 8, 2007.

I would now like to turn the call 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 Michael Forrest, interim chief executive officer, Alan Timmins, president and chief operating officer and Mark Webber, chief financial officer.

Earlier today, AVI BioPharma released financial results for the second quarter of 2007 and in a separate release, announced refocused clinical development strategies.

If you’ve not received these news releases or if you’d like to be added to the company’s distribution list, please Lippert/Heilshorn in Los Angeles at 310–691–7100 and speak with Lateisha Hall.

Before we begin, I’d like to state the comments made by management during this conference call will include forward–looking statements within the meaning of federal securities laws.

These forward–looking statements involved material risks and uncertainties. For discussion of risk factors, I encourage you to review the AVI BioPharma Annual Report on Form 10–K and subsequent reports filed, with the SEC.

Furthermore, the content of this conference call contains time sensitive information that is accurate only as of the date of the live broadcast, August 8, 2007.

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 now like to turn the call over to Michael Forrest.

Mike.

Michael Forrest: Thanks, Jody and my thanks to each of you for joining us today.

In this call, I’ll provide you with an overview of where we’re heading with our clinical and research programs. Mark Webber will present the financial overview.

Alan Timmins will give some additional details on our current programs and then I’ll add some summary comments. After that, we look forward to taking some questions from you.

During our first quarter conference call, we announced our intent to reevaluate AVI’s programs to determine which of them hold the greatest near term commercialization potential. As you know, based on the versatility of our NeuGene antisense technology, we have, over the years, been exploring quite a number of promising programs. But as a small development stage company, we need to sharply focus our resources, both financial and intellectual, on those that are the most promising near–term prospects.

Our focus at AVI going forward will be on:

Number 1, advancing the clinical development of NeuGene drug candidates targeting specific cardiovascular indications;

Two, using our new exon–skipping pre–RNA interference technology, or ESPRIT, for the treatment of selected genetic diseases;

Three, continuing to pursue opportunities provided under our relationships with the Department of Defense to develop prophylactic and therapeutic agents that have the potential to offset the tremendous loss of life that might occur to the development and deployment of lethal biological weapons by terrorists groups, and
Four, continuing our efforts to develop a product that maybe effective in combating an outbreak of pandemic influenza caused by the H5N1 strain of avian flu.

Integral to our focusing efforts, we decided to immediately discontinue our current hepatitis C clinical development program. We believe that the potency of the current compound is insufficient for practical commercial use. Discontinuation of this trial will free up cash and human resources that will be used to support ongoing clinical development efforts in our coronary artery bypass grafting, or CABG, and our Duchenne muscular dystrophy programs, or DMD.

Our discovery research programs will be redirected and tightly concentrated on programs designed to improve the potency, delivery, efficacy and safety of the products just mentioned, including continued efforts in hepatitis C.

We will of course continue to search for new applications of our NeuGene and ESPRIT exon–skipping technologies. These efforts will be prioritized in the context of medical needs, commercial attractiveness, the ready applicability of our technologies to such needs and our available resources.

We’ll continue to actively move forward with our ongoing clinical trial to test the ability of AVI–5126 to prevent the blocking of saphenous vein grafts following their use in CABG surgery.

We have very good reasons to advance this program. CABG is one of the most common surgeries in the United States with approximately 427,000 procedures performed in 2004 according to the American Heart Association at an average cost of approximately $35,000 to $50,000 per procedure. CABG surgery often uses saphenous veins to bypass blocked or narrowed arteries in order to restore sufficient blood flow to the heart muscle. Although CABG surgery is effective in restoring blood flow, 30% to 50% of the saphenous vein grafts eventually become partially or completely blocked due to a restenosis–like effect and will fail. A treatment to reduce blockage in vein grafts represents both an unmet medical need and a sizeable market opportunity.

Clinical results have demonstrated the ability of our NeuGene compound to turn off the c–myc gene, which regulates many of the downstream genes that cause cells to proliferate. Excess cell proliferation is believed to be responsible for the restenosis–like effect that eventually causes vein grafts to fail following CABG surgery.

We’ve previously reported that we have commenced the enrollment of patients in our European clinical trial in which we’re using our NeuGene drug AVI–5126. AVI–5126 is a more potent version of AVI–4126, which has already demonstrated promise in preventing or reducing restenosis following angioplasty procedures in which the placement of a bare–metal stent was employed. AVI–5126 is a PMA — and it employs the use of a peptide to enhance the delivery of the antisense agent to the appropriate cells. Alan Timmins will provide details on this clinical program later in the call.

I'd like to express our appreciation to our partner Cook Medical for providing updates on its programs with AVI–licensed NeuGene compounds. We're pleased with Cook's progress and stated desire to rapidly commercialize NeuGene products for the cardiology market. Cook Medical licensed NeuGene product candidates from AVI back in March 2006 for the use in certain vascular diseases.

Global Therapeutics, the Cook Medical company responsible for the NeuGene program, announced last month that it had completed a six–month follow–up study on patients enrolled in the Phase II APPRAISAL clinical trial. This trial was designed to study the effects of our NeuGene compound AVI–4126 delivered systemically via microparticles to prevent cardiovascular restenosis when used in conjunction with the placement of one or more bare–metal stents. Cook announced that the data from this clinical trial will be presented at the Transcatheter Cardiovascular Therapeutics or TCT conference in late October of this year.

In a second announcement also in July, Global Therapeutics announced its plans to initiate the clinical trial for the inhibition of restenosis in patients following angioplasty using a bare–metal, cobalt chromium stent, a drug delivery catheter and AVI–5126 -- the very same compound that AVI is currently testing in its CABG trial. Global Therapeutics indicated this trial was planned to begin before 2007 year end, of course, subject to regulatory approval. This trial will be designed to incorporate up to 20 investigational centers throughout Europe with the intent to support a CE Mark filing as a medical device in Europe.

If efficacy and safety are borne out, we see great potential with the NeuGene compounds in combination with bare–metal stents as an alternative to use of drug–eluting stents for the prevention of restenosis. Recent concerns regarding the safety of drug–eluting stents have prompted decline in their use by physicians around the world. In the US for example, drug–eluting stents are currently used in about 2/3 of procedures performed to open clog arteries. This is down sharply from their use in 90% of all procedures early last summer. The drug–eluting stent market is about a $6 billion global market segment. Surely, a product that performs well in preventing restenosis will enjoy considerable success in this sector.

We will be pleased to help Global Therapeutics in any way we can to ensure that their trials are a success.

Moving to our ESPRIT program, we’re also very excited about developing drug candidates based upon our exon–skipping pre–RNA interference technology.

ESPRIT holds potential as a highly potent tool for altering many disease mechanisms. Rather than simply blocking protein production as is the case with conventional antisense drugs, ESPRIT–based drugs can induce the cellular machinery to skip over a targeted exon. An exon is a packet of genetic information used in part to build a protein. In some cases mutations in an exon sometimes results in no protein being produced, a harmful protein being produced or a production of a protein that is not harmful but is not functional. The ESPRIT mechanism provides a fine–tuned approach to altering the disease process such that functionality of the protein can potentially be restored. This is truly remarkable technology that could result in the cure or improvement of patients that currently are untreatable.

As previously reported — our first application in this technology is the genetic condition, Duchenne muscular dystrophy, or DMD. Alan will also provide a more detailed report on this program later on.

Turning to our Department of Defense efforts, we have a two–year $28 million research contract with the Defense Threat Reduction Agency or DTRA, a Department of Defense agency for the development of compounds to treat Ebola, Marburg and Junin hemorrhagic viruses. We’re also receiving funds from a 2006 defense appropriations act to fund our programs including Ebola, Marburg and dengue viruses as well as anthrax and ricin toxins. Based on our collaborative efforts with the United States Army Medical Research Institute for Infectious Disease, or USAMRIID, we’re seeing very encouraging results from our preclinical work targeting certain of these potential bioterror threats.
These preclinical efforts with NeuGene antisense are being conducted in a high contained setting. Importantly, the knowledge we gain from these programs is potentially transferable to the development of drugs targeting both viral and nonviral targets in the commercial arena. The cost to run these programs is covered by the government contract. Mark Webber will provide an update on the funds received from the government as of the end of the second quarter.

We also plan to continue to work on our H5N1 influenza program for the development of an agent targeting this potentially pandemic disease. As previously announced, we’ve demonstrated efficacy with the NeuGene PMO in an animal model following aggressive challenges by two strains of seasonal flu. While we hope to attract a partner for the large seasonal flu market, our internal influenza program is focused exclusively on combating the H5N1 subtype, which fits our stated objective of pursuing the fastest regulatory pathway to drug approval while maximizing the use of our resources. We will continue evaluating compounds for efficacy in additional animal models as the next step in supporting a filing of an IND for this indication.

I can assure you that while evaluating our development programs, we’ve continue to make good progress on our commercial and government programs.

AVI’s board of directors is also moving forward with the search for a permanent CEO. With our direction clearly defined, the board is actively interviewing candidates with the appropriate experience to lead our company forward.

With those introductory comments, I’d like to now turn the call over to Mark Webber to review our financial results.

Mark Webber: Thanks Mike.

Today, I’d like to review our 2007 second quarter financial results and cash position and I’ll update our 2007 financial guidance.

Revenues from license fee, grants, and research contracts in the second quarter of 2007 were $2.4 million, compared revenues of $19,000 reported in the second quarter of 2006. The increase reflects higher research contract revenues of $2.4 million and licensing fees of $31,000, partially offset by decreases in grant revenues of $8,000.

Operating expenses for the 2007 second quarter were $11.2 million, compared with $7.4 million for the 2006 second quarter. This increase was due primarily to higher research and development expenses, which increased to $9.2 million from $5.9 million in the second quarter of 2006.

R&D expenses in the 2007 second quarter included higher clinical cost of $1.4 million for the expansion of clinical programs and approximately $1.8 million in the expenses for government research contracts.

General and administrative expenses for the 2007 second quarter were $2 million versus $1.5 million in the prior year quarter. The increase in general and administrative expenses was due primarily to increases in legal expenses of $315,000, compensation costs of $225,000, partially offset by decreases in SFAS 123R expenses of $75,000.

We reported net loss for the second quarter of 2007 of $8.5 million, or $0.16 per share, which compares with a net loss $6.9 million, or $0.13 per share, for the second quarter of 2006.

For the first half of 2007, we reported revenues of $2.9 million, compared with $85,000 for the first half of 2006. This increase reflects the increase in research contracts revenues of $2.2 million and license fees of $63,000, partially offset by decreases in grants revenues of $55,000.

Operating expenses for the first half of 2007 were $21.8 million, compared with $17 million in the first half of 2006. This increase was due to higher R&D costs of approximately $15.5 million in the 2007 period, compared with $12.7 million in the 2006 period. The increase in R&D expenses was due to higher net clinical costs of $700,000: including $170,000 in contracting costs for the production of GMP subunits, $2.1 million in expenses for government research contracts, increases in chemical and lab supply costs of $390,000, professional consultant costs of $240,000, and leasehold and patent amortization expenses of $50,000. These increases in R&D were partially offset by decreases in employee costs of $430,000 was related to the acceleration of the vesting of certain stock options in the first quarter of 2006 and decreases in SFAS 123R expenses of $290,000 and salaries and bonuses of $250,000.

General and administrative expenses increased to $6.3 million for the first six months of 2007 from $4.3 million in the comparable period a year ago. The increase in G&A expenses was due primarily to increases in compensation costs of $1.4 million of which $1.6 million was related to the separation and release agreement with the company’s former chief executive officer that included $563,000 in cash compensation and $1.1 million in SFAS 123R expenses. This is partially offset by decreases in SFAS 123R expenses of $200,000. General and administrative expenses also included increases in legal expenses of $545,000 and accounting expenses of $60,000.

Our net loss for the first half of 2007 was $18.3 million, or $0.34 per share. This compares with a net loss for the first half of 2006 of $16 million, or $0.31 per share.

Reviewing our balance sheet, we reported cash, cash equivalents and short-term securities of $19.3 million as of June 30, 2007, a decrease of $13.8 million from December 31, 2006. This decrease was due primarily to $12.7 million used in operations and $1.1 million used for purchases of property and equipment and patent–related costs.

In December 2006, we announced the execution of a two–year $28 million research contract with the Defense Threat Reduction Agency, or DTRA, an agency of the United States Department of Defense. The contract is directed to our funding — or development of antisense therapeutic to treat the effects of Ebola, Marburg and Junin hemorrhagic viruses, which are seen as biological warfare and bioterrorism agents. In the second quarter of 2007, we recognized $1.3 million bringing our total for the first half of 2007 to $1.7 million under this contract.

In January 2006, we reported in accordance with the final version of the 2006 Defense Appropriations Act approved by President Bush, AVI will be allocated $11.0 million to fund our ongoing defense–related programs, including Ebola, Marburg and dengue viruses, as well as anthrax and Ricin toxins. Of this amount, we expect to receive up to $9.8 million net of government administrative expenses. During the second quarter, we recognized $1.1 million under these contracts. We expect to receive these funds later or possibly next year as research is completed and invoiced to the
government. Contracts are in place for Ebola, Marburg and Ricin/Anthrax projects. The fourth project on the original allocation, dengue virus, is still on the discussion stage.

For our financial guidance, we are increasing our expected net cash burn for the year to be in the range of $22 to $24 million from our previous expectation of between $10 to $17 million. This increase is due to expenditures and government projects, additional costs related to the purchase of the manufacturing facility and higher clinical expenses. The expenditures may be reduced slightly in 2007 and significantly in 2008 because of the following:

Our expectation of our partner, Ercole Biotech, will cover 50% of the cost related to the systemic DMD study; Our decision to stage the construction of our manufacturing facility in order to conserve cash while still meeting anticipated needs for clinical and commercial materials. We now anticipate completion of the Stage 1 unit of the manufacturing facility by the middle of 2008.

Additionally, as discussed, we are not currently proceeding with the HCV clinical trials.

With that overview, I would like now to turn the call over to Alan.

Alan Timmins: Thanks, Mark. And let me have my welcome to those of you joining us this morning on the call and on the Internet.

First, I’d like to discuss our ongoing clinical programs starting with our evaluation of AVI–5126 used in CABG procedures.

CABG procedure involves harvesting the saphenous vein from the leg and grafting it into the coronary artery to bypass blockages or narrowed passageways. Our CABG trial involved ex vivo, or outside the body, application of AVI–5126 to the saphenous vein after harvest and prior to engraftment. This compound incorporates a delivery peptide, which is in effect a transporter tail designed to enhance drug delivery. The saphenous vein is soaked in a solution containing the drug for 20 to 30 minutes. The delivery peptide dramatically enhances the uptake of the drug into the vein graft in a short time period. As Mike discussed, the goal of the study is to determine if AVI–5126 reduces the incidence of graft blockage or failure following the procedure.

This trial is a pivotal multicenter, double blinded, randomized placebo–controlled study. It’s being conducted in well–respected high–volume cardiovascular study sites in the Ukraine with additional sites expected to come on board soon in Poland. The study will include up to 600 patients. We’re currently in the Phase 1b/II portion of the study, which includes the first 110 patients. This portion will monitor major adverse events including death, myocardial attacks, or the emergency need for a repeat CABG procedure.

We’ve established a drug safety monitoring committee comprised of independent third parties to periodically evaluate safety data. We’re pleased to report that no significant safety issues involving the drug have been reported to–date.

This study is proceeding on track with the safety data from the first 110 patients expected in the first quarter of 2008. Based upon favorable safety data, we’ll consider initiation of the broader clinical trial. At that time, the study can become a pivotal program. Patients will be under study surveillance for one year after the CABG procedure. During that period, they’ll be evaluated systematically by standard criteria that includes blockage of the saphenous vein graft of 75% or more as measured by quantitative angiography.

Our ultimate goal of this program is to pursue a filing for regulatory approval in Europe and to work with partners to conduct additional trials that may be required in the US to commercialize the product.

Turning to our ESPRIT program in Duchenne muscular dystrophy: DMD is the most common form of muscular dystrophy, affecting one in 3,500 young males. An estimated 17,000 boys and young men are afflicted with DMD in the US alone. There is no approved therapy for this progressively debilitating and fatal disease. DMD is caused by one or more mutations in the gene that code for a crucial protein for muscle function call dystrophin. Most of these mutations cause subsequent enzymes to be misread by the cell machinery so that no functional dystrophin is produced.

Our current program objective is to use the ESPRIT–based therapeutic, AVI–4658, to skip exon 51 to put the subsequent exons back in the correct reading frame. This will allow for production of a truncated but functional version of dystrophin. We estimate that 15% of all DMD patients may benefit from skipping exon 51.

Approval is expected shortly from the MHRA, a UK regulatory body equivalent to the FDA, for research teams at the Imperial College of London to begin a proof–of–principle, dose escalating trial using AVI–4658. This trial will include up to nine boys with DMD, each receiving a single intramuscular administration of the drug. Two to three weeks following the injection, the muscle will be biopsied and examined for molecular evidence of dystrophin production.

We’re also aggressively pursuing in parallel, the expansion of the clinical development of AVI–4658 to a multicenter dose ranging systemic administration trial for the treatment of DMD in conjunction with our cross–licensing and development partner, Ercole Biotech. This trial will be designed to assess the functional efficacy of exon–skipping in DMD.

As Mike mentioned, DMD represents the first of what we believed are multiple opportunities we expect to pursue with the ESPRIT program.

With that update, I’d like to turn the call back to Mike.

Michael Forrest: Thanks, Alan.

Before we take your questions, I’d like to recap our key programs.

First, in the cardiovascular program, we’re on track with our CABG trial with AVI–5126. We currently have sites actively enrolling patients and the drug safety monitoring board will closely monitor the first 110 patients and this would give us an indicator of safety sometime early in 2008.

Cook Medical has announced plans to present data from the Phase II APPRAISAL clinical trial at the TCT conference on October and they’ve additionally indicated that they plan to move into clinical testing later this year with a kit including AVI–5126.

With our first program based on ESPRIT therapeutics, we expect regulatory approval soon from the UK authorities to begin dosing patients in a pilot study in DMD targeting exon 51.
Perhaps more importantly, we’re moving forward aggressively with preparations for a Phase II clinical trial design to determine a safe and effective systemic dose for the treatment of this devastating condition. Our partner, Ercole Biotech has indicated its intention to fund 50% of the cost of the DMD program.

In our flu program, we’re applying to further test delivery of our compounds in animals affected with the aggressive strains of seasonal flu and animals infected with the H5N1 subtype of avian flu. We plan to conduct these studies at commercial labs in order to maintain better influence over the timeliness of the work. If successful, these studies are expected to provide sufficient preclinical data to support filing of an IND with the FDA for use in H5N1 avian flu.

And finally, our research and development efforts will be redirected and tightly concentrated on programs designed to improving the delivery of our compounds to targeted cells, increasing potency and lowering overall basic requirements thereby improving the potential efficacy and safety of our products. This program will include hepatitis C, which we continue to believe is an attractive target for our NeuGene antisense technology.

With the completion of our evaluation, we now believe that we’re firmly focused on those programs that demonstrate the greatest near-term commercial opportunities.

I also want to announce that we’ve started construction on the first stage of our 34,000 square-foot facility in Corvallis that will house a large scale GMP production facility. The construction will occur in stages, with each stage coming online in order to meet the anticipated clinical and bulk-drug requirements for AVI, as well as for our partners. Our staged build-up program is designed to conserve the use of cash. We anticipate that the initial build out of our first stage will be completed and the facility will be operational by the middle of 2008.

So with that update, I’d now like to open the call to your questions, and operator, we are ready for the first question.

Operator: Ladies and gentlemen, if you wish to register for a question for today’s question and answer session, you will need to press then the number 1 on your telephone. You will hear a prompt signal to request.

If your question has been answered and you wish to withdraw your polling request, you may do so by pressing star then a number 2.

If you are using a speaker phone, please lift up your handset before entering your request.

One moment please for the first question.

Our first question is from Ding Ding with Maxim Group. Please go ahead with you question.

Ding Ding: Great. Good morning everyone.

Mike Forrest: Good morning.

Ding Ding: Good morning.

I wanted to first congratulate you for completing the evaluation of the pipeline. And I personally applaud your decision to discontinue the hep C program. I think it’s a very good decision for you to continue to focus the resources going forward.

Just a few questions here -- first on the Resten–NG and the Resten–MP, you mentioned Cook has announced its plan to conduct additional clinical study with bare–metal stent as well as catheter delivery.

Given the current data we have, the Phase II data, you already had with the catheter delivery as well as systemic delivery following the bare–metal stent placement, what’s the — can you provide some additional color as for what is the purpose of this additional study? Do we consider this study to be part of the registration study for commercialization and the regulatory filing?

Mike Forrest: Thank you, Ding Ding. That’s a very good question and unfortunately, at this point in time, we don’t have access to the strategic decisions of Cook. We know, as you were correct in pointing out, that there was efficacy that’s been demonstrated with 4126. But we also know based upon our own experience that there is a significantly increased potency of our next–generation peptide–based product, which is 5126.

We — I just can’t comment because I don’t know as to whether Cook will continue both of these programs in parallel or substitute one for the other.

Ding Ding: So the new study is going to focus on 5126 rather than 4126?

Mike Forrest: That’s correct. And part of the strategy, I think, is that they’re looking at moving this into a kit–based approval, which will allow the use of the product to be delivered with a specialized catheter that will administer the product directly into the vein that’s being — where the stent is being placed in order to localize the treatment.

And in this fashion, they will be able to use the entire package -- the catheter, the drug and the bare–metal stent -- as the basis for application at the CE Mark which is a — would be the fundamental basis for approval in Europe and probably only one study would be required.

Ding Ding: I see. Do we have any body language from Cook as for their plan and timing for moving the 4126 into regulatory process or that is no longer the focus now going forward?

Mike Forrest: I just — I don’t know because I think Cook is still deciding what they wish to do and whether they want to move both programs at the same time or switch to the 5126 program.

Ding Ding: Okay.

For the CABG program, you mentioned that no safety issue have been reported so far. How many patients have been enrolled and how long have these patients had the procedure and when should we expect to see any efficacy data from this trial?

Mike Forrest: Ding Ding, we don’t like to talk on a day–to–day basis about the number of patients that have been enrolled, but there have been a reasonable number that have been included in the trial already and many of these have been on the study for up to 60 to 90 days.
So as a consequence of this, we have the drug safety monitoring board which is evaluating these patients on an ongoing basis. And as a function of that, they have told us that the whole trial seems to be very clean and they have encouraged us to just continue moving forward as quickly as we can for the first step of the Phase I/IIb program that Alan mentioned -- the Phase I program essentially, of enrolling the first 110 patients.

At that point in time, we won't actually receive data because the data would represent then an un–blinding of the study which I'm not sure we want at this point in time. But it certainly would then -- the DSMB, would then give us a nod as to whether the program should be halted from a safety perspective, which unlikely it would because if it would need to be halted, it would be halted sooner than that, or on the contrary and what we expect, is that the program would then be given a nod to move forward into what's the pivotal portion of the trial.

Now, with regard to efficacy, it's a very good question, and AVI is, right now, we have no interim look planned for the study. However, we are actively discussing this from a strategic standpoint with our clinical people, with outside experts and with our statisticians who, as you know, are a breed to themselves, in order to determine what the statistical penalty might be if we decide to take an efficacy look on an interim basis. We haven't come to that conclusion yet and if we decide to stop some trial at some predetermined point in order to take a look at efficacy, we will certainly let you know. Right now, that's not in the cards — or it's not in the table.

Ding Ding: Okay. So the DSMB stopping criteria is only going to be based on safety while you're going to look at interim data on the safe — on the efficacy end...

Mike Forrest: Well, we may decide to look at interim data on efficacy. That decision has not yet been made. There’re possible outcomes from the DSMB.

One is that they tell us to go forward because the safety looks good.

Highly unlikely because these things don’t usually take place in this way, but there is an outside chance that they may say you should stop the study because the efficacy is so outstanding that we are now denying patients the opportunity to get the drug. That would be an unbelievably good outcome and not something that we’re expecting because typically, these trials take a long time and involved a very large number of patients before one can come to that conclusion.

So the response from the DSMB at the end of the 110 patients will be based on — primarily on safety.

Ding Ding: Okay. Great. That’s very helpful.

And lastly if I may and I'll be back to queue, for the flu program, I understand your internal focus will be on avian flu and not seasonal flu going forward. Have we started the animal study with H5N1 avian flu strain infection in animal models?

Mike Forrest: The simple answer is no, we've not, but it's a little bit more complicated than that. The difficulty is that the H5N1 strain is now becoming closely guarded by many people who possess it, including government agencies overseas. And so it’s been a little bit more difficult than we had anticipated in order to get access to this lethal strain for use in animal testing.

We believed we've lined up a couple of sites that have access to it and we'll shortly — and we are contacting those to see if we can get the studies put in place.

On the other hand, we want to take a look at potentially using pulmonary delivery for the — our PMOs because we believe that that has a very significant possibility of even greater efficacy than that which we've seen already in the preclinical results.

So we may be running a parallel program doing pulmonary studies to test the efficacy of the product as well.

Ding Ding: Great. Thanks very much for added color.

Mike Forrest: You're welcome.

Operator: Once again ladies and gentlemen, as a reminder, to register for a question, please press star then a number 1 on you telephone.

Our next question is from Ren Benjamin with Rodman. Please go ahead with your question.

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

Mike Forrest: Hi, Ren.

Ren Benjamin: Just a couple of additional details. Can you just remind us of the deal with Cook, what exactly they have access to, what they don't have access to? And then as they get ready to initiate this — you know, this new trial — and I think you mentioned it was a pivotal trial, are there milestones associated with it and if not, when — you know, what sort of clinical development needs to occur in order for milestones to be triggered?

Alan Timmins: Right. Hi, Ren.

The deal with Cook is that they have licensed the NeuGene technology from us in the cardiovascular disease areas, specifically excluded from that is CABG.

There are, as you might recall from when the deal was signed, there are no clinical type benchmarks going forward. We have forgone that in exchange for a higher royalty at the success—end of things. And we've disclosed that royalty as being a low double digit royalty.

And so they — basically, that's their playing field — cardiovascular disease using various NeuGene technologies.

Ren Benjamin: Okay.

Regarding the timing of the cardiovascular program, you mentioned that the safety data, you know, is likely to be expected at least from the first 110 patients in say early 2008.
And could you give us an idea as to, you know, if you get the nod to go forward and they'll expand this and go — you know, move this into a much larger trial, how long will it — how long do you think it will take based on sort of current enrollment rates and what you can get enrollment rates up to, how long would it take to get to the 600 patients and when do you envision that data being available?

Alan Timmins: We believed that we can get to the 600–patient level in 2009 and so the data would be available at a point after that. So it would take essentially the rest of 2008 and somewhat in the 2009 to enroll those additional patients.

Ren Benjamin: Okay.

And do you have any idea — when you have some details regarding the pivotal trials from Cook, do you have any idea as to how many patients they plan on enrolling and how long the development timeline could be for that program?

Alan Timmins: Yes. I don't think that they are far enough down the pathway yet that they have determined or announced those figures. Ding Ding used a very nice term there which she asked about “body language” from Cook. And, I think that you can interpret the body language from Cook, as well as their statements in their releases in July, that they are keying on the quickest possible route to commercialization for their products incorporating NeuGene technology, and we take that as very good news indeed.

Ren Benjamin: Okay.

So one last question on the Cook side, they were supposed to -- you know correct me if I'm wrong -- present this data at the PCR conference -- I think there was a conference in April -- but that was somehow pushed back.

And now, it looks like it's the same data that we're going to have presented now at the TCT conference. Do you know why that was pushed back?

Alan Timmins: I think specifically, it was because follow–up had not been completed on a couple of patients and they did not want to present an incomplete package at the initial conference. Cook's tendency and desire is to present their data at the big name, marquee conferences, and so TCT is the next of those.

Ren Benjamin: Okay.

So moving onto the ESPRIT program, you mentioned that the MHRA is expected to approve this protocol fairly soon. Do you expect that to occur in this quarter?

And, you know, since you're talking with the site involved and you're only looking at nine boys with DMD, do you expect this trial to enroll fairly quickly and to get the results fairly quickly, so say by the fourth quarter of this year?

Michael Forrest: Ren, it's Mike again. It's a good question.

The answer for the first part on timing: we have been expecting approval from the MHRA for about four or five months now so it's — this process is inexplicably long and painfully delayed. But we unfortunately have no control over, you know, the decision–making or the bureaucracy with the MHRA.

We originally had a good outcome and then somebody said, “Well, wait a minute, we want to look at one other thing,” and they're still in the process of looking at that one other thing. Neither of the things that they are looking at in our view are consequential. So yes, we're hoping that it will be approved during this quarter, but we can't absolutely guarantee it.

Now, the nine boys that will be enrolled, potentially could be enrolled very quickly although the logistics as you might imagine of bringing people around from various parts of the UK into the center for treatment could be a little bit complex. And I think we're not anticipating that the trial will be completed sometime next year. They will be testing these boys actually one at a time. So the first one gets treated, they wait three or four weeks to do — see whether there is — to give the drug enough time to work — to produce dystrophin on the basis of what we've seen in some of the preclinical studies then they do an ex–plant of the muscle into which the PMO has been injected.

They then homogenize the ex–plant and look to see whether dystrophin has been produced, and that's really — the endpoint of the study is to see whether or not dystrophin has been produced, and if so, at what level. So it's not an efficacy study per se because there's no functional outcome.

On the other hand, the study that we — that I referred to earlier is one that is designed to look at efficacy in the stage away first at the dose ranging study and then moving into the efficacy parameters although there's a possibility that we may get some peak of efficacy early on.

And that study is being extremely aggressively pursued by us and I can't give you an absolute prediction, but we certainly hope to get the trial going in the absence of any contrary feedback from regulatory authorities, we hope to be able to get that going sometime in the first half of 2008 and we expect that that trial could actually recruit fairly quickly.

Ren Benjamin: So that provides a good segue to my next question that is, you know, in the US trial, can you just give us some details as to how that trial is going to be conducted and, you know, how big do you think it is and what are the endpoints there? Is it going to be something similar to the UK or are you going to look for functional endpoints?

Mike Forrest: We're going to be looking for — no, it's not similar to the UK. This would be a subcutaneous injection that's given in the early stages at different doses to four different cohorts of boys, so increasing the dose up to — from a low dose up to a higher dose all within the bounds of safety data that we have on the product.

And the study will be designed to — at some point in time, after the subcutaneous injections of the boys -- to do biopsies of muscles, probably the arm muscle of the boys, to determine if dystrophin has been produced. And what we're looking for is to see whether dystrophin is being produced at the level that we are estimating to be — or not estimating -- that we are hoping would be at least 30% of what the normal dystrophin levels that are being produced are.

And children afflicted with a less severe condition of this disease called Becker's muscular dystrophy — children or even adult live to be ripe old age with dystrophin production that approximates 20% of normal. So our target of 30% that we think is a good one to give us a good indicator to whether efficacy will be produced.
So, with the amount of sort of time and effort and money that AVI has put into, you know, the NeuGene therapeutics, clearly at the very least, one can say that a significant safety database has been amassed. And so if that’s the case, while the function maybe different here or the mechanism of action maybe different here, what do you think, you know, could be a hold up or what sort of issues do you think the FDA can bring up in sort of — not delaying but, you know, slowly moving the application forward to actually get to a clinical trial?

Mike Forrest: Well, the only possible thing can be since there is no possibility to do preclinical studies in a human model that exactly duplicates DMD. So therefore the models have all been done with artificially induced muscular dystrophy in both mice and in dogs. So the relevance of those in terms of the sequence that we’re using for boys is totally different. Animals are unique to animals and this is a human condition.

Ren Benjamin: Got it.

One last or two last questions regarding the funding for the government grants that you've obtained, can you just give me sort of a total as to — I guess a total monetary value as to the number of grants that have been granted -- sorry, for lack of a better word -- by the government — by the US government to AVI?

And when you think — I think Mark Webber mentioned that, you know, $9 million will be recognized over the next 12 months, but could you give us some more clarity as to how the timing of these grants will be recognized?

Mike Forrest: Alan.

Alan Timmins: Yes, we can. Our current grant and/or contracts with the government fall into two categories. There’s the $28 million contract which covers Ebola, Marburg and Junin and other hemorrhagic viruses.

And we’ve received a small amount of funding on that thus far. We expect that to increase significantly in the next couple of quarters and that basically as we ramp up and do the more expensive types of studies.

And the other aspect is through four separate smaller grant–like contracts of which we have signed three of the contracts -- the fourth one is sort of the final discussion phases. That’s where the $9.8 million--number that Mark mentioned came from.

We expect those contracts — the three contracts were just signed I believed this quarter or late last quarter. So there is ramp up that’s going on with those as well as with the fourth contract that’s in discussion.

So I think you’ll see a somewhat of a ramp up on the $28 million over the next couple of quarters and then a reasonably smooth receipt of funds over next year with that.

With these three smaller contracts, I think you’ll still have another quarter or few months of ramp up then followed by — you’ll see those funds being received into — through late 2008 as well.

Ren Benjamin: Is there a time limit by which these funds need to be used?

Alan Timmins: There are time limits in it, but success breeds cooperation at the government level as you might imagine. And so, we would hope that if there were some sort of a time limit that we would have capability of extending that if we hadn’t completed the testing by that point in time. It’s a little bit interesting and that we’re a contractor for the government and then the government is a subcontractor to us, you know, doing the work in USAMRIID in many of the cases on the contracts. So, you know, there’s a lot of government interaction there and therefore a lot of coordination that needs to take place.

Ren Benjamin: Okay, great.

That’s it for me. Thank you very much for answering my questions.

Alan Timmins: Ren, thank you.

Operator: Our next question is from Ding Ding with Maxim Group. Please go ahead with your question.

Ding Ding: Sorry. Thank you.

Just for a quick follow up, any updates you could share with us on the partnership discussion from — particularly as it relates to the exon–skipping program and the cytochrome P450 program?

Mike Forrest: We continue to have people that are interested in the cytochrome P450 program, but these evaluations by the large pharmaceutical partners take time. And generally they are looking for the target drug that should be used in conjunction of cytochrome P450 inhibition to produce a good clinical outcome and something that might have great commercial value.

The things that we’ve done experiments with are Midazolam, which you don’t really need to increase the efficacy of Midazolam, but it certainly
provided us good principle and that’s the basis on which the pharmaceutical companies are interested.

I think the next step might be that we — if we can continue their interests -- to have a selected proper target that has relevance to the — from a commercial perspective -- as to what one of the interested company has and do additional trials, of course supported by those companies. So it’s ongoing but we’re — these things always take time as you know.

Ding Ding: Great.

Maybe just a follow up question on the Duchenne muscular dystrophy program, focusing on the US side, have had the chance to schedule a pre IND meeting the FDA? Is it still — do you still expect it sometime in the summer or second half of the year?

And secondly, you’ve provide some additional color and I was just trying to think through what other additional steps we need to go through in order to prove — to move this program into clinic in the US?

Mike Forrest: Yeah. But we actually are trying to move the program simultaneously in the US and in Europe. The contacts with the MHRA in the UK, to give you a little bit of additional color, some people in the Imperial College and even some of the regulatory people within the MHRA have asked us why we weren’t just doing a systemic study as opposed to the intramuscular study that I described to you. We think that the prospects for getting approval moving at the Europe were actually quite good.

We are scheduling discussions with the FDA regarding the protocol that I’ve mentioned earlier but those — no formal meeting has yet been set.

Ding Ding: Uh–huh.

Mike Forrest: We need to accumulate all of our data first we do that.

Ding Ding: Uh–huh.

Any additional steps before we move this program into clinic in the US?

Mike Forrest: We hope not — the only possible way as I mentioned before to Ren is that the — we may need to do some additional safety toxicology studies in animal models, but we’re not sure exactly how that would be done since this is a human protein that we’re going after, and it does not exist in animals, at least not in the same form.

So that can only be clarified with our discussions with the FDA, which we obviously will be proceeding to get clarity on as soon as we probably can.

Ding Ding: Uh–huh.

Mike Forrest: Other than that, we’re ready to go actually.

Ding Ding: Sorry, did you mention — do you have a target timeframe as for when to have that meeting with FDA?

Mike Forrest: Let’s say within the next three months we should be able to have a meeting scheduled.

Ding Ding: Okay, great. Thank you.

Mike Forrest: Welcome.

Operator: There are no further questions at this time.

Please proceed with your presentation or any closing remark.

Mike Forrest: Okay. Thank you very much. Just as a closing comment, I’d like to thank you very much for joining us today and for your support and your questions. We will do our very best to keep you informed on our progress as we go through some of these steps that I’ve outlined and/or at our next conference call.

Good day to all of you.

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

END