



AVI BioPharma Incorporated Third Quarter 2007 Results Conference Call Transcript

11/16/07

Lippert Heilshorn & Associates

Moderator: Bruce Voss

November 6, 2007, 7:00 a.m. Pacific Time

Operator: Welcome to the AVI BioPharma third 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 question and answer session for professional investors.

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 November 6, 2007.

I would now like to turn the conference over to Bruce Voss. Please go ahead, sir.

Bruce Voss: Thank you.

This is Bruce Voss with Lippert Heilshorn and Associates. Thank you all for participating in today's call. Joining me from AVI BioPharma are Michael Forest, 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 2007 third quarter. If you have not received this news release or if 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 (Brandy Floberg).

Before we begin, I'd like to state 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 10K and subsequent reports as 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 November 6, 2007. 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 like to turn the call over Michael Forest. Mike?

Michael Forest: Thanks, Bruce, and my thanks to each of you for joining us.

I'll begin this morning's call with the discussion of several recent events. Mark Webber will present a financial overview. Alan Timmins will provide additional details on our ESPRIT and infectious disease programs. And then I'll add some summary comments. After that we'll look forward to taking some questions.

Starting with our cardiovascular programs, we're pleased to report that our partner Global Therapeutic hosted a symposium at last month's prestigious TCT conference to discuss observations with the Phase II APPRAISAL clinical trial.

Global Therapeutics, a Cook Medical company, assumed responsibility for this ongoing clinical trial in March of 2006 when we licensed NeuGene product candidates to Cook for use in certain vascular diseases.

The APPRAISAL trial was designed to steady the affects of Resten-MP to prevent cardiovascular restenosis when used in conjunction with a placement of one or more bare metal stents.

Resten-MP is the NeuGene compound AVI-4126 delivered systemically via microparticles. Dr. Stephen Sack the principal investigator of the APPRAISAL trial and head of the cath lab at the University of Essen West German Heart Center presented his observations from the APPRAISAL trial.

And additionally, Dr. Sebastian Philipp who is also affiliated with University of Essen West German Heart Center, noted that AVI-4126 had no systemic side effects, which is consistent with results from prior clinical trials with our NeuGene compounds; and also that the 30-day major adverse cardiac events, or MACE as it's sometimes referred to, at the West German Heart Center was zero.

Dr. Philipp also reported that the six-month intravascular ultrasound, or IVUS, testing showed promising AVI-4126 efficacy in preventing restenosis with results that were comparable to those produced with drug eluting stents at his institution. IVUS uses ultrasound technology to image the blocked vessels.

In July, Global Therapeutics announced plans to initiate a clinical trial for the inhibition of restenosis in patients following angioplasty with a kit that consists of bare metal cobalt chromium stents, a delivery catheter and AVI-5126. AVI-5126, which is AVI-4126 with a peptide incorporated in order to simplify delivery and enhance potency, is the same compound that AVI is using in our ongoing CABG clinical trial.

The decision by Global Therapeutics to pursue a kit is based upon its evaluation of the quickest path to product commercialization. Plans have been

announced to begin the initial clinical testing of the kit in a multi-center trial in Europe. This trial is expected to commence in the first quarter of 2008 subject of course to regulatory approval.

The 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.

We're very pleased with our relationship with Cook and with the progress at Global Therapeutics. We believe the initial observations from the APPRAISAL trial bode well with regard to safety and potential efficacy of NeuGene compounds in combination with bare metal stents as an alternative to drug eluting stents for the prevention of restenosis.

In other corporate developments, we're very encouraged by the caliber of candidates that we've met for our Chief Executive Officer position. We're making very good progress and are looking forward to announcing successful completion with the search at the appropriate time.

Additionally we announced last week the appointment of two new members of the AVI Board of Directors. These appointments were made pursuant to an agreement following an open collaborative discussion with the — or discussions rather — with the AVI Shareholder Advocacy Trust.

We're confident that this agreement is in the best interest of all AVI shareholders. We are pleased to welcome our new directors, Dr. Gil Price and Mr. William Goolsbee.

Dr. Price is a physician who has more than 18 years of senior level experience in therapeutic drug development and who's especially experienced in the clinical side of the process. He currently serves as Chief Executive Officer and Chief Medical Officer of Drug Safety Solutions and is a member of the American Medical Association, the Academy of Pharmaceutical Physicians and the American Society for Microbiology.

Mr. Goolsbee brings us a results-driven focus and corporate governance experience through an impressive 30-year career in the bio-pharmaceutical and medical device industries. He founded and served as Chairman and Chief Executive Officer of Horizon Medical and was a founding Director and later Chairman of ImmunoTherapy Corporation, a company that was acquired by AVI in 1998.

On behalf of the board, we're delighted to welcome our new directors and the fresh ideas that they'll bring to the company. I also want to express the board's appreciation to Alan Timmins and Dr. Jim Hicks who have resigned as directors. Both Alan and Jim remain committed to AVI's success. As you know, Alan continues to serve the companies — serve the company as President and Chief Operating Officer. And Jim is serving as a consultant.

With those comments, I'd like to now turn the call over to Mark Webber who will review our financial results. Mark?

Mark Webber: Thanks, Mike.

Today, I'd like to review our 2007 third quarter financial results and cash positions and then I'll affirm our 2007 financial guidance.

Revenues from license fees, grants and research contracts in the third quarter of 2007 were \$2.9 million compared with \$13,000 in the third quarter in 2006. The increase reflects higher research contract revenues of \$2.9 million and licensing fees of \$31,000 partially offset by decreases in grant revenues of \$2,000.

Operating expenses for the 2007 third quarter were \$11.4 million compared with \$7.2 million for the 2006 third quarter. This increase was due primarily to higher research and development expenses, which increased to \$9.9 million from \$5.9 million last year.

R&D expenses for the 2007 third quarter included \$2.1 million in expenses for government research contracts, \$1.9 million in contracting costs for the production of GMP subunits and \$470,000 in expenses for professional consulting. The increase in R&D was partially offset by a \$510,000 decrease in net clinical costs.

General and administrative expenses for the quarter were \$1.5 million versus \$1.2 million last year. The increase in G&A expenses was due to primarily to increases in compensation costs of \$165,000, legal expenses of \$55,000 and accounting costs of \$20,000 partially offset by decreases in SFAS 123R expenses of \$65,000.

We reported a net loss in the third quarter of 2007 of \$7 million or 13 cents per share, which compares to the net loss of \$6.2 million or 12 cents per share for the third quarter of 2006.

For the first nine months of 2007, we reported revenues of \$5.8 million compared with \$98,000 for first nine months of 2006. This increase reflects higher research contract revenues of \$5.7 million and license fees of \$94,000 partially offset by decreases in grants revenues of \$57,000.

Operating expenses the first nine months of 2007 were \$33.2 million compared with \$24.2 million in the first nine months of 2006. This increase is due to higher R&D cost of \$25.4 million in the 2007 period compared with \$18.6 million in the 2006 period. And increases in G&A expenses to \$7.9 million in the 2007 period compared to \$5.7 million in 2006 period.

The increase in R&D expenses was due to \$4.2 million in expenses for government research contracts and \$2 million in contracting costs for the production of GMP subunits. Increases in R&D also include increases in professional consulting costs of \$710,000, chemical and lab supply costs of \$350,000, net clinical expenses of \$190,000 and leasehold and patent amortization expenses of \$90,000.

These increases in R&D were partially offset by decreases in employee costs of \$1.1 million of which \$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 \$440,000 and salaries and bonuses of \$200,000.

The increase in G&A expenses was due primarily to increases in compensation costs of \$1.8 million of which \$1.6 million was related to the separation and release agreement with the company's former Chief Executive Officer that included \$552,000 in cash compensation and \$1.1 million in SFAS 123R expenses that was partially by decreases in SFAS 123R of \$265,000. General and administrative expenses also included increases of legal expenses of \$600,000 and accounting expenses of \$80,000.

Our net loss for the first nine months of 2007 was \$22 million or 43 cents per share. This compared to net loss of the first nine months of 2006 of \$22.6 million or 43 cents per share.

Reviewing our balance sheet — we reported cash, cash equivalents and short term securities of \$14 million as of September 30, 2007, a decrease of \$19.1 million from December 31, 2006.

This decrease was due primarily to \$17.2 million used in operations and \$1.8 million used for the purchase of property and equipment and patent related costs.

December 2006 we announced 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 toward funding our development of antisense therapeutics to treat the effects of Ebola, Marburg, Junin hemorrhagic viruses, which are seen as biological warfare and bioterrorism agents. Under the contract, we recognize \$1.8 million during the third quarter and have recognized a total of \$3.6 million to date.

In January of 2006, we were informed in accordance with the final version of the 2006 Defense Appropriations Act approved by President Bush, AVI will be allocated \$11 million to fund our ongoing defense rated programs including Ebola, Marburg and dengue viruses as well as anthrax and ricin toxins. Of this amount, we expect to report up to \$9.8 million net of government administrative expenses have now received signed contract for this amount.

During the third quarter, we received the final signed contracts for \$2.7 million. We expect to receive the remainder of these funds over approximately the next year as research is completed and invoiced to the government. Contracts are in place for the Ebola, Marburg, dengue and ricin/anthrax projects.

In accordance with our Securities and Exchange Commission report, we have filed an amended form 10-K for 2006 and amended form 10-Q for the first and second quarters of 2007. These amended filings are based on a non-cash reclassification of warrants. These changes are technical in nature and do not affect overall cash flow, performance or prospects.

Turning now to 2007 financial guidance, we are affirming our expected net cash burn for the year to be in the range of \$22 to \$24 million dollars. Expenditures may be reduced slightly in 2007 and significantly in 2008 because of the following.

Our expectation that our partner of Ercole Biotech will cover 50% of cost related to the systemic DMD stay and our decision to stage the construction of our manufacturing in order to conserve cash while still maintaining anticipated needs for clinical and commercial materials. We continue to anticipate completion of the stage one unit of the manufacturing facility by the middle of 2008.

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

Alan Timmins: Thanks, Mark, and thanks and good morning to all of you joining us on the call and over the internet.

I'd like to start by discussing developments with our exon skipping pre-RNA interference technology or ESPRIT program into Duchenne muscular dystrophy. ESPRIT holds potential as a highly potent tool for altering many disease mechanisms. ESPRIT-based drugs can induce cellular machinery to skip over a targeted exon, which is a packet of genetic information used in part to build a protein.

In some diseases, a mutation in an exon results in no protein being produced or a harmful protein being produced or 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 hopefully be restored.

DMD is an incurable muscle wasting disease associated with specific errors in the gene that expresses dystrophin. Dystrophin is a protein that plays an important structural role in muscle fibers. When dystrophin is missing or non-functional due to a mutation in the dystrophin gene as it is in DMD, it leads to degeneration and death of the muscle fiber. Approximately one in 3,500 boys is born with DMD and estimated 15,000 to 20,000 children are afflicted with DMD in the United States alone.

As an update, first it was announced recently the Medicine and Healthcare Products Regulatory Agency or MHRA has given research teams at the Imperial College of London working in collaboration with the U. K. based MDEX Consortium approval to move forward with an active screening of patients for a proof of principal dose escalating clinical trial using AVI-4658.

AVI-4658 is designed to benefit patients with mutations in the gene for dystrophin that can be neutralized by skipping exon 51. The trial will include up to nine boys with DMD, each of whom will receive 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 improved dystrophin production. The screening of patients for this trial could be completed before the end of this year. AVI will serve in a clinical development collaborator capacity for this study.

Last week we announced the granting by FDA of orphan drug designation to AVI-4658 for the treatment of DMD. Orphan drug designation is reserved for the development of drugs intended to treat diseases that affect fewer than 200,000 people in the U. S. The orphan drug designation entitles AVI to seven years of market exclusivity for AVI-4658 upon approval in this indication as well as other benefits.

We're currently planning with our cross licensing and collaboration partner Ercole Biotech a multi-center dose ranging trial using systemic administration of this drug candidate. Program brings together experts on exon skipping from around the world in a significant collaboration.

Additionally, we were recently awarded a \$2.45 million research and development grant from the non-profit organization Charley's Fund, which funds DMD specific drug development and discover initiatives. This is the largest grant ever made by Charley's Fund and is the largest ever received by AVI from a non-profit foundation.

This grant is particularly gratifying as the Charley's Fund organization and AVI share a commitment to finding a cure for DMD. We believe the granting of these funds represents recognition of our progress toward that goal.

With Ercole Biotech, we'll select and develop a lead molecule designed to skip exon 50. Mutations in this exon may also result in DMD. Funding under the Charley's Fund grant is anticipated over the next several quarters.

Turning to our bio-defense programs, we're delighted to report the presentation of very positive data from pre-clinical studies with our NeuGene Plus

therapeutic compounds. These studies were conducted at the U. S. Army Medical Research Institute of Infectious Diseases or USAMRIID.

The results indicated strong survival benefits and elimination of the deadly Ebola virus in non-human primates. Our NeuGene Plus compounds also demonstrated encouraging pre-clinical results against the Marburg with additional results in both deadly viruses announced today. These studies were funded through our two year, \$28 million research contract with DTRA and at no cost to AVI.

We continue to gain knowledge from these programs that's critical to our bio-defense efforts with the government as well as gaining knowledge that's potentially transferable to development of drugs aimed at viral and non-viral targets in the commercial arena.

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

Michael Forest: Thanks, Alan, for that good overview. And before we take your questions, I'd like to recap the tangible progress we've made this year with well defined programs that we believe hold significant near term commercialization potential.

First in our cardiovascular program, AVI has initiated a 600 patient Phase II clinical trial using AVI-5126 for the treatment of restenosis and saphenous veins following their engraftment in coronary artery bypass surgery procedures or CABG. We're actively enrolling patients in this pivotal, multi-center, double blinded randomized and placebo controlled European clinical study. Enrollment is progressing as expected and new sites are expected to open soon in Poland. We've established an independent drug safety monitoring committee that will closely monitor the first 110 patients and will give us an indication of safety early in 2008. A treatment to reduce blockage in vein grafts represents both an unmet medical need and a very sizable market opportunity.

There has been a considerable progress also made by AVI's partner, Cook Medical in the evaluation of AVI-4126 and AVI-5126 as candidates for the prevention of restenosis in patients following placement of bare metal stents during angioplasty procedures. Cook has now selected AVI-5126 as its lead candidate and we expect them to initiate a clinical program in Europe during the first quarter of 2008. The safety of drug eluting stents was among the major topics at this year's TCT conference with several studies including Cook's presented as potential therapeutic alternatives to DES'. As previously stated, we stand ready to help Cook Therapeutics and Global — Cook Medical and Global Therapeutics in any way we can to ensure that its trials are successful.

In our ESPRIT program, we've accelerated our evaluation and development of ESPRIT, which is exon skipping pre-RNA interference technology for the treatment of serious medical conditions. And at this — as selected — as Alan has mentioned Duchenne muscular dystrophy as our lead program.

In this program, we've made considerable progress including receipt of a \$2.45 million grant from Charley's Fund for the development of an ESPRIT product targeted at exon 50 mutations in DMD patients, receipt of an orphan drug designation from the U. S. FDA for an ESPRIT product targeted at exon 51 mutations in DMD patients.

Approval by the Medicines and Healthcare Products Regulatory Agency or MHRA and the U. K. to commence a pilot intramuscular study with AVI-4658 in DMD boys afflicted with an exon 51 mutation. Patient screening in this study is now underway.

We've also designed and are moving forward with preparations for a Phase I/II clinical study to determine a safe and effective systemic dose of our drug AVI-4658 for the treatment of DMD patients. This product candidate if successful could improve the lives of many thousands of people suffering from this debilitating condition. We're currently in exploratory conversations with regulatory authorities to determine the type and extent of any additional pre-clinical studies that might be required before moving into the clinic.

In our government programs, we've received confirmation of \$35 million in contracts with the U. S. Department of Defense for the development of NeuGene-based products for the prevention of and treatment of life threatening conditions caused by bioterrorist agents.

And we've announced impressive clinical — pre-clinical results demonstrating the ability of NeuGene drugs to provide up to 100% protection against lethal challenges with Ebola and Marburg viruses in non-human primates.

In our influenza program, we've achieved promising results so far with subcutaneous, intraperitoneal and most recently pulmonary delivery of our compounds in animals infected with the most aggressive strains of seasonal flu. These are in fact lethal challenges of these aggressive seasonal flu strains. We now want to confirm the pulmonary results before moving into animals infected with the H5N1 subtype of avian flu. We plan to control — to conduct these studies at commercial labs in order to maintain better control over the timeliness of the work. And if successful, the studies are expected to provide sufficient pre-clinical efficacy data to support the additional toxicology work required for the filing of an IND with the FDA.

And finally, our research and development efforts have been redirected and tightly concentrated on programs designed to improve the delivery of our compounds to targeted cells, increasing potency and lowering dosage requirements thereby improving the potential efficacy, safety and economics of our products.

In closing, we feel we're making very good products in clearly defined programs with excellent commercial potential. There's still much to do but we're headed in this right direction.

Now I'd like to open the call to your questions. Operator, we're ready for the first question.

Operator: Ladies and gentlemen, if you wish to register for a question for the question and answer session, you will need to press star then the number 1 on your telephone keypad. 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 star then the number 2.

If you are using a speakerphone, please pick up your handset before entering your request. Again, we request that if you have pressed star 1 to ask a question before this time, please press it once more to ensure that you enter the queue. One moment please for the first question.

Our first question comes from Ren Benjamin with Rodman and Renshaw. Please go ahead with your question.

Ling: Hi, this is actually Ling on behalf of Ren. Thank you for taking my question. Couple of questions — the first one is regarding your cardiovascular program. Can you share us, you know, like more detail data regarding, you know, the APPRAISAL trial? For example, you know the detail restenosis rate and the MACE rate of 4126 versus, you know, the bare metal stents?

Michael Forest:Ling, we unfortunately have not received any more data than has been released to the public by Cook Medical. So what we can say is that they have presented their opinion, which is that the top line results for this trial for them is very encouraging.

And that they intend act upon what they've seen and move forward into the clinic using preferably 5126 as opposed to 4126 mostly because they've stated they are very enthusiastic about the increase in potency and the lower amount of drug that needs to be administered.

So I unfortunately cannot comment because I simply don't know as to the details of the results. But we like Cook are encouraged by their body language and their comments about their enthusiasm with regard to these — to this compound.

Ling:Okay. And from your understanding, you know, the new trial they're going to release it in the first quarter of '08 with 5126; is that trial going to be a registrational quality trial for — to get the mark in the Europe or is this is another trial need to explore before, you know, the...

Michael Forest:The details of the trial are not yet known but the understanding we have is that it will be a multi-faceted trial that will allow it to progress as information is gathered over the patient accrual and data uncovering period do a pivotal study that will be used for CE Mark.

This was the original intention with 4126 and with 5126 Cook expects that the process will be perhaps even faster — the quickest way to the market. So the answer is yes. We expect that it will be ultimately a pivotal style — study designed to obtain CE Mark in Europe.

Ling:Okay. And also can you explain it to us, you know, by pursuant of, you know, a kit, what is the advantage, you know, of this strategy? And what potential impact in the market potential?

Michael Forest:Well, it's an interesting question and the — we have been told by Cook that they have had discussions with the regulatory — with key regulatory authorities in Europe and that by incorporating 5126 into a kit, which will include a catheter and a bare metal stent or bare metal stents to be administered as part of an angioplasty procedure that the product or the kit itself will be considered as a device rather than as a drug.

And on the basis of the conversations that Cook has had with these regulatory authorities, they're quite confident that the products — the kit will be approved as a device, which as you know, is usually much faster than going through a regular drug approval process.

Ling:Okay but do you expect that maybe the market potential will be lower I guess versus to get it approved as a drug?

Michael Forest:I think not. I think that probably the best way from a market standpoint is to — first of all speed to market is, as you know, extremely important. And, secondly, the ability to have a kit available for a physician to use as kind of an all in one procedure for an angioplasty is something I think is quite attractive. So I don't think there's any detriment to marketing it as part of a kit as opposed to a standalone drug.

Ling:Okay and regarding the 5126 program, you know, it's a pivotal program with, you know, 600 patients. Maybe you can, you know, let us know, you know, how much approximately you expect the trial to cost? And have you ever thought about, you know, pursuing a partnership for this program as well?

Michael Forest:Yes, the — this is a 600 patient, randomize, placebo controlled, double blind study and it is accruing 600 patients. And we expect those 600 patients to be accrued sometime by the end of 2008. So the accrual process is actually expected to be quite timely.

Ling:Uh-huh.

Michael Forest:The trial will cost in the range of \$8 million and we are of course extremely interested in the possibility of partnering this compound and are having preliminary discussions with people who are interested.

I think that as we gather more data the interest level — as we more approach the conclusion of the study I think the interest level will be heightened. But we have set aside our own money to conduct this study and are pursuing it quite aggressively.

Ling:Okay and then turning to the DMD program — first of all can you — I guess can you give us a timeline, you know, regarding when you expect the enrollment of the nine boys like completed or when do you expect to see any data?

Michael Forest:Yes, that's a very good point. I think that we may be able to see data as we go along. How relevant it's actually going to be in the aggregate is probably not clear until all nine boys are treated. But the process is likely to be somewhat more lengthy than what we would see even in a systemic clinical trial.

And the reason for its lengthiness is that each boy will be treated and then wait for a period of several weeks before a biopsy can be taken from the muscle that has been injected. And then the biopsy's examined for evidence of production of functional dystrophin.

Ling:Uh-huh.

Michael Forest:The — and until all of that process has taken place the next boy will not be treated and an assessment will be made on the basis of the first boy as to what the — whether there needs to be an increase or a decrease in the dosage as they go forward.

So it's going to be a methodical and not as a timely a process as we would like to normally see in a systemic clinical trial. And so I think that probably we won't be able to get all the patients treated before the end of 2008 maybe — I'm sorry 2009. We of course would like to be surprised with a more speedy response in that but at this point in time that's the timeframe that we're looking at.

Ling:So the sequential dosing of the boys are like, you know, specified in a protocol ...

Michael Forest:That's correct.

Ling:Okay. And my last question is, is there — I just want to get a better understanding, you know, regarding the (process counts) of, you know, (low dose) administration versus systematic administration of this drug, you know, in particular in this disease (indication)?

Michael Forest:That's also an excellent question and the answer is that there are some indications that with the DMD children or patients rather that — who have progressed to a point of being totally immobilized with the exception of being able to ride around in a motorized vehicle using a joystick. And theoretically — or not theoretically, practically the only muscles that remain functional are in their hands and in their feet.

So the intramuscular injection into localized muscles may be an alternative for children of this type that are — that have progressed to a pretty advanced stage. So that's — could be an interesting, very significant enhancement in the quality of life for kids that are that far along.

On the other hand, systemic administration from an overall treatment benefit perspective is far more interesting to everyone including the children and to AVI.

Systemic administration really means that we would be able to administer the drug and have it penetrate into the appropriate cells to produce dystrophin throughout the body whether that's in the major muscle of arms and legs but also into the lungs and into the cardiac muscle, which also is affected over a period of time and is ultimately what causes the children to demise because the heart and or the lungs just stop working.

So systemic administration is really the ultimate goal of this therapy and it's the one that we are pressing the hardest with from AVI's perspective. And the one which we have already designed actually a clinical trial for systemic delivery of the product and are now in active discussions with several regulatory agencies to determine whether it — there is anything that remains to be done from a safety perspective before we're allowed to move into clinical trials.

So we're hopeful we will get an answer that will be positive to AVI such that these trials can begin sometime next year and hopefully be finished sort of in the end of 2008 or perhaps the middle of 2009.

But that timeline is entirely dependent on the view of regulatory authorities as to any potential requirement for additional toxicology work that might be necessary before moving into systemic administration in children.

Ling: Okay and the trial we're talking about is still ex-U. S. only or also in the U.S.?

Michael Forest: We're hopeful to be able to conduct both in the United States and in Europe but that has not been completely defined at this point.

Ling: Okay, thank you very much for taking my questions.

Michael Forest: You're quite welcome.

Operator: Once again, ladies and gentlemen, as a reminder, if you are a professional investor and would like to register for a question, please press star then the number 1 on your telephone.

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

Michael Forest: Well, thank you very much, everyone, for joining us today and for your support and your questions. We do look forward to keeping you updated on our progress at next conference call or as we obtain additional information for release to the public.

As usual if you feel like you wish to talk to us directly then don't hesitate to call either myself or Alan at the company and we'll be glad to provide you with additional information provided of course that it is all in the public domain.

Have a good day.

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