AVI BioPharma Incorporated First Quarter 2007 Financial Results Conference Call Transcript

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Moderator: Michael Forrest

May 9, 2007, 8:00 a.m. Pacific Time

Operator: Welcome to the AVI BioPharma First 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 the conference please press star 0 for Operator assistance.

As a reminder the conference is being recorded Wednesday, May 9, 2007.

I would now like to turn the conference over to Miss Jody Cain. Please go ahead ma'am.

Jody Cain: This Jody Cain with Lippert/Heilshorn & Associates. Thank you for participating on 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 2007 first quarter.

If you've not received this news release or if you'd like to be added to the company's distribution list please call Lippert/Heilshorn in Los Angeles at 310-691-7100 and speak with Brandi Floberg.

Before we begin I'd like to say 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 discussion of risk factors I encourage you to review the AVI BioPharma Annual Report on Form 10-K and subsequent reports as filed with the SEC.

Furthermore, the content of this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, May 9, 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 to Michael Forrest. Mike?

Michael Forrest: Thank you Jody. And my thanks to each of you who are joining us.

On today's call Mark Webber will review our financial results. Alan Timmins will provide updates on two programs - influenza and Duchenne Muscular Dystrophy - and I will comment on some additional efforts of the company.

First, however, I'd like to make a few remarks.

Having served as the - a member of the AVI BioPharma Board of Directors for more than two years, I have good understanding of our technology and I'm very familiar with the opportunities and challenges that our company faces.

My understanding of these areas has been further bolstered during the time that I've recently spent as a member of the AVI executive team.

Let me assure you that during this time of chief executive transition, our company has lost no momentum and we continue to make progress with a number of pre-clinical and clinical programs.

We've also begun a process of reevaluating all of our programs to identify those that have the greatest potential for near-term commercialization. This process was requested by the AVI Board of Directors as it will assist us in selecting a successor CEO with the appropriate experience to lead our company forward in the future.

As announced in late March, Jack Bowman - also a Board member for several years - accepted the position of Chairman of the Board. I assumed the roles as Interim Chief Executive Officer. As a courtesy to investors who may not know us, I'd like to briefly review our backgrounds.

Jack Bowman is an accomplished, experienced and well regarded leader in the pharmaceutical industry. His career spans more than 40 years at large pharma and smaller biotech companies.

Jack previously has served as company Group Chairman of Johnson & Johnson with global responsibility for much of J&J's pharmaceutical and diagnostic businesses. He also has served as Executive Vice President and President of American Cyanamid's Global Pharmaceutical, Medical

Device and Consumer Products businesses; has been President of Lederle Laboratories; and Executive Vice President of Ciba-Geigy's U.S. pharmaceutical businesses.

Jack has also served as Chairman and Chief Executive Officer of the biopharmaceutical company NeoRx Corporation in Seattle, and he currently serves on the Board of Directors of one of the largest biotechnology companies in the United States - Celgene Corporation - as its lead Independent Director.

My background includes more than 35 years of biotech and pharmaceutical experience in executive management, research oversight, clinical product and business development, strategic planning and M&A, marketing and sales positions in the U.S. and overseas markets. Most recently I served as President, Chief Executive Officer and a Director of Cellegy Pharmaceuticals, and prior to that I was President and Chief Executive Officer of Mercator Genetics, and President and Chief Executive Officer of Transkaryotic Therapies. Prior to that, I held senior management and marketing positions with Pfizer and with Lederle. I am currently a Director of Inex Pharmaceuticals, a Canadian company - a public company - developing cancer and immunotherapy products, and I'm also Chairman of Apex BioVentures, LLC, a private investing and consulting company that focuses on the emerging healthcare industry.

I'd like to personally thank Denis Burger for his tremendous contributions over the years to AVI and for his unwavering commitment to our company and to our science. There is no question that Denis was instrumental in AVI's growth and was a driving force behind the development of the technologies that have brought us to where we are today.

Now I'd like to turn the call over to Mark Webber to review our financial results. Mark?

Mark Webber: Thanks Mike.

Today I'd like to give you our 2007 first quarter financial results and cash position. And then I'll affirm our 2007 financial guidance.

Revenues from license fees, grants and research contracts in the first quarter of 2007 were $536,000 compared to revenues of $66,000 reported in the first quarter of 2006. The increase reflects higher research contract revenues of $485,000 and licensing fees of $31,000, partially offset by decreases in grant revenues of $46,000.

Operating expenses for the 2007 first quarter were $10.6 million compared with $9.6 million in the 2006 first quarter. This increase was due primarily to higher general and administrative expenses, which increased to $4.2 million from $2.8 million in the first quarter of 2006.

General and administrative expenses in the 2007 first quarter included employee costs of approximately $1.2 million. Of this amount, approximately $1.6 million related to the separation and release agreement with the company's former Chief Executive Officer including $563,000 in cash compensation and $1.1 million in SFAS123R expenses. G&A expenses also included increases in legal costs of $230,000 and accounting expenses of $50,000. The increase in G&A expenses was partially offset by decreases in SFAS123R expenses of $130,000 and salaries and bonuses of $330,000.

Research and development expenses decreased in the 2007 first quarter to $6.3 million versus $6.8 million in the prior year quarter. The decreases in R&D expenses included decreases in employee costs of $940,000, of which $430,000 was related to the acceleration of the vesting of certain stock options in the first quarter of 2006, SFAS123R expenses of $140,000, salaries and bonuses of $360,000 and clinical trial-related expenses of $500,000. The decrease in R&D expenses was partially offset by increases in chemical and lab supply costs of $390,000, government contract-related equipment expenses of $350,000, professional consultant costs of $160,000, lease hold and patent amortization expenses of $50,000 and facility costs of $40,000.

We reported net loss for the first quarter of 2007 of $9.7 million or 18 cents per share, which compares to the net loss of $9.1 million or 18 cents per share for the first quarter of 2006.

Reviewing our balance sheet -- we reported cash, cash-equivalent and short-term securities of $27 million as of March 31, 2007, a decrease of $6.1 million for December 31, 2006. This decrease was due primarily to $5.5 million used in operations and $610,000 used for the purchase of property, 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 toward funding our development of antisense therapeutics to treat the effects of Ebola, Marburg, and Junin hemorrhagic viruses, which are seen as biological warfare and bioterrorism agents. In the first quarter of 2007 we received $485,000 from DTRA under this contract.

In January 2006 we were informed that in accordance with the final version of a 2006 Defense Appropriation Act approved by President Bush, AVI will be allocated $11 million to fund our ongoing defense-related programs including Ebola, Marburg and Dengue viruses as well as anthrax and ricin toxins. Of this amount we expect to receive up to $9.8 million net of government administrative expenses. Last week we received signed contracts valued at $7.1 million that include $2.7 million each for Ebola and Marburg projects and $1.8 million for anthrax and ricin projects.

We expect to receive these funds over approximately the next year as research is completed and invoiced to the government. The final project under the original allocation - dengue virus - is in the final stages of discussion.

In reviewing our 2007 financial guidance, we expect to continue our net cash burn for the year to be in the range of $10 million to $17 million, principally depending on the extent of reimbursement from our government programs.

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

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 influenza program.

As previously announced, we've published confirmations through independent laboratories of efficacy in pre-clinical in vitro experiments against multiple strains of influenza. Included in these is the avian influenza strain, H5N1, a potential world-wide public health threat.

Just this past week we announced the results of pre-clinical in vivo experiments in a mouse model. The NeuGene® PMO demonstrated efficacy in an animal model following aggressive challenges by two strains of seasonal flu. We're hopeful that these data will be of interest to one or more of the players in the seasonal influenza business. The goal of our internal influenza program is to develop a drug to combat the H5N1 subtype of avian flu.

We based our decision to pursue this target, rather than seasonal influenza, on what we believe is the fastest regulatory pathway to drug approval, thereby maximizing the use of our resources. We're taking the next step to support the filing of an IND In this indication which is the evaluation of our compounds in additional animal models to test the potential efficacy directly against the H5N1 subtype of avian flu.

Turning to our NeuGene-based exon-skipping pre-RNA interference technology, or ESPRIT, I want to note that we see many opportunities with the therapeutic technology. ESPRIT technology was developed to have the ability to delete disease-causing genetic sequences or skip mutated sequences to allow expression of functional proteins in certain diseases. As such, ESPRIT represents a potentially highly potent tool for altering many disease mechanisms.

Our first clinical target with ESPRIT is Duchenne muscular dystrophy, or DMD. Briefly, DMD is a rare, lethal genetic disease that afflicts boys and is caused by mutations in the dystrophin gene such that dystrophin - which is required for muscle function - is not produced. A defect in exon 51 is the most common genetic abnormality in DMD, accounting for approximately 17% of all cases. Our current program objective is to use an ESPRIT-based therapeutic, AVI-4658, to skip exon 51 so the functional version of dystrophin might be produced.

We're waiting for regulatory approval to begin our first clinical trial which will be conducted in collaboration with the MDEX Consortium in the United Kingdom. The study will recruit up to nine boys with DMD. Each boy will receive a single intramuscular administration of AVI-4658 at a pre-determined dosage level. Approximately four weeks following dosing, the injected muscle will be biopsied and examined for molecular evidence of dystrophin production. The identification of dystrophin within the biopsied muscle will be one of the endpoints of the study.

We believe that this study will be an important step in furthering our ESPRIT therapeutic approach. The study is expected to provide us with useful safety and pharmacokinetic information for our activities to expand AVI-4658 clinical development to systemic administration for treating DMD. To prepare for the systemic study, we'll hold a pre-IND meeting with the FDA and we're already exploring domestic and international clinical sites to evaluate the safety and efficacy of our ESPRIT compound in DMD patients.

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

Michael Forrest: Thank you Alan. Before we take your questions I'd like to spend a couple more minutes to review and recap our key programs.

First in the cardiovascular program, we are on track with our coronary artery bypass graft clinical trial. There are two sites that are actively enrolling patients and we hope to evaluate the interim safety results in the third quarter following the treatment of the first 30 subjects. Assuming the safety profile is acceptable we can then proceed into the next phase of this study and expect to receive safety results from the first 110 patients early in 2008.

As an update to our license agreement with the Cook Group for development of NeuGenes for vascular disease - in a very recent conversation Cook indicated to us that the last patients in the APPRAISAL trial will be evaluated in early June and that Cook intends to provide a preliminary non-adjudicated overview of the study results following their review of the data from that last patient.

Turning to our work in infectious diseases, in our program for the treatment of Hepatitis C virus, we're currently awaiting regulatory approval to begin enrolling chronic HCV patients in an open-label, dose-escalating clinical trial. The trial protocol has been designed to increase the blood concentration of AVI-4065 with the objective of achieving a clinically significant reduction in viral load. We have identified overseas clinical sites and have produced the drug for conducting this trial. Following review of the data from this trial, we will then be in a position to determine the next steps for the HCV program.

In our influenza program, as Alan mentioned, now that we've obtained positive results with our PMOs in animal model for seasonal flu, we'll be permitted to test our compounds in animals inflicted - or affected with, rather - the aggressive H5N1 subtype of avian flu. AVI intends to conduct these studies at commercial labs in order to better maintain influence over the timeliness of the work. If successful, the studies are expected to provide sufficient pre-clinical data to support the filing of an IND to permit a Phase I safety study in healthy volunteers.

With our first program based on ESPRIT therapeutics, or exon skipping, we're awaiting regulatory approval, as Alan mentioned, from the UK authorities to begin dosing in the pilot clinical study in DMD, targeting exon 51. And as he also mentioned, we're already making preparations for a systemic study to treat boys afflicted with this particular mutation.

And finally as we announced in late April, we've acquired a 34,000-square-foot facility in Corvallis that will house additional capability for the large-scale GMP production of AVI's proprietary PMOs and for the recovery and purification of PMO precursors. This facility is expected to provide the additional capacity required for both of these processes in order to meet the anticipated bulk drug supply requirements for both AVI and its partners and potential partners.

Again, we're making progress in evaluating each and every one of our programs with the purpose of providing an increase focus on those programs that demonstrate the greatest near-term commercial opportunities.

So with that update, I'd like to open the call to your 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 you 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 speaker phone, please pick up your handset before entering your request.

One moment please for the first question.

Michael Forrest: Operator, while we're waiting for the first question I'd like to let everyone know that Alan Timmins will be presenting and the Rodman & Renshaw Fourth Annual Global Healthcare Conference that's being held in Monte Carlo on May 14 and 15.

And additionally we have two upcoming presentations by senior scientific staff. First, Dr. Hong Moulton will be making an invited oral presentation on peptides used in PMOs for enhanced cell delivery while minimizing toxicity at the Biochemistry Society Transactions meeting in London, tomorrow, May 10. And David Stein will be making a presentation on May 26 at the Positive Strand RNA Virus meeting discussing our work on corona viruses.

Operator I think we're now ready.

Operator: Your first question will come from the line of Ling Wang with Rodman & Renshaw. Please go ahead with your question.

Ling Wang: Hi. Thank you for taking my questions.

My first question is regarding the DMD program. You mentioned you're waiting - still awaiting - on approval from the EU Agency. Can you maybe comment on what are the pending issues for initiating this trial and when do you expect, you know, to dose the first patient?

Michael Forrest: It's - as is usually the case when you're dealing in a regulatory situation, you never can predict exactly what's going to happen.

But in Europe - and in this case it's the UK – it's the NHRA there, which is the regulatory body that's equivalent to the FDA, is considering the antisense treatment of Duchenne patients to be a gene therapy-like treatment. And as such, it's had to go through two different approval processes. One is the Gene Therapy Advisory Committee, which it's now passed and they've blessed it and said that it's safe and effective - potentially effective - and should be accepted.

And now it's in front of the regulatory authorities, who like any good regulatory, need to review all of the data that is associated with such treatments before they can sign off and give you approval to proceed. It's largely bureaucratic and unfortunately we can't make a prediction as to when the approval is granted. However approval is expected.

There is a site lined up that will be handling the nine boys that Alan mentioned in the UK; so as soon as we get the go-ahead from the government that site will start enrolling. And I think patients are already pretty much lined up to enter once the approval is given. So after that starts, then we'll be in a better position to update you on what we think the timeline might be.

Ling Wang: Okay. My second question is regarding the, you know, your APPRAISAL trial with Cook. Is Cook still on track to present the data the Euro PRC meeting this month?

Michael Forrest: Well you know that's a good question. I presumed that they were not on track to do that because in a very, very recent conversation - I think it was a matter of a day or so ago - the people at Cook indicated to us that they're waiting for the finishing - the last patient in the APPRAISAL study and that they expect to be able to review the data on that patient in June. So I'm presuming that they're waiting to make the review of that data that they will not be presenting in May. But I don't know that for certain.

Ling Wang: Okay. But you would expect the pretty much complete analysis in maybe third quarter of this year?

Michael Forrest: They've indicated to us that as soon as they finish reviewing the last patient that they will make their own data - make that information available.

Ling Wang: Okay. All right. And my last question's about the HCV program. You mentioned you wanted to initiate the dose-ranging study in EU. Just want to, you know, understand why make it - what drives you to make the decision, you know, to switch it from the U.S. to overseas?

And also based on the experience that you have learned from previous clinical trials and also pre-clinical studies, what are the dosing range that you are going to test in this trial?

Michael Forrest: That's a number of questions. Thank you.

The - we decided to take the study overseas because we thought it would be much faster and less expensive trying to conserve our hard-earned dollars here. So and we know that the medical capabilities are very high in the areas where we're planning to do this. So that's the reason for going overseas.

The study is designed to move to quite high doses to see if we're able to achieve sufficiently robust viral titer - in other words something that we think is clinically meaningful - and that would be a one and a half log reduction in viral load or perhaps greater. And the dose levels will be at three different levels - 100 mg of drug that's delivered every four hours IV, the second cohort will be 200 mg every four hours IV, and the third will be 300 mg IV. And these will be sequential tests in order to examine patients for both efficacy and safety and as I said it seems a pretty straight forward trial and we're expecting approval from the regulatory authorities and should be able to get that underway as soon as the approval is given.

Ling Wang: Okay. Thank you very much for taking my questions.

Michael Forrest: You're welcome.

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

Your next question will come from the line of Ding Ding with Maxim. Please go ahead with your question.

Ding Ding: Great. Thank you. Good morning.

Michael Forrest: Good morning.

Ding Ding: Good morning. Thanks for taking the question - a few questions here. First, thanks Michael for sharing additional details of your and Jack's background with us. I think that's very helpful.

Would you please give us an update of how the transition period has been going and what are the focus areas for you as since you've become the new CEO of the company?

Michael Forrest: Yes. First of all I think the transition's gone quite smoothly. We've - no one's run for the door so I that's a good idea - or a good sign. And we're not planning any further management changes so I think that's also good. So I think the situation is relatively stable.

What I've been concentrating on is at the request of the Board to take an in depth look at all of our programs in order to ascertain which of those are - we're able to move the quickest into the clinical setting so that we can begin to produce some additional value for the company. There's a tremendous amount of research that's available in the company - a tremendous amount of technology and some very, very smart people. So we want to take a look at not only the programs that we've just discussed with you, but also other programs that are in the pipeline which may not yet have surfaced and perhaps deserve to be elevated to a faster track status. So we're going through that entire process, as well as a review of the manufacturing issues and to best position the manufacturing plant for quick turnaround and begin to get it online as soon as possible.

And this is the 34,000 foot facility that we just bought. So there's a lot going on. There's a lot of dialogue that's taking place at the senior management level and below and I think things are actually progressing quite nicely.

Ding Ding: Great. That's helpful.

And secondly I understand that the management team was most recently at the BIO Conference in Boston earlier this week. Any color you can share with us on the partnership discussions specifically related to the drug metabolism program, exon skipping and today you also mentioned the avian flu that could also be open to partnership opportunities. Any color your can provide?

Michael Forrest: I can give you some flavor, yes, but I'd like Alan to chip in on this as well. The - in terms of the meetings that I sat in on - I wasn't able to sit in on all of them - and first I'll preface this by saying that none of these meetings are designed to sit down and make deals. They're designed to update some potential partners on where we are since we last saw them and to see if there's any change in their ideas about programs that they need help on.

So, and those several meetings that I was in - rather than talk about specifics I'll just say that there seems to be a tremendous amount of interest in our exon skipping technology and if you mention - as you mentioned specifically the idea of using our NeuGene technology to work in the area of cytochrome P450 inhibition is also something that's gathering a significant amount of attention. I was actually quite encouraged by the enthusiasm that we were hearing from some very sophisticated people in the largest pharmaceutical companies that you can imagine. Alan would you like to add to that?

Alan Timmins: Yes Mike. Thank you. And thanks for the question, Ding Ding. There was also quite a bit of interest just in monitoring the progress going forward in the CABG program as well. I think what Mike and I are both trying to communicate is that the interest level seems to be quite good for our products and our technology.

I think that the ESPRIT application of our technology has maybe broken that page that's existed for so long wherein we were bound somewhat by the failures of other antisense companies in high level clinical trials previously.

I think people are now seeing that because our technology once again is reflecting its great flexibility and applicability across a number of projects, you know, we're starting to see people - for lack of a better word - come back to the table, express interest, try to discern ways that our technology may be applicable in their own particular clinical and development areas of interest.

So I was quite encouraged and I did attend all of the partnering meetings that we had over the first couple of days and I'm very encouraged by attitude and the openness that people had and the interest that they had in our technology. It was clear that companies had been paying attention and following our progress.

Ding Ding: Great. That's very helpful.

And on the Resten-MP program I understand we may not see the data at Euro PCR meeting but based on your communication with Cook are you still under the impression that in terms of a clinical development strategy of both Resten-MP and-NG going forward will be dependent on this data?

Michael Forrest: My understanding is that the people at Cook are still - are very positive about the results that they have seen and their expectations for the program. We have not looked at the data so I can't make a comment and I can't comment on what they will actually end of saying about the results of the trial that they've been taken. But I have no indicators that anything other than - that they're going forward in good faith and with a great deal of positivity.

Ding Ding: Okay. Maybe just one last question before coming back to the queue. On the flu program, if a partner is to be involved - first of all are we still waiting to receive animal data from the three independent investigator before we file for IND? And what are the studies that need to be done before we file for IND?

Michael Forrest: Thank you. That's actually a very good question.

To be honest I think that we kind of lost our way on the flu program a little bit. And it shifted away from what we originally intended it to be, which was a focus on the pandemic H5N1 program as opposed to pursuing aggressively the - an approach for the treatment of all seasonal types of flu.

While it's a great idea to pursue seasonal flu, unfortunately the cost of clinical development in this area is huge - I think Tamiflu, for example, spent $600 million and multiple years and a Phase III clinical trial to get that - have that product approved.

So our focus is not going to be on taking it all the way to the clinic with seasonal influenza. And we're hopeful that the data we've just generated will be sufficient to at least pique the interest of some of the companies that are involved in the traditional avian influenza area. So we don't intend to do a great deal more work in that broad seasonal flu field unless we get an indicator from a partner that they would like us to do some work on their behalf.

The target is really H5N1. And with H5N1 what we're doing - and the reason for H5N1 is because it's a much faster regulatory path and a much more defined outcome - so what we want to do now is that we've completed enough preclinical work in animal models to allow us to be able to have access to models in which the animals can be challenged with a very aggressive H5N1 subtype of avian flu. Those - we expect that we'll be doing two or perhaps three animal tests as soon as we possibly can to have them challenged with H5N1 and pretreated and/or treated with our PMOs. Assuming it does pass the test then I think that we will have a sufficient amount of data to be able to go to the FDA and say, "Here's all the safety information that we've done. Here's the potential efficacy we've seen in animal models.

Now what we'd like to do is to test the PMO in healthy human volunteers to ensure that there's no safety issues associated with that particular PMO when given to man.

If that works out then I think that we - under the new animal regulations- would be in a position to potentially sell the product to the government for stockpiling or have it available in an emergency basis if there were an outbreak of pandemic influenza. So I think we're on the right pathway. I think we're on the right track and I can assure you we're going to be pushing this very hard.

Ding Ding: Great. That's very helpful. Thank you.

Michael Forrest: You're welcome.

Operator: Your next question will come from the line of Lanny Stout with National Planning Corporation. Please go ahead with your question.

Lanny Stout: Hi Mr. Forrest. Question on Ercole - its role that they're going to play with the Duchenne muscular dystrophy project and could you also bring us up to date on Eleos a little bit of what your plans are with that recent collaboration you're doing there?

Michael Forrest: Okay. I'll answer the first question. Ercole - the arrangement with Ercole is that - and this last deal that we've just announced is a focus on Duchenne muscular dystrophy and beta-thalassemia. Beta-thalassemia as you know is probably one of the most highly prevalent genetic disorder in the world but its prevalence varies depending on areas of the world. It's much more highly prevalent in Asians, for example than in Caucasians.

The program is such that Ercole will focus their efforts on beta-thalassemia - developing a product for beta-thalassemia, and we're focusing our efforts on developing a treatment for Duchenne muscular dystrophy. Either of us has the option to fund such programs at a rate of 50% of the cost of those programs and if that funding is maintained at that 50% level then the companies will - the funding company will enjoy the right to share 50% of the profitability associated - the ultimate profitability associated with that product.

So far we have taken the lead on DMD, are moving very quickly. Ercole has not yet declared to us whether they intend to support it from a financial standpoint - but we'd be very pleased if they do. And they're in the early stages with beta-thalassemia and depending on the way the program that they design looks we may be interested in participating in that ourselves. But. it's too early to say at this point in time because they just don't have that much data. Now I believe either - with regard to your second question - either Alan - perhaps you could comment on this or have someone help you with that?

Alan Timmins: Yes. I can comment on that. Eleos has a very strong intellectual property position surrounding a gene known as p53. And so our deal with ELEOS in p53 - they have already conducted or are conducing a Phase II clinical trial in p53 applications for cancer using a different antisense structural type than ours.

The Eleos interest in our technology is to have access to perhaps a better antisense technology before addressing p53 in cancer and so we entered into this collaboration to give them some access to our NeuGene technology to apply in p53 in cancer which is what they're active in the clinic now.

So the potential exists for them to in essence bridge over to our compound from the other antisense technology that they're using. What we got in return on this - besides a cash infusion that will be recognized as revenue over the next four years or so - is we got access to their intellectual property for p53 for infectious disease which is an area, obviously that ties in both with our government efforts and then with some other efforts.

Infectious disease, of course, include hepatitis C, etc. So what you see there is a true cross-licensing. It allows them access to our technology in a narrowly focused are of cancer which we ourselves would not have pursued - p53 in cancer. And it allows us access to what we believe is potentially a broad area which is p53 application in infectious disease. So, a win-win for both companies.

Lanny Stout: So they really wanted you technology antisense to go after the p53 gene and where they'll do that (unintelligible) target therapies out there for p53.

Alan Timmins: Right. And where they'll that is in cancer.

Lanny Stout: Okay. Well that's generally what they go after in p53 because it's a cancer-suppressor gene, so.

Alan Timmins: Well but it's also - well we believe that it's a very good target in infectious disease so that was part of our motivation for entering into the….

Larry Stout: That's why I was trying to figure out why since there's other people competing with p53 in cancer - what was your interest in that Eleos deal with the antisense on the infection part, so. That was it - I appreciate that.

Alan Timmins: Thanks for your question.

Operator: Your next question will come from the line of Phillip Wiggins with Pharm South. Please go ahead with your question.

Phillip Wiggins: Yes. This is in reference to ESPRIT. Since Genzyme has gene therapy trials ongoing, do you see Genzyme as more of a potential partner or competitor at this time?

Michael Forrest: I think that we look at anybody who is a potential competitor as a potential partner. If you understand what I mean.

I think that the technology that Genzyme has in their approach to genetic diseases is broad and it's varied. It's not quite the same as the technology

that we have. So I would think that since they're interested in some of these genetic diseases that one could look of them probably more appropriately as a potential partner. But it depends on how we make progress with our own projects particularly in DMD - we may decide to take this one all the way ourselves.

Phillip Wiggins: Thank you and one last question. There was no reference to the NeuBiotics program for resistant gram-negative bacteria. Is that program still viable?

Michael Forrest: That program, to the best of my understanding, is still viable. It's not one that I personally have reviewed but it's one that's very high on my list because it holds, I think, tremendous potential. So I - Alan if you want to add something to this, you can. But I answered to the best of my knowledge.

Alan Timmins: Yes. We do have some ongoing efforts in that arena.

Perhaps why you're not hearing NeuBiotics is a trademark for us that we've pursued, we tended to not use that term now as it's also a trademark that's pursued by, you know, a couple of hundred other pharmaceutical companies. So we - at the research level - we don't call our things by trademark names. But we are looking at specifically we are still active in that at the research level and moving forward.

Phillip Wiggins: Well I just wanted to comment on that - I appreciate that and I know you, you know, you can't go after all programs as was stated earlier in the beginning. But knowing that gram positive organism resistance is - we have some drugs, like Zyvox and Cubicin - but my understanding in the gram negative resistance are even when gonorrhea is now becoming resistant to just about every drug - I think that's a smart market target - just the gram negatives.

Michael Forrest: You know, just as a parenthetical comment, I completely agree with you, having a lot of experience in this area and in an earlier life. And I will be looking very carefully at the program in the weeks and months ahead.

Phillip Wiggins: Thank you very much.

Michael Forrest: You're welcome.

Operator: Your next question is a follow-up question from the line of Ding Ding with Maxim.

Ding Ding: Thank you for taking the follow-up question. Just a few follow up. One on the hep-C program; besides the dose escalation is the protocol largely consistent with Phase Ib we completed earlier in terms of treatment duration? Is it 14 days or 28 days or - what's the consideration there?

Michael Forrest: You know, I think the duration is seven days in this case but I'm not - I'm speaking from memory which may be failing me for the moment; Alan do you recall?

Alan Timmins: Yes. It is seven consecutive days and it's an IV infusion rather than a subcutaneous route of administration but it is for seven consecutive days.

Ding Ding: Great. And IV infusion every four hours.

Michael Forrest: Every four hours - that's correct. Well the drug is administered every four hours by IV.

Alan Timmins: Right.

Ding Ding: Okay good. And secondly on the DMD program, it was my previous understanding that the IND filing is independent from the pilot study you are conducting in UK. Is that still the case? And secondly you mentioned that you're preparing for systemic delivery. Do we have a formulation developed or is it still to be done?

Michael Forrest: Those are excellent questions.

The IND filing is believed to be independent of the study that's taking place in the UK but it's not known to be independent. So we are in the process of pulling together all of the information that we have on DMD, which is quite substantial. And are making an appointment with the FDA as part of a discussion on a pre-IND basis so we can have a good understanding as to what they are going to - how they will be viewing a clinical program - the systemic clinical program for the treatment of this deadly disease.

We have obviously have the molecules that we're using for intramuscular injection in the UK. And we believe that that same PMO will be appropriate for systemic use but we'll have a little bit better of an idea when we get the results back from the DMD study in the UK.

So the answer is that it's not necessary - we don't believe that it's necessary to have the additional data from the UK study before starting the systemic study but I think given first our emphasis on safety and our know expectations of the FDA and other authorities it probably would be helpful. So to clear the way we're having the pre-IND meeting with the FDA and we'll have a much better understanding at that time.

Ding Ding: Okay. That's very good. And lastly on the CABG program, can you give us any color as to how the patient enrollment is coming along? What's the next data point we should expect to see? Do we need to wait till the first 110 patients are enrolled or are we going to have some safety read from the first 30 patients by mid-year?

Michael Forrest: We are going to have some safety read from the first 30 patients. Of course, it's going to tell us nothing other than the product is - seems to be safe in comparison to untreated patients - in other words no real difference from a safety standpoint. But of course we will have no indicators of efficacy, otherwise the trial would become unblended.

So when we get to the 30 patient stage and assuming that the green light is given by the safety monitoring committee, then we'll be able to say - tell you that we've proceeded to the next phase and that the safety parameters seem to be okay. But we won't be able to tell - as we won't know - what's going on from an efficacy standpoint.

Ding Ding: Great. Thank you very much.

Michael Forrest: You’re welcome.

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

Michael Forrest: Okay well thank you very much for all of us joining today. And thank you very much for your excellent questions.

We appreciate the opportunity to update you and we will try to do so as crisply and as forthrightly as is possible in all future communication.

And we look forward to doing just that at our next conference call or sooner should it be necessary.

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 line.

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