AVI BioPharma Incorporated First Quarter 2006 Financial Results Conference Call Transcript

5/10/06

Moderator: Jody Cain

May 5, 2006, 8:00 a.m. Pacific Time

Operator: Welcome to the AVI BioPharma 2006 First Quarter Financial Results conference call. At this time all participants are in a listen–only mode.

Following management's prepared remarks we'll hold a Q&A session. To ask a question, please press star followed by 1 on your touchtone phone. If anyone has difficulty hearing the conference, please press star 0 for operator assistance.

As a reminder, this conference is being recorded Friday, May 5, 2006.

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

Jody Cain: This is Jody Cain with Lippert Heilshorn & Associates. Thank you for participating in today's call.

Joining me from AVI BioPharma are Denis Burger, chairman and chief executive officer, Alan Timmins, president and chief operating officer, and Mark Webber, chief financial officer.

This morning AVI BioPharma released financial results for the 2006 first quarter. If you've not received this news release or you'd like to be added to the distribution list, please call Lippert Heilshorn in Los Angeles at 310–691–7100 and speak with Cheryl Park.

This call is also being broadcast live over the Internet at www.avibio.com. And a replay of the call will be available on the company's Web site for the next two weeks.

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

These forward–looking statements involve material risks and uncertainties. For a discussion of risk factors, I encourage you to review the AVI BioPharma annual report on Form 10–K and subsequent reports as filed with the Securities and Exchange Commission.

Furthermore, the content of this conference call contains time–sensitive information that is accurate only as of the date of the live broadcast -- May 5, 2006. The company undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this conference call.

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

Denis Burger: Thank you, Jody and thank you all for joining us today. I want to start today's call with a brief progress report on our cardiovascular program and on our hepatitis C trial.

Mark Webber will summarize our financial results. And Alan Timmins will spotlight our recent license agreement with Cook Group to develop our NeuGene® drugs for vascular diseases.

I will conclude with a review of key near–term activities and milestones and we will then take your questions.

First, in our cardiovascular program we are delighted with our licensing agreement with the Cook Group to develop NeuGene drugs for the treatment of vascular diseases.

Our agreement covers AVI–4126, which includes Resten–NG® and Resten–MP™ with a down–regulation of the c–myc gene, which is the key regulator in the development of cardiovascular restenosis.

I want to share with you the strategic importance of this relationship to AVI. First, we are in the enviable position of having an antisense technology that has potential applications in many unmet medical needs, some of which represent large market opportunities.

This means that we have the option to out–license drug development for certain indications while focusing internal resources in the development of others.

With the decision to out–license AVI–4126 for the treatment of vascular diseases to Cook, we are now in the — able to focus our cardiovascular efforts internally on coronary artery bypass grafting.

Second, we have completed the development of AVI–4126 for restenosis through relatively inexpensive phase 1 and phase 2 trials. And now could have faced more expensive phase 3 trials in both Europe and the U.S. that could reach $50 million to $90 million over the next two to five years.

Third, we would have needed to acquire additional licenses for both catheter and balloon technologies that could have led to legal delays, and could have been quite costly.

Finally, with this agreement our technology is being developed by one of the preeminent vascular device companies in the world.

Cook has the resources, licenses and the experience to run large clinical programs, which could mean faster development timeline. Further, Cook has the sales and marketing resources for product commercialization.

We believe with Cook's device expertise and our antisense technology, we have a formidable combination to address vascular diseases.

Now turning to our hepatitis C program, we will present initial data from the first few patients to complete the treatment protocol from the second phase of our study with AVI–4065 for the treatment of chronic active hepatitis C virus infection at the International Congress on Antiviral Research in an oral presentation on May 10.

This trial will include up to 40 hepatitis C patients divided equally between two cohorts -- those who have not received other therapies and those who have failed current standard therapy, which is interferon and ribavirin.

This phase of the trial assesses safety, pharmacokinetics, tolerability and early indications as — of efficacy as measured by HCV virological responses over the 14–day treatment protocol and subsequent follow–up.

Also at the ICAR meeting, we will present an update on our avian influenza program on May 9.

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

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

Our revenues from license fees, grants and research contracts in the first quarter of 2006 increased to approximately $66,000, up from revenues of approximately $45,000 reported in the first quarter of 2005. This increase was due to higher grant revenues.

Operating expenses in the 2006 first quarter increased to $9.6 million compared with $5.6 million in the comparable 2005 quarter.

This increase was due primarily to higher research and development expenses, including increases in R&D employee costs of approximately $1.1 million, of which approximately $540,000 was upon adoption of SFAS 123R. And approximately $430,000 related to the acceleration of a vesting of certain stock options.

This R&D increase also includes $500,000 in AVI common stock issued to Chiron Corporation as the first milestone payment under a license agreement, granting AVI a nonexclusive license to Chiron's patents and patent applications for the research, development and commercialization of antisense therapeutics against hepatitis C virus.

In addition, this R&D increase includes approximately $400,000 in contracting costs for the production of GMP subunits, which are used to manufacture compounds for future clinical trials.

The remaining R&D increase was due to increases in clinical trial and consultant costs.

General and administrative expenses increased to $2.8 million in the first quarter of 2006 from $1.4 million in the first quarter of 2005.

This G&E increase was due primarily to increases in employee costs of approximately $1.2 million, of which approximately $510,000 was on adoption of SFAS 123R and approximately $400,000 related to the acceleration of a vesting of certain stock options.

The remaining G&A increase was due to increases in accounting and legal costs.

We reported a net loss for the first quarter of 2006 of $9.1 million or 18 cents per share. That's compared to the net loss of $5.5 million or 13 cents per share for the first quarter of 2005.

Our 2006 first quarter results include stock–based compensation expenses of $1.9 million.

Of note is that this is the first time that compensation costs for stock options have been reflected in our financial statements under the new regulations. As has been our practice for more than ten years, eligible employees receive stock option grants each year.

To put the new reporting guidelines into perspective, our cash used in operations in the first quarter of 2006 was in line with expectations.

Reviewing our balance sheet, we reported cash, cash equivalents and short–term securities of $49.4 million as of March 31, 2006. This represents an increase of $2.4 million from December 31, 2005.

The increase is attributed primarily to the receipt of $5 million in net proceeds from a stock purchase agreement with the Cook Group and $3 million in exercise of warrants and options during the first quarter of 2006.

This is offset by $5.2 million used in operations and approximately $290,000 used for purchases of property and equipment and patent–related costs.

Additionally, in January 2006 we were informed that the final version of the 2006 Defense Appropriations Act had been approved. AVI expects an allocation of approximately $11 million to fund our ongoing defense–related programs including Ebola, Marburg, dengue viruses, as well as anthrax and ricin toxins.

These funds have yet to be received and are not reflected in our first quarter financial statements.

Today we are affirming our financial guidance for 2006. We expect cash burn for 2006 to be in the range of $15 million to $20 million.

With that overview, I'd like now to turn the call over to Alan Timmins. 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.

Today I want to discuss our licensing agreement with Cook Group to develop and commercialize products for vascular diseases, which we announced in March.

As Denis mentioned, Cook is a truly powerful partner for this program. In fact, Cook is the world's largest privately held medical device company, and is the leading designer, manufacturer and global distributor of minimally invasive medical device technology for diagnostic and therapeutic procedures.

Cook has specifically licensed our NeuGene agent AVI–4126 for down–regulating the expression of the c–myc gene in the field of vascular disease. The license to Cook includes device delivery of Resten–NG and Resten–MP, the microparticle formulation of our drug.

Excluded from this license are NeuGene applications in coronary artery bypass grafting, congestive heart failure and cancer. Cardiovascular restenosis is the renarrowing or reclogging of arteries following balloon angioplasty or the placement of a stent.

Rates of restenosis following these procedures can range between 10% and 40%, depending on the type of vessel treated and the patient's medical history. The c–myc gene is believed to regulate the many downstream genes that produce the pathology of restenosis.

Injury to the vascular lining during angioplasty and stent placement immediately initiates an elevated expression of c–myc, which can result in increased cellular proliferation and tissue growth.

While conventional pharmaceutical compounds work by retarding certain aspects of the restenosis response, AVI–4126 targets the c–myc gene. C–myc activation peaks at 24 to 48 hours before subsiding.

Our NeuGene antisense drugs are particularly suited to prevent this process because they can be delivered immediately following injury to the angioplasty site by either catheter or stent elution, or by systemic delivery using AVI's microparticle delivery system.

Cook Group has already assumed control of the ongoing late–stage Resten–MP trial called APPRAISAL, as well as the Resten–NG drug alluding stent program.

The APPRAISAL trial is a placebo controlled study and it's being conducted at multiple major medical centers in Germany in collaboration with the Harvard Clinical Research Institute or HCRI.

HCRI is an internationally recognized organization specializing in the management of trials in coronary artery disease and stents. Resten–MP is being delivered via IV injection to angioplasty patients after bare metal stent placement.

The primary goal of the study is to assess Resten–MP's ability to reduce late loss or the decrease in luminal diameter from the time of the intervention to patient follow–up at six months.

These results will be compared with the historic data from Harvard Clinical Research Institute's database, which includes information for more than 20,000 patients.

As part of the agreement, Cook will fully fund the development, clinical and regulatory costs of these programs in the U.S. and in Europe through to production — to product commercialization. This funding is expected to result in expenditures by Cook that could reach $100 million.

We have also entered into a supply agreement under which we'll sell to Cook the drugs for development, clinical studies and commercialization at a manufacturing margin.

In conjunction with the licensing agreement, Joe Horn, who was our VP of Cardiology and his team in Colorado have rejoined Cook to advance these programs through clinical development and into commercialization.

During the past year at AVI Joe and his team were instrumental in moving AVI–4126 cardiovascular programs forward. And we're exceptionally pleased that they will continue their great work to bring these products to market.

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

Denis Burger: Thanks Alan. Before opening the call to your questions, I'd like to review our upcoming milestones.

Based on our partnership with Cook we are able to apply resources more aggressively toward our internal programs. Let me start with a review of our cardiovascular program.

We have focused our internal cardiovascular efforts exclusively on coronary artery bypass grafting program. We expect to move this program into a phase 1b/2 clinical trial later this year.

We see this program as an ideal one for internal development. We have strong preclinical data in this indication and currently there are no competing products on the market.

The American Heart Association estimates that there are about half a million coronary artery bypass grafting operations performed in the U.S. each year. This means that we are addressing a large market opportunity.

In our infectious disease program we are focusing commercial development on HCV hepatitis C, influenza and dengue virus diseases. As discussed, next week we'll be announcing data from the initial patients to complete the treatment regime in the second phase of our hepatitis C program.

In addition, we are continuing to monitor trial patients at one, three, six months to further assess patient responses to AVI–4065.

In avian flu, based on strong preclinical results from independent laboratories, we have now moved into animal testing at multiple institutions. We expect to file an IND with the FDA for this indication later this year.

Finally, we expect to finish preclinical work with the dengue virus program this year. This is expected to be the next viral program to move into clinical development.

With our NeuGene–based exon skipping technology, or ESPRIT, program we expect a clinical trial for the treatment of patients with Duchenne muscular dystrophy to begin again later this year.

Currently we are working with a consortium that includes pharmaceutical companies, academic institutions and foundations with an interest in muscular dystrophy.

A member of this consortium, GlaxoSmithKline, has posted the clinical trial outline using our technology to the FDA Web site, ClinicalTrials.gov.

So in closing, we are making considerable progress. We have a premier industry partner to advance late–stage drug development in vascular disease. We have a strong drug development pipeline.

We are focused on developing drugs with large market opportunities. And we have a strong balance sheet to support these programs.

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

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

If your 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. One moment please for the first question.

Denis Burger: While we wait for the first couple of questions, I have a couple additional meeting announcements to make you aware of.

First, we will be making a corporate presentation at the upcoming Rodman & Renshaw Annual Global Healthcare Conference on Monday, May 11 to May 15.

And next we will presenting at the Rodman & Renshaw Annual Security Biodefense and Connectivity Investor Conference on June 19. We encourage you to meet with us in person should you be attending either of these conferences.

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

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

Ren Benjamin: Hi. Good morning, everyone and congratulations on your progress.

Denis Burger: Thank you.

Ren Benjamin: A couple of questions. We have this data that's coming out on May 10 — a pretty important milestone for you guys, our first look at the potential for this drug in HCV.

You mentioned that we'll be looking at the first few patients. How many patients — you know, how many patients are we going to be looking at? And do you think that we'll be able to make any meaningful conclusions from this first look?

Denis Burger: Well as is our continued strategy, we don't give indications of patient enrollment ahead of making formal announcements. And since this call represents usually 25 to 50 professionals and investors, we'll reserve the full details of the presentation for the official announcement on the 10th.

So I'm not going to today, give you any additional details into the presentation at the ICAR meeting.

Ren Benjamin: Okay. Fair enough. How about we talk a little bit about what you would consider as good data? When you see this data before the presentation, what would you as a scientist and as a company consider good data to move the program forward?

Denis Burger: Well there's several components to what represent good data.

First this, as we've said all along, is the first in–man study for 4065. And as I think everyone in hepatitis C appreciates, there aren't good animal models that are predictive of chronic active hepatitis in humans.

So first up is safety information in the patients that actually have chronic active hepatitis.

Next is whether or not there are changes in the pharmacokinetic profile as determined by differences between the normal subjects that we've previously done and the active patients.

And of course with a drug like ours and a mechanism of action like our drug, we might expect to see some changes in pharmacokinetics that are relevant to the drug reaching the target tissue and the target virus.

Tolerability will be an important issue. These are all important issues because these are problems for all the current drugs either approved or in development.

And finally, of course we'd like to see signs that it is influencing how the virus replicates. So all of these — those are going to be important put together.

With — a lot of the drugs that have a very short plasma clearance half–life. So they've given as a bolus and they immediately arrive in the liver. And their resonance time in the plasma is a short few hours.

With those drugs you expect a rapid, immediate drop of the HCV titer. And what's usually accepted as a non–arguable event is a two log reduction. So that's one of the benchmarks.

But drugs with different mechanism of actions as we've seen with other drugs in the development pipeline, can have a slower or longer period of activity where they influence viral replication.

So we will both present the data and comment on that at the upcoming conference.

Ren Benjamin: Okay. Okay. The avian data that's also going to be presented, is that — will that contain any animal results or is this primarily preclinical as we've seen before? For example, at the…

Denis Burger: Even animal data would be preclinical, but it will not contain any of the results from the ongoing animal studies.

But it will contain some new information that hasn't previously been reported from the independent confirmations of our activity against the various strains of influenza, including avian from the four independent laboratories that have been working on this.

Ren Benjamin: Okay. One final question — not to leave Mark out. Mark, can you tell us how to project the options — the expense for options going forward? Any advice on that?

Mark Webber: Probably the big thing I can say there is we do most of our option grants at AVI to employees in the first quarter of each year. So the first quarter is going to be very heavily weighted.

As our discussions we've had with our auditors, et cetera, it's fairly involved to make any good guess. It will be less going forward but as you have to deal with the various components to calculate this, which include the volatility, et cetera, it's a massively moving number when you put these into the model.

It will be less going forward but I wouldn't feel comfortable giving you any firm numbers.

Ren Benjamin: So it's safe to assume that it'll be less for the second, third and fourth quarter and then again you'll see a…

Mark Webber: … during those times.

Denis Burger: I guess when I look at those numbers my comment is that our cash burn — our cash expenditures for operations in the first quarter was a little over $5 million, which is in line with previous quarters and in line with our expectations.

And as Mark said — he reiterated our cash burn for the year, which we expect to be between $15 million and $20 million.

And like most biotechnology companies, it's the cash position that's key rather than the accounting manipulations to account for options that influence full disclosure under the new rules.

Ren Benjamin: Fair enough. Thank you very much and good luck next week.

Denis Burger: Thank you.

Operator: Your next question comes from the line of Richard Macary with Corporate Insights.

Richard Macary: Hi guys. How are you?

Denis Burger: Good morning.

Richard Macary: Just two quick questions. One, I wanted to see if we could get an update on the status of grants regarding avian flu or regarding any of the programs that are ongoing in the biodefense area.

And the second part of that would be you mentioned the muscular dystrophy — moving forward in a trial there.

Is there a timeline when that's going to become, you know, official announcement in terms of this consortium coming together and making announcement regarding these trials?

Denis Burger: Yeah. Why don't I let Alan answer the first question and I'll deal with the second one. Alan?

Alan Timmins: Yeah. In relation to the grants and other government funding, unfortunately the government once again moves at its own pace in these sorts of things. So we don't have a clear delineation of when we would expect decisions and/or funding on any of the grant applications.

But we do feel that we've given good effort in our applications. Certainly we are discussing programs that are natural add–ons and offshoots of work that we've done previously that's been funded by the government.

So we remain optimistic going forward but we'll — you know, we'll know when the government decides to tell us.

Denis Burger: The answer to the second question is that the consortium dealing with muscular dystrophy includes a number of significant pharmaceutical companies.

The one that's been mentioned is GlaxoSmithKline in — also academic institutions — and a number of patient advocacy groups and other charitable funding organizations.

And the organizers, which include some key individuals at Glaxo, want to have all components of this tied up into the consortium before a formal announcement is made.

And although we expect that sometime soon, we — it's sort of, again out of our hands a bit. But I would certainly expect something formal from this group in the second quarter.

Richard Macary: Thank you.

Denis Burger: So not too far off.

Richard Macary: Thank you.

Operator: Your next question comes from S. Ramakanth with First Albany.

S. Ramakanth: Hi. I was just wondering what kinds of preclinical studies are needed to be completed for the avian flu program? And what additional new studies would be done?

Denis Burger: That's a very good question. And with avian there are three prominent kinds of animal models that are available. All of the culture data obtained to date has been supportive.

And it's been confirmed by four different independent laboratories that the drugs that we're using are directed against conserved regions of the influenza virus and are efficacious against all of the strains -- the strains of seasonal influenza and the strain H5N1 and the other two animal strains.

The additional studies include fertilized eggs. That's the principal model for avian. It is a bird disease and a fertilized egg is the key model. Those studies are currently ongoing. Two additional models include infection of mice and a key model is a larger animal model -- infection of ferrets.

And we expect to pursue all three of those models and that will become the — a part of the key data that we need to file our IND. And we expect to file that IND this year.

S. Ramakanth: Okay. Thank you. And generally speaking, how do you see the NeuGene–based drug be used? And how can — what are the benefits the NeuGene -based program gives compared to what is being tested out there currently in the marketplace?

Denis Burger: I'd like to answer that question in terms of all viruses because the drugs that are currently in the marketplace for all viruses work on mechanisms that are common to a number of viruses and also to some cellular mechanisms.

And that's why the current drugs have some toxicities, tolerability issues, safety issues, et cetera.

Our specific program has the key advantage that our drug specifically recognizes the gene sequence, a selected gene sequence, from the virus. That gene sequence is not found in the human genome so we don't have off–target effects.

Based on that and based on the chemistry of the backbone of NeuGenes, we have an outstanding, quite stunning safety tolerability record in that now over treating — treating over 300 subjects and patients at doses that range much higher than the dose expected for efficacy in the clinical programs, we've not seen a single drug–related severe adverse event.

So we have the combination of one of the first technologies to specifically recognize single virus families and all the viruses in a family.

So as a specific example here, in hepatitis C some of the current drugs in development are principally for genotype 1 versus some of the other genotypes and don't necessarily represent efficacy against all species.

Because of how we target, we expect the drug to behave relatively the same against all species. In avian that's also the case where we target a conserved region and therefore recognize all the subtypes, both that represent seasonal and the avian type of diseases.

So compared to other drug development, we have advantage in specificity, lack of off–target activity, safety and then the ability to target entire families. Thanks.

S. Ramakanth: Can I ask a quick follow–up?

Denis Burger: Sure.

S. Ramakanth: I was just wondering how — I was just wondering in terms of dose pairing and also in storage situations because those two remain to be, you know, not really charted out because there's nothing really which can help in dose pairing yet.

Denis Burger: I'm sorry. I didn't quite get your question because there's some interference on the phone line. Can you say that again, please?

S. Ramakanth: Yeah. Can the NeuGene antisense program — can it help in dose pairing by any means?

Denis Burger: Dose pairing?

S. Ramakanth: Yeah.

Denis Burger: I don't know what that means.

S. Ramakanth: Can it be used in combination with something — other…

Denis Burger: Oh, oh, oh. Thank you. Thank you for the question. Sorry I didn't get it at first.

Yes, one of the key advantages of our technology is that it can be added to other types of drug therapies for two reasons -- one, it doesn't have a deleterious safety profile so when you add it or make a combination with it, you don't add any additional tox. or safety issues; and secondly, it's clearly a different mechanism of action.

And so the kinds of drugs you want to add in combination are things that have different mechanisms of action so that you produce an augmented efficacy response.

So not just against influenza or not just in hepatitis C and not just in viruses but in other indications, combinations with drugs like this are very appropriate. And can really bring a lot additionally to the table.

S. Ramakanth: Thank you very much.

Operator: Your next question comes from Chuck Clark with Wachovia.

Chuck Clark: Good morning all.

Denis Burger: Good morning, Chuck.

Chuck Clark: A couple of questions. In that the hepatitis C is such a massive market, why would we not be having a sampling greater than up to 40 patients? It would seem to be a pretty slight sampling based on the potential market.

Denis Burger: When one does initial clinical trials with a new agent, it wouldn't be appropriate and isn't done by any company whether it's biotech companies or big pharma, to do more than a screening with the initial applications.

So in our phase 1 safety study the FDA considered three cohorts with three different doses to total approximately 30 patients to be the appropriate size. As you move forward for early indications in efficacy, usually the first trials are similar.

As an example, one of the companies developing hepatitis C drugs is Vertex and they've had some success over the past year. And their first report of a trial indicated — involved about six patients on the first release of data.

So remember, this is just the first indication before moving forward into larger phase 2 studies that incorporate different subpopulations of patients and well before moving into pivotal trials that would be the kind of trial you'd do for the approval process.

Chuck Clark: And one more quick question that is — it gets a little bit contrary in nature, but with the new cost of the stock option vesting and so forth, with the company being as cash conscious as it has been, why now as opposed to later? It seems a little overly self–serving to install that now, especially since the proposed cost variable is so indeterminate.

Denis Burger: All companies now have had to put those numbers into those first quarter results because of the law. And Mark, I don't know what the specifics of…

Mark Webber: Yeah. It's just FAS 123R. Every company that files financial statements as of January 1, 2006 must expense their stock options because these are the rules now.

Chuck Clark: No, I understand they must expense it, which puts more pressure on the P&<. Why now when the company's basically being supported by outside sources and not revenues?

Mark Webber: Why now what?

Chuck Clark: Why now escalate the stock options for the employees?

Mark Webber: We haven't. We do this — the last ten years we've granted similar amounts of stock options. So this is the same as we've always done.

Denis Burger: Oh, I think what he's asking is: there's two components to the reporting — one was the grant and one was escalation. And maybe you can tell me what that means.

Chuck Clark: Well what was it in the new prospectus that you sent out that's being voted on?

Alan Timmins: That was options for the — excuse me — shares approved for selling to employees under the employee stock purchase plan. So that's an item where cash will come into the company in exchange for shares.

Chuck Clark: Okay. Okay. Thanks fellas.

Denis Burger: Yeah. You bet. Thank you.

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 comes from Phillip Wiggins with Pharm South.

Phillip Wiggins: Yes. One quick question. Can one of the company officers expound a bit more on the CABG research program?

Denis Burger: Phil — hi. This is Denis Burger and the preclinical program has been quite extensive. It started with joint work at Thomas Jefferson Medical School in Philadelphia.

And with a key investigator there we did a number of studies demonstrating that our drug AVI–5126, which is a formulation of the c–myc drug, was very effective in turning down the c–myc gene in saphenous veins in a short period of incubation before eventual transplantation.

And Thomas Jefferson has done a considerable amount of research in that area. And it was reported and they've also patented the approach to using down–regulation of c–myc as a way of controlling eventual restenosis–like mechanism that leads to saphenous vein graft failure.

So this is very similar mechanism and clinical outcome as in cardiovascular restenosis after stenting.

So the clinical — the preclinical work has involved a number of models and a number of experimental protocols and regimes to establish that the drug would down–regulate the gene. And that we would get the appropriate anti–restenosis outcome after transplantation.

In addition, the preclinical work has involved showing that that's also the case in human saphenous vein vessels, that we can down–regulate the gene in that case also. And so we're now ready to move into a controlled phase 1b/2 clinical trial.

Phillip Wiggins: Well that makes excellent sense and it sounds like a great market to be in because so many people, probably due to genetics just — those grafts really get clogged up quick.

So thank you very much. I was just not up on that particular research area. Thank you.

Denis Burger: Yeah. You bet, Phil.

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

Denis Burger: Well as a closing remark I'd like to again thank you for joining us today, for your support and for your questions.

This is proving to be a very active and productive time for AVI. We look forward to reporting results from our ongoing studies and trials over the next few months and the next quarter — quarters later this year.

And we'll keep you updated on our progress at our next conference call. Thank you.

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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