AVI BioPharma Incorporated First Quarter 2008 Results Conference Call Transcript

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Guest Speaker

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Conference Call Participants

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Presentation

Operator Good morning, ladies and gentlemen. Welcome to the AVI BioPharma Quarterly Earnings call. Please be advised that this conference is being recorded. There will be a question and answer session during the conference. If you wish to ask a question, you may press star one on your telephone keypad. If at any time during the call you are having difficulty with the sound, please press star zero for operator assistance. I would now like to turn the meeting over to Mr. Michael Hubbard, Director of Corporate Communications. Please go ahead, Mr. Hubbard.

Michael Hubbard Thank you, Julian. This is Michael Hubbard, Director of Corporate Communications for AVI BioPharma. Thank you for participating in today's call. Yesterday we released our financial results for the first quarter of 2008, which are available on our website at www.avibio.com. Joining me this morning from AVI are Dr. Leslie Hudson, Chief Executive Officer, and Alan Timmins, President and Chief Operating Officer.

Before we begin, I'd like to remind you 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'd 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 13th, 2008. 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, I'd like to turn the call over to Dr. Hudson.

Les Hudson Thanks, Michael. And thanks to all of you for joining us today. We want to give you an update on our financial report and earnings release. But before that, I'd like also to very briefly use the corporate priorities as a way of actually updating you on things that are, in terms of our R&D program and the partnership priorities, important to the company as s whole.

So you remember that our corporate priorities overall first of all were to advance the clinical programs. These are both Duchenne and cardiovascular restenosis, as well as our whole viral program in Ebola, Marburg, Junin and Dengue virus infections. And then secondly, around DMD in particular, we… the company has actually focused in on particular exons, and we'll say more about Exon 51, 50, and 46. We expect to have approval shortly to go into a systemic study for AVI 4658.

And we are also in a situation where, having been granted orphan drug status by the FDA, we're in the process of filing for similar status in Europe. With CABG we're conducting a futility analysis. This is in fact CABG, the trial which is being conducted by AVI itself for the prevention of occlusion after grafting with saphenous veins. And this is for AVI-5126. I'll say more about that later.

For Ebola and Marburg, we issued a press release about 35 minutes ago which summarized some of the advances that we've actually been able to record with USAMRIID. The reason for the release in particular is we actually have a lot of repeat data now which has confirmed some of our earlier findings that have already been reported. So we'll go into that in… in somewhat more depth, both in terms of my remarks after Alan and also in terms of the question and answer session, I suspect.

With Junin and Dengue, we basically don't have any update this morning, other than to say that we now have a contract in place for the Junin study.

This will be a lab study for animal testing. And in terms of Dengue, we expect that to advance according to the corporate priorities which we've already communicated earlier. Later in this year we expect that to go forward, and we can talk about that.

You saw also yesterday a press release around the TNF receptor 2 project. That was published in Molecular Therapy, and that was the subject of a separate press release.

The other areas in terms of our corporate priorities is to complete the portfolio of discovery projects for drug candidates which direct alternative splicing. Since the last call you will have saw that we appointed Richard Kole, Ryszard Kole, as Senior Vice–President of Discovery Research. There've been a few other senior changes which I'll review after Alan's financial overview.

And then finally, in terms of the ability to secure an additional revenue producing partnership, we think that the Ebola and Marburg work we've been doing has ground–breaking potential, and are actively seeking a commercial partner as we… as we gear up for the next stage of clinical and commercial development of this very exciting program.

So I'll give you some more detail, both as prepared remarks and during the Q&A part of this call, once Alan has been through our quarterly numbers. So without further ado, I shall turn the call over to Alan Timmins for an overview of our first quarter earnings release. Alan?

Alan Timmins Thank you, Les, and good morning to all of you joining us on the call and over the Internet. Today I'd like to review our 2008 first quarter financial results, including our current cash position, and also discuss our continued 2008 financial guidance.

Our revenues for the first quarter of 2008 were 5.6 million, up from 536,000 in the first quarter of 2007, reflecting an increase in research contract revenues of 5.1 million, partially offset by a decrease in grant revenues of 19,500. Our operating expenses for the 2008 first quarter were 19.4 million, compared with 10.6 million for the 2007 first quarter. This increase was due primarily to asset acquisition of Ercole Biotech Inc., and due to some higher research and development expenses. During the first quarter of this year, we completed an asset acquisition of Ercole resulting in a $9.9 million acquired in… in–process research and development expense. So please note that the expensing of the in–process R&D of 9.9 million and other Ercole–related entries in the first quarter are essentially the entire financial statement impact of this acquisition. Other than that expense, we've not seen, nor do we expect to see, a significant net increase in the ongoing operating expenses of the now–combined companies.

Our research and development expenses for the quarter increased to 7.5 million from 6.3 million in the first quarter of 2007. This increase reflects $800,000 in government research contract expense, a $580,000 increase in compensation costs, 402,000 in severance payments to certain Ercole employees, and a $400,000 increase in net clinical expenses. These increases were partially offset by a $425,000 decrease in professional consultant costs; a $245,000 decrease in chemical costs; a $225,000 decrease in purchases of government contract related equipment; and, a $190,000 decrease in the amortization of patents and lease holds.

Our general and administrative, or G&A, expenses decreased to 2.0 million from 4.3 million in the prior year period. The decrease was due primarily to a $2.2 million decrease in employee costs, of which 1.6 million, including 562,000 in cash compensation and 1.1 million in SFAS 123(R) expenses, were related to the separation and release agreement with the company's former Chief Executive Officer during the first quarter of 2007. Additionally, there was a $530,000 decrease in SFAR 123(R) expenses. G&A expenses also included a $150,000 decrease in legal fees.

We recorded a net loss for the first quarter of 2008 of $15 million or 23 cents per share, inclusive of the aforementioned 9.9 million of acquired in–process R&D expense, compared with a net loss for the first quarter of 2007 of 8.2 million or 15 cents per share.

Reviewing our balance sheet, we reported cash, cash equivalents, and short–term securities of 20.2 million as of March 31st, 2008, a decrease of 4.8 million from December 31st, 2007. This decrease was primarily due to $4.4 million used in operations and $339,000 used for purchases of equipment and patent–related costs. This decrease included approximately $900,000 advanced to Ercole for its use in retiring certain of its debts prior to the closing of the Ercole asset purchase.

For our 2008 financial guidance, we expect our net cash burn for the year to be in the range of 16 to $19 million. With those comments, I'd like to turn the call back to Les.

Les Hudson Thanks, Alan. So in essence, then, our financial strategy has been in the near term to cover as much of our R&D programs as possible. You know obviously about the work that we're doing with the government. That… that's a fully funded contract in the antiviral programs that we have already talked about and will about again this morning. Also, for example, in DMV, that has now become a very important program, not only to us but also actually at the level of national funding in the United States. And so for example, one of the areas around Exon 50 is funded by Charley's fund. Those sorts of near–term opportunities are very important to us. Not only does it give us actually a financial offset, but at the same time, it gives us an opportunity to work with the quite well–established and evolving clinical networks.

The restructuring programs, both in… the restructuring of the company, both in terms of programs and also the company itself, that will take further hold as we actually move through. Some of those announcements have already been made, and we expect to actually continue that with our new business plan as that actually kicks in in the year that we're actually currently in, in 2008.

So in April we announced some key appointments, along with some changes in roles, all geared to our corporate goal of becoming a company that is focused on product development. So first we… we welcomed, as you heard, Richard Kole, so Ryszard Kole -- either will do -- as Senior Vice–President of Discovery Research. Richard resigned from his professorship at UNC and is already working with us here in Corvallis on the west coast. As many of you will know, Richard is a pioneer in the use of oligonucleotides for the modulation of splicing. He was indeed the cofounder and president of Ercole Biotech. That appointment then allowed Pat Iversen to assume a new role on… as Senior Vice–President of Strategic Alliances. As you know, Pat was our Senior Vice–President of Research and Development. And in his new role, he'll manage AVI's ongoing programs in government contracting as well as focusing our external collaborator network for the identification of normal drug targets, both for the company and also for external partner R&D programs. So again, you will see that that focus on the government programs is important not just because we have government contracts, but also because we believe it's a major partnering opportunity. And in the same way, we believe that there are applications of Antisense which will become increasingly realized by future potential partners for us.

Both Dr. Kole and Dr. Iversen are very passionately committed to drug discovery and have very complementary skills. They provide excellent synergy, both in their new roles and also as people. So AVI technology and infrastructure has the capacity to drive now only its own in–house R&D programs but also those of external partners. Currently, as you know, we have just one partnership, which is actually with Cook Medical, for the development of

AVI-5126. So one of the corporate priorities is to increase that.

In addition to these roles, we also welcomed Hans Wigzell to the new corporate strategy board. Hans, although he's exceptionally gifted as a scientist, he also has a very special understanding and indeed track record on commercialization. The legacy of his time as President of the Karolinska Institute and Chairman of the Nobel Prize Committee transcended his scientific contribution alone. And so from that point of view, we are actually very pleased that Hans is going to be working with us.

In terms of our clinical development portfolio, the AVI-4658 DMD program in Duchenne muscular dystrophy, as you know, we have an ongoing program in the United Kingdom. We saw, as indeed many of you would have seen last week, that MDEX, which is the collaborative group that we're working with, announced that, given the safety profile, they have requested a protocol modification to skip to the highest dose allowed of the three dose groups. We see this as a positive outcome. As you can imagine, these trials are very, very carefully monitored because basically they involve young children. And that's part of the reason why the study's protocol was being conducted patient by patient. But given the… the end points of the particular study that we've seen, we view this positive change as being something which we welcome.

Equally importantly, the Medicine and Health Care Product Regulatory Agency -- this is the European regulatory agency -- indicated that the existing data package should support the proposed systemic study or IV clinical study in ambulatory DMD patients. And as you know from our corporate goals, we believe that we will have the opportunity of conducting that study of AVI-4659 later this year. Clearly, systemic exposure is extremely important for us.

The focus around Exon 51 and 50 and also 46 is something which we believe was very important initially to start with exon skipping applied to single exons. And we can talk about more of this in terms of the strategy in the Q&A session, depending on the degree of interest. The… that's really a clinical strategy. In terms of our discovery research, we expect to start looking at the ability to skip not just one but potentially one and more exons at the same time. This notion of block skipping would clearly allow one then to address a wider and wider proportion of the Duchenne muscular dystrophy patient population rather than approaching each disease one exon at a time.

In terms of the cardiovascular program, the status as far as Cook is concerned is unchanged. We are supporting their program. As you know, Cook, as a private company, has no reporting requirements. And other than looking very happy, which on the telephone is… is useless obviously in terms of the body language, I… I cannot actually add anything to that.

In terms of CABG, we were looking for a 50% reduction in graft failure. We'd already reported that, per protocol, we'd had a review of the first 30 subjects, which by the time we'd completed the review we'd added an additional subjects. We've already now stated that we're in the process of conducting a futility analysis really to determine what the best course will be for the company with regard to that program, both for the company and also obviously for our patient subjects.

In the antiviral program, we've already reported that we've actually filed pre–NDs… pre–INDs for Ebola and also for Marburg. This is a very important program for us. And so from that point of view, we will actually have an opportunity, we believe, of pushing this as a partnering priority. There are some very well established companies now who operate in this government contracting sector. And from that point of view, I think that is a very important opportunity for the company.

Finally, before moving to our Q&A, I want to return to our acquisition of Ercole and describe some of the benefits of the actions and how they translate into another important discovery and clinical program, and obviously ultimately disease application. Those of you that had the chance of actually following through on the molecular therapy website will have seen that in fact we have been able to have an influence that influences therapeutic outcome in models of inflammation in… in mice. These models are very reliant upon the effects of TNF. In one case we're looking at hepatitis, in the other case in arthritis. And we are intending now, as the next step, to go into a monkey study in non… in non–human primates. The important thing also about that study, it's with a locked nucleic acid derivative, which basically AVI–3378 is based on LNA chemistry which has been cross–licensed from Santaris Pharma. And so from that point of view, it is another opportunity as we diversify the chemistry approaches as well as our biology approaches.

Now we will take questions. I'd like to hand this call over to our operator, Julian. Julian, please.

Question and Answer Session

Operator Thank you. We will now take questions from the telephone lines. If you have a question and you are using a speaker phone, please lift your handset before making your selection. If you have a question, please press star one on your telephone keypad. If at any time you wish to cancel your question, you may press the pound sign. Please press star one at this time if you have a question. There will be a brief pause while the participants register for questions. We thank you for your patience.

The first question comes from Yale Jen from Maxim Group. Please go ahead.

Yale Jen Good morning, gentlemen.

Unidentified Male Good morning, Yale.

Yale Jen Thanks for take… taking the call. First of all, I just want to get some of the time lines…maybe you can sort of supply some more details. In terms of the… the DMD… I'm sorry. Start with the CABG program. You said that you were conducting the futility study right now. And when will you anticipate to see the sort of preliminary outcome and maybe decision making (inaudible)?

Les Hudson So thanks, Yale. I mean, first of all, as you know, a futility analysis has the advantage that it can be conducted without any penalties. It's not an intermediate analysis or an interim analysis that one is actually carrying out on the data. The reason for doing it is basically because this trial over the last 12 months has been recruiting for three months, and essentially on voluntary recruiting hold for about nine months, as we've been trying to understand whatever the DSMV has seen in the first set of data. First of all, there was no safety signals. Secondly, the DSMV did give us clearance to go through to the next protocol level of recruitment for analysis, which was up to 120, and specifically recommended, as was intended, to diversify the number of sites. And in our case, this would have been to add on sites, which we've already opened up in Poland.

The reason for the futility analysis, just to know why in fact the recruitment is taking so long. And we want to know whether it's in fact a problem of the… the way in which the data is being assembled or whether we're actually seeing a signal of lack of efficacy with regard to the drug–treated group

itself. That's usually a relatively short and fast analysis. It is actively on going. And so it is something which in fact is… is not going to take more than a few weeks. It will be very short term. And of course obviously, once we've seen that and the company's made its decision, then under those circumstances we will actually communicate it. The… the decision could be, for example, to assume that in fact everything is fine, that the futility analysis, if this trend continues, whatever the trend it is, it will be unblinded to the DSMV but not to us. We… we will… we will still have only blinded data. If the trend is… continues and there is a chance of success, one would… clearly would have the opportunity of continuing the study. If in fact it does look futile, one of the options the company has is for this first 47 patients is to actually unblind the data, but not to stop the trial, simply to actually see what the DSMV see. All of those are very acute, short–term things which we intend to look at.

Yale Jen So you will… would that be sort of possible to say that the… by end of third… second quarter, maybe third quarter, you may have some clue of what the directions might be, and that may be the time you communicate to the street of what the discovery will be.

Les Hudson It's a matter of weeks rather than months, Yale.

Yale Jen OK. So it will be very soon then. Great. OK. And the second question comes down to the revenue and expenses. As you… you guided us 16 to 19 cash burn for the whole year, and the… when I look, the cash… the… the revenue stream at that moment, would I consider this quarter be a little bit… sort of… sort of normal or… normalized as the rest of the quarters, or that would be a little bit lumpy moving forward

Les Hudson Well, I mean, honestly, there are two things. The first is the acquisition of Ercole has been fully expensed, and… and Alan…

Yale Jen Right.

Les Hudson …will comment on that in a second. So from that point of view, we will not be making an acquisition every quarter, so certainly that is lumpy.

Secondly, you saw an increase in the range. That was partly due to the fact that we want to make sure that we can bracket our spend and Ercole's spend, and also then the spend of the merged company, because we will actually be one company in one place. But let me actually hand it over to Alan to specifically answer your question.

Alan Timmins Thank you. Yes, Yale, I believe that what you see is as Les indicated, exclusive of the Ercole acquisition. I think, that is, you've seen a very representative quarter of how the rest of the year will unfold. You know, there's going to be some plus or minus in there based upon what particular efforts we have ongoing, specifically as relates to our government contracts. At certain points we're… we're more focused in internal research with those government contracts; at other points we're more focused on external or partner research in fulfilling those contracts. But generally I think what you're seeing here is a… you know, a reasonable model for quarters throughout the remainder of the year.

Yale Jen Great. Thanks. And the last question I have is in regarding the… the Ebola and Marburg studies. And now you're ready for the pre… IND study in the future. what should I think about the potential partners would be? Was there any sort of… can… can you sort of elaborate a little bit more?

Les Hudson Well, I mean, certainly in terms of the sector of companies that have been successful and made really quite a good business of partnering in the biological part of government contracting, there are, as you know, both botulinum toxin as well as anthrax contracts that have actually been awarded, and the companies who actually hold those have done very well. You know also that, I think by the end of this month, there was a new RFP which is out to be finished by the end of this month for the supply of the next generation of the anthrax contracts. You saw also that in our press release it wasn't just us, but actually it included a comment from the head of USAMRIID himself. I think this is an opportunity where Ebola and Marburg, but then if you include also Junin and particularly Dengue, which are all in the same program, these have government contracting opportunities.

But if you look also at what else is in that program, there is an IL–10 component which looks at the immune response to these viruses. I think this could either appeal to a company which either is already or has the ambition to become a major government contractor, in other words will actually pick up a lot of the weight in terms of the commercialization phase as well as the late registration phase of the development of these two compounds, but also there is an opportunity, particularly with regard to Dengue and also control of the immune response, for it to have an appeal to a partner which will either take the whole of that program or indeed focus in on things, which in the case of Dengue is much more community–acquired than anything which is associated solely with the bioterrorist threat.

Yale Jen OK, great. Thanks a lot, and I'll get back to the queue.

Les Hudson Thanks, Yale.

Operator Thank you. Once again, if you have a question, please press star one on your telephone keypad. The next question comes from Reni Benjamin from Rodman and Remshaw. Please go ahead.

Ling Hi. This is actually Ling on behalf of Ren. Good morning. Thank you for taking my questions.

Les Hudson Good morning.

Ling So my first question is regard… is actually a follow–up, you know, for Yale's question regarding the CABG program. So you mentioned in a couple of weeks you're going to… to, you know, get… get… get a sense, you know, what… what the fertility analysis is. I'm just… just wanted to get clarification. So this analysis will, you know, include just the… the first 47 patients, or you know, it's also going to include 30 additional patients?

Les Hudson No, this will be… on those first 47 patients the futility analysis will simply ask if the trend, whatever the trend is, continues, is there a likelihood that this trial could be successful. And so it will be the… the block of 47 patients that have already been fully assessed by the DSMV.

Ling OK. But right now the… the trial continues to enroll patients, up to 120. Is that right?

Les Hudson We have clearance to do that, and we actually have sites in Poland that are open. And so from that point of view, you can see that there is obviously a lot of time pressure on us looking at this and making this decision. Because even if we continue, you can imagine nobody wants to run a clinical trial where three–quarters of the year are actually spent trying to figure out why in fact one isn't recruiting as fast as one should be recruiting. So one way or the other, this is a very important analysis and decision for us.

Ling OK. And then the next question's regarding the… the… the DMD program. So you mentioned, you know, the… the… the trial is going to skip t

highest dose cohort. Can you maybe elaborate on, you know, what… what exactly does… are the reasons for this modification, and what signal.. what safety signal you see and what efficacy signal you see… you have seen?

Les Hudson So first of all, we reported that, at the lowest dose, we had had no significant side events or… or.. that would actually cause us any problems.

Ling Mm–hmm.

Les Hudson So that clearly is an important observation. It was a trial where in fact the intramuscular injection occurred both into one foot of a young boy and then a control, which was saline, into the other foot, directly into the muscle. We in fact saw no adverse events. The Medex group them was encouraged to actually go to the highest group. And so from that point of view, it is an opportunity for us to simply not do that dose escalation.

We are also in a situation where the expression that we've seen of dystrophin is enough to encourage us to go to that level, where essentially we will be looking at an order of magnitude increase in the amount of material that will be injected into the patient. Clearly, though, this is a trial where the most interesting observations will be made after systemic exposure, so that also is something which we're pushing very hard.

Ling Just wanted to make sure I understand it correctly. So you know, by skipping the highest dose, it is because you… you think the lower dose is… doses aren't going to be sufficient for the efficacy, or it's because of, you know, you speculate a high dose might have, you know… you know, unfavorable side effects that you don't… you… you don't see at lower dose?

Les Hudson No, it's exactly the opposite. We're skipping to the highest dose. So we're skipping the intermediate dose and we're going to the highest dose, quite simply because the doses that we tested in two patients had no side effects whatsoever of… of significance. So under those circumstances, we feel safe, indeed it's the MDEX group themselves, feel safe in terms of the risk to the patient of being able to miss out the intermediate dose and go to the highest dose.

Ling I see. Thank you for the clarification. (Inaudible)…

Les Hudson Yeah. No, I'm sorry. It… I'm on a rather old telephone in a hotel in Seattle. I didn't make it back to the company last night because of the problems of flight operations on the east coast, which is probably why my voice is breaking up a bit.

Ling (Laughs)… You're fine. Thank you.

Les Hudson Really? Thanks.

Ling And then… so… so I guess, you know, this program already treated three patients already, or…

Les Hudson That's right. We're actually very early, obviously, in this. But at the same time, we've treated enough patients to be able to at least see what the initial profile of adverse events might be.

Ling I see. And when do you, you know, given that you're going to… you're going to have to skip one dose, when do you think you can, you know, sort of announce the… the data from this trial?

Les Hudson Well, I mean, we work very closely with the MDEX group. It's a trial where the funding for it both comes from ourselves, for example the supply of drugs, as well from the UK. Thus far at least, de facto they've been much faster than we have in… in getting stuff out onto the Internet. So we certainly are going to be working increasingly closely with them. And both for finishing this trial and also starting the IV trial, that's something which we clearly are very much focused on. And you know also, in terms of our corporate development milestones for AVI–4658, we anticipate dosing the first patient in the systemic study for Exon 51 in the third quarter this year. So you know, these are all near–term events.

Ling OK. And then regarding your Ebola and, you know, Marburg program, I… I might have missed it. So what… when you discuss your (inaudible) R&D for… for… for those programs?

Les Hudson Ah, good question. Usually, and in this case definitely, the response is always the same. So we… we've filed the pre–IND for both of them. That went in on time…

Ling Mm–hmm.

Les Hudson …actually during the first quarter. We believe that the internal meeting in the FDA may already have happened, but you know, that's based on… on rumors rather than fact. You will know, I'm sure, also that for pre–IND discussions now, that is conducted solely in writing. The FDA no longer takes face–to–face meetings. So really the step is under the control of the FDA. But again, it's a situation where we've already communicated, that is we… we're anticipating filing both INDs in the fourth quarter of 2008.

Ling OK. And then… so also wanted to, you know, get a little bit more information about the pre–clinical study. So in the press release you put out earlier this morning, so how many… how many animals were treated in the… in… in… in both studie

Les Hudson You know, there's a wonderful report of that actually in… in the paper, which is… is published in Molecular Therapy, which is part of the.. the nature group. So you're referring to the… the TNF alpha receptor 2 study.

Ling Oh, no, I'm sorry, actually I'm talking about the… the Ebola and…

Les Hudson Oh, I'm sorry, the… the pre… OK. Yes. OK. I understand. Sorry. I didn't realize you were still on the same topic.

Ling (Laughs)… OK.

Les Hudson We haven't actually disclosed a lot of details around this, and the reason for doing it is that we expect to be publishing this as a scientific paper, and that is something where in fact the data that we have is already being assembled specifically for that purpose. As you know, there's a lot of sensitivity about releasing too much data through a press release in advance of publishing in… in a peer–reviewed journal.

Ling Right.

Les Hudson What we… what we've given is indications of, I think, a fairly remarkable under… an… a remarkable outcome in terms of survival data

Ling Yes.

Les Hudson …both in Ebola and also Marburg.

Ling Yes.

Les Hudson But you could imagine also, because of the fact that it involves non–human primates, the… the… the groups are not large. But because we're part of the government collaborative network with USAMRIID in this regard, the whole of the statistical design of those experiments is… is very much rigorously monitored, both by ourselves and also the USAMRIID labs.

Ling I see. And then, you know, just regarding the… the substantial regulatory pathway for both Ebola and Marburg program, let's say, you know, going forward, in… in, you know, the program advanced to that clinical stage, do… do you expect, you know, the… the… the agency might require, y know, efficacy data in… in human, or… you know, can… can you… can you give… give us, you know, some… some thoughts on t

Les Hudson So in terms of the ability to get approval under the animal rule, particularly for the use of both Ebola and Marburg drug therapies, essentially with fighting personnel, this is not necessarily for a civilian application in times of peace, like for example, it would be with Dengue, I think the expectation is that there would be a necessity to do a… for example, a phase one safety study because of the nature of the disease and the infection, which is uniformly… uniformly fatal and not containable outside of a Class 4 laboratory. It's very unlikely one would ever actually have a requirement to conduct those sorts of trials in human patients. Clearly, it's a situation where, as we signaled in the press release, there are places which in fact work on this as an experimental virus study, and indeed the genesis of this program was under an emergency IND because there'd been a… what was believed to be a needle stick with an infected syringe. I think the necessity of doing a human study outside of a safety study is very unlikely.

Part of the reason, though, why having an experienced partner on board, it's both for the late clinical development as well as also commercialization. The clinical development part of it, government contracting and the ability to actually work within the regulatory confines on the animal rule, there are companies who have that experience, and we don't. That's one of the reasons why we are very anxious and committed to getting a partner.

Ling I see. And you know, since you talked about, you know, your… your partner strategy, can you maybe give us an idea, let's say, you know, the size of the virus infection program, and what… what are the other program (inaudible) you know, as partner (inaudible) or, you know, down the road you might… you might also wanted to look for partners.

Les Hudson The virus program has priority. I think we've communicated that very clearly, and I know you… you were not under any mistake as far as that's concerned.

Ling Mm–hmm.

Les Hudson I think the… the general approach, indeed part of the reason why when I came on board with AVI I personally felt that my due diligence had turned up a very persuadable result, is that these drugs are starting now to take on drug–like character. The interest in being able to actually direct alternative splicing is something which antisense molecules, I believe, can do. This is an area where in fact the interest created by all the RNAi investments that have been made, both in large pharma and also in mid–size pharma, I believe that is a partnering opportunity down the road for AVI, without any doubt.

Ling I see. And then the last question's regarding your, you know, TNF LNA program that you acquire from… from Ercole. Maybe just can you briefly, you know, talk about the… let's say, you know, the… the… the… the progress right now and what… what will be the… let's say the next event or milestone we should look at.

Les Hudson Yeah. So what we reported, and what I already in error started answering in the… in the molecular therapy paper was studies in mice. Basically the next event will be studies in non–human primates. They're… they're already programmed, and it's something which we're committed to do. And also, in this case in particular, with the sequence that we're working with, with the Exon 7 of the TNF alpha receptor -- this is receptor 2…

Ling Mm–hmm.

Les Hudson …the actual sequence is the same in non–human primates and in humans. So our next step is an efficacy study in monkeys.

Ling OK. And when… I guess, if you can, maybe can you tell us, you know, when… how long does this study, you know, going to take, and when.. when do you expect maybe and R&D for this program as well?

Les Hudson Yeah, that is not yet on our corporate time lines, but will be. And that is something which, once we have all that sewn up, obviously we'll communicate it. I think that must have been your last–last question. Do you have a last–last–last question?

Ling No, I… I'm sorry. Yeah, this is my last…

Les Hudson (Laughs)… Thank you.

Ling …question. Thank you so much for taking the time.

Les Hudson My pleasure.

Operator Thank you. There is a follow–up question from Yale Jen from Maxim Group. Please go ahead.

Yale Jen Hi. Thanks for taking up my follow–up questions. This is back to the systemic delivery for the DMD program. Could you remind us two things? You mentioned that the first patient will be dosed the third quarter of this year. And do we… first of all, do we anticipate any interim data sometime in '09, or you anticipate a sort of full data set later on, afterward?

Les Hudson So this is a situation where we are expecting to go to the UK to have a discussion around both the design and indeed obviously to secure approval for this study. I think we will communicate out the opportunities for data communication in '09, when we've secured that discussion a little

more precisely than we have today, Yale. It would be difficult to speculate in advance of the meeting with the European regulatory authorities.

Yale Jen Sure. And can you remind us of the overall trial design for this study, or that… is that being reviewed?

Les Hudson Well, again, that's something which we have our proposals. And… and clearly, it's something which the European authorities may well have their own views on. You will remember from the last call we actually talked about the fact that, when we went to them with the initial intramuscular design, they'd asked us at that stage why we weren't going directly to an IV system…

Yale Jen Right.

Les Hudson …design. So you know, I think these are areas where in fact the European authorities in their thinking are far ahead of what we, at least to date, have been able to actually garner in terms of with our interaction with the FDA. So it's really a very, very important area of discussion, both in the United States and in Europe, which is very much in flux at the present time. And the reason for that of course is that it's really been the point where the number and types of these trials have been really quite limited, simply because nobody's had the therapeutic opportunity to intervene, beyond… beyond obviously the nonsense mutations which, as you know, is already in the clinic with TCP Pharma.

Yale Jen Correct. And then the last question -- again, this is the last question…

Les Hudson (Laughs)…

Yale Jen …is for the (inaudible). Let me just ask a contrarian… some questions. Why… is any other alternative way to… to… to create such a decoy counter TNF, say compared to the differential splicing? And if so, what would be the… as advantage of differential splicing, the product generated from the differential splicing, compared to other alternatives?

Les Hudson Yeah. No, that's a very good question. So first of all, in terms of will it work and will it show any benefit, the good thing is that we have, both with Enbrel and Humira and Remicade…

Yale Jen Right.

Les Hudson …a fairly well laid out pathway full of data for these TNF blockers. You know as well as I do the challenges that they've been facing, and it's really the challenges for the administration of a large amount of exogenous protein. And so the real question here is, if you were able to generate not an exogenous protein but actually the… the body's own protein in situ, and to do that chronically, without these huge peaks and troughs, and then at the same time not only do we create the decoy but we de facto decrease the number of TNF receptors in the liver, what therapeutic benefit does that have?

And you know, it's one of those questions which one asks at this stage, is this worth knowing about in clinical trials? And I think the answer is yes, this is worth knowing about. The question is what benefit will it show. And I think it's a situation where, as this program matures -- and basically our next step here is to get the full development program laid our for the corporation -- that will be something which will, I think, be extremely informative to us in terms of how we go forward with it. Because you know, the fact of the matter is this is a major opportunity. It's a $10 billion market. It… it's not something which is on the level, for example, of… of Duchenne muscular dystrophy from a commercial point of view.

Yale Jen Sure, absolutely. And certainly it's a very interesting program and certainly has the potential there. So again, thanks a lot for taking the question and for the last… for the other endeavors.

Les Hudson Thanks.

Operator Thank you. The next question comes from Lanny Stout from National Planning Company. Please go ahead.

Lanny Stout Hi there. This is Lanny.

Les Hudson Morning.

Lanny Stout You know, you're getting ready to do some INDs on Dengue and Ebola and maybe some of the other virus programs. Do you have a corporate philosophy on how you're going to fund those? Are you going to do them… not going to do them unless you have a partner or a contract with a government contracting agency?

And second question, and it will be my last, can you give us a little idea what the future contract income is going to be for this year, whether it's either committed contracts currently that you got through… through the government, or… obviously you won't know yet about the partnering ones, but just a little idea about what the cash flow coming to you in the next, you know, three or four quarters.

Les Hudson If we could, let's take it in reverse order because, I think in terms of specificity, Alan will actually have what we've already communicated in terms of the potential income, and his level of confidence to us to be able to actually collect that. And then I… I won't forget, I'll pick up the… the partnering question and also the future plan. Go ahead, Alan, please.

Alan Timmins Yes, Lanny, the… in terms of contracts we have essentially five contracts. One is a large contract that's a total of $28 million. The other is a… the other four are smaller contracts that total up to just above $9 million. We anticipate receiving much or all of those… what remain on those during the current year. So as I was indicating earlier to Yale, this quarter is a… would be a decently indicative quarter of what you'll see for the remainder of the year.

Lanny Stout OK.

Les Hudson Then in terms of OK, so what will you do in the future with regard to developing these programs, I think first of all, although I obviously can't draw any definitive conclusions from them, that the fact that USAMRIID decided not only to allow us to make the press release but to actually join us in… in terms of having the… the Colonel, who runs USAMRIID, actually be quoted in person, that's fairly unusual, and I guess it must signal some degree of excitement in this regard.

I think secondly, looking at this area of biological… or biologicals–based government contracting, it was an area which was sort of like a quiet

backwater where, particularly with regard to Anthrax, there'd been one or two companies that had done this extremely well. I know from my personal competitive intelligence that I've been doing over the last few weeks that, with the Anthrax RFP, there are about ten players now in this area. So it's become a very active area, where there is a high degree of… of professionalism that's actually being built up.

I think it's a very interesting program with some very, very ground–breaking… breaking results. And the question is going to be during this year, what's the likelihood of us being able to actually find a partner and actually have a partnership where there could be an opportunity for some partnering–associated revenue payments. And I think it's a situation where I believe it's a very appealing program, and this has a very high degree of priority for me, and it's been something where I've actually personally been on the road, as well as other members of the team, over the last few weeks. That's a lot of focus on this program. It's really exciting work.

Lanny Stout Thanks.

Operator Thank you. There are no further questions registered at this time.

There is a question registered from Tim Richards, a private investor. Please go ahead.

Tim Richards Yes, this is Tim Richards. What is the current status and approaching milestones for the general manufacturing facility for supporting all these opportunities?

Les Hudson So Alan, do you want to pick that up in… in the detail that we've previously communicated around this?

Alan Timmins Yes. We've previously stated that we would be working toward meeting our Phase 2 requirements in manufacturing during the course of this year. At this time, because of the… the nature of those trials, we believe that our current, in–house manufacturing capability is adequate to meet those needs. So as we go forward and our clinical path becomes more clear in the specific applications where we are… where we are now conducting trials, then we'll work to expand our capacity, likely in Corvallis and… and/or through the use of outside manufacturing contractors to… to meet those needs. So we don't see it as a… as a huge hurdle going forward, either from the standpoint of our own manufacturing capability and capacity or from the standpoint of, on a timely basis, finding outside contract manufacturers to meet the needs that we anticipate.

Les Hudson So Tim, specifically, just picking up Alan's point there on the use of the external contract manufacturers, you probably know that we already have our sub–unit supply secured through an external contractor. So that relationship's already in place. The ability to go up to Phase 2 GMP for the supply of clinical material is important because it obviously gives us a speed advantage. Once one gets into Phase 3 and then the go–to–market supply, that is something which philosophically we would in fact contract out, quite simply because the quantity that one is talking about then really becomes quite… quite astronomic, particularly for the sort of opportunities that one's looking at, for example, with the TNF receptor.

Tim Richards Outstanding. Thank you.

Les Hudson Thank you.

Operator Thank you. There are no further questions registered at this time. I will turn the meeting back over to Dr. Hudson. Please go ahead.

Les Hudson Thanks, Julian. Thanks for joining us. And if you heard background… you thought you heard airplanes in the background, indeed you did. I hope it wasn't actually too incursive.

Final thing which I'd like to communicate, obviously, although we're early on in the… many of these programs, one of the things as a corporation that it struck us is that sometimes the depth of what we have to communicate gets lost on these rather brief interactions. We're intending to have a science day in New York City probably around about the 10th of September, and we're in the process of finalizing the contract around that, so we will make an announcement. And our intention there is really to give people who are interested parties the opportunity to see the depth of what we have in our cupboard here from an R&D point of view. And so it will be in fact where our scientific strengths will have a chance to shine… excuse me… shine through. That's particularly important for a company that's become so intensely product–focused. These updates will continue to be focused around corporate priorities and also our product candidates that are in the clinic.

I thank you all very much indeed for your time, and look forward to the next time we have a chance of interacting through one of these calls. Thank you very much indeed. Good–bye.

Operator Thank you. The conference has now ended. Please disconnect your lines at this time. We thank you for your participation.