GeoVax Labs, Incorporated

2022 Second Quarter Financial Results

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**CORPORATE PARTICIPANTS**

**David Dodd -** *Chairman and CEO*

**Mark Reynolds -** *Chief Financial Officer*

**Mark Newman, Ph.D. -** *Chief Scientific Officer*

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**PRESENTATION**

**Operator**

Good afternoon. And welcome, everyone, to the GeoVax second quarter 2022 corporate update call. I am Andrew with Chorus Call and will facilitate today’s call. With me are David Dodd, Chairman and CEO; Mark Reynolds, Chief Financial Officer; Mark Newman, Ph.D., Chief Scientific Officer; Kelly McKee, MD, MPH, Chief Medical Officer; and John Sharkey, Ph.D., Vice President Business Development.

All participants will be in listen-only mode. Should you need assistance, please signal a conference specialist by pressing the \* key followed by 0. After today’s presentation, there will be an opportunity to ask questions. To ask a question, you may press \* then 1 on your telephone keypad. To withdraw your question, please press \* then 2. Please note this event is being recorded. Please note the following. Certain statements in this presentation may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act. These statements are based on management’s current expectations and are subject to uncertainty and changes in circumstances.

Actual results may differ materially from those included in these statements, due to a variety of factors, including whether GeoVax can develop and manufacture its vaccines with the desired characteristics in a timely manner, GeoVax’s vaccines will be safe for human use, GeoVax’s vaccines will effectively prevent targeted infections in humans, GeoVax’s vaccines will receive regulatory approvals necessary to be licensed and marketed, GeoVax raises required capital to complete vaccine developments, there is development of competitive products that may be more effective or easier to use than GeoVax’s products, GeoVax will be able to enter into favorable manufacturing and distribution agreements, and other factors over which GeoVax has no control.

GeoVax assumes no obligation to update these forward-looking statements and does not intend to do so. More information about these factors is contained in GeoVax’s filing with the Securities and Exchange Commission, including those set forth at risk factors in GeoVax’s form 10-K. It is now my pleasure to introduce the Chairman and CEO of GeoVax, David Dodd.

**David Dodd**

Thank you. Good afternoon everyone. Thank you for participating in the 2022 second quarter update call. The second quarter represented an exciting and critical period for GeoVax in that we advanced clinical-stage development status within the two priority areas of COVID-19 vaccine development and cancer therapies. In addition, we continued to advance our pre-clinical development stage programs. We also successfully strengthened our balance sheet during a very difficult investment environment, especially for the biotech sector.

Our mission is to improve lives, worldwide, preventing, or treating some of the world’s most challenging infectious diseases and cancers. Our pursuit is to deliver safe, affordable products delivering increased value to shareholders and stakeholders while providing motivating career development opportunities to members of our team. The end licensing of GEO-CM04S1 and Gedeptin have provided potential, significant value expansion for the company.

CM04S1 is leading, next-generation COVID-19 vaccine in phase-II clinical development, targeting both antibody and cellular immunity with the goal of providing more robust and durable protection than the current, authorized vaccines. This vaccine holds promise from several critical areas of differentiation and value over the current authorized vaccines. Gedeptin is a is a cancer therapy currently in an expanding, multi-site evaluation among patients suffering from advanced head and neck cancers.

The product has received orphan drug designation from the FDA as well as the initial funding and support of the current clinical trial coming from the FDA orphan drugs clinical trials program. We believe that Gedeptin holds significant, clinical promise, including a potential accelerated development pathway. Both CM04S1 and Gedeptin are now under the sponsorship of GeoVax and our focus is on accelerating the clinical development of each of these products, including the potential for expedited regulatory review.

At the same time, we continue to advance other internal, development programs on the path to IND filing. Earlier this year, we issued a 2021 milestone report addressing the goals we established and communicated early last year. That report outlined our successful performance in executing upon our 2021 goals. In addition, we provided our goals for 2022. Our focus and activities remain on this year’s goals, primarily reflecting and focusing on the acceleration of clinical development for Gedeptin and CM04S1 and the transition to a more-efficient, higher-yield MVA manufacturing process.

In January, we strengthened our balance sheet with a $10 million direct investment. In May, we closed a $20 million direct investment. In fact, just this week, an additional $5 million was added as a result of the exercise of warrants. We continue to receive strong interest related to investment capital, which we’ll evaluate. But we’re focused on execution towards our 2022 goals and building shareholder value. Mark Reynolds, GeoVax’s CFO, will provide a more comprehensive overview of our financials.

Regarding Gedeptin, we previously confirmed two additional clinical sites in the assignment of Allucent as our CRO partner responsible for leading the expansion and acceleration of the Gedeptin clinical program. Our focus on accelerated and expanded patient enrollment is actively underway, with the goal to complete patient enrollment in early 2023, followed by completion of patient evaluations by the end of 2023 or 2024. Should the results be supportive, a BLA filing may follow shortly thereafter, but that will determine, based on further discussions with the FDA.

In parallel with the ongoing clinical program, we are also engaged with a CDMO to ensure sufficient product for the expanded clinical program as well as to prepare for commercial manufacture. We are confident that the Gedeptin phase II program will be successfully managed for Allucent and our clinical operations team, with possible expansion of further additional clinical sites. We are highly excited about the outlook and promise of Gedeptin within advanced head and neck cancer.

In addition, there are promising opportunities relative to the expanded use of Gedeptin in other indications, as well as the GDEP technology in conjunction with other therapies and potential synergy with our MVA-VLP, tumor-associated antigen approach. We are looking forward to providing milestone updates throughout this year about the progress of our Gedeptin program.

We are highly focused on the clinical development of CM04S1 against COVID-19, including the continued emerging variance of concern. CM04S1 utilizes synthetic, Modified Vaccinia Ankra technology, similar to our other vaccine programs under development at GeoVax. CM04S1 induces immunity to SARS-CoV2 by stimulating the immune system to produce antibodies against SARS-CoV2 that can block the virus from entering healthy cells while the immune system can also grow new, disease-fighting T-cells that can recognize and destroy infected cells.

The vaccine includes both SARS-CoV2 spike and nucleocapsid proteins, differing from the current authorized vaccines, which only include spike protein. This is an important distinction. By inserting both of these proteins into our vaccine design, the MVA delivery vehicle is able to drive the expression of both proteins within the body of the vaccine recipient, inducing immune responses.

The role of the s-protein is to elicit a neutralizing antibody response against the initial infection, while the n-protein elicits a T-cell response to directly attack virus-infected cells, reduce viral replication, and reduce severity and provide viral clearance. Thus the vaccine is designed to induce both neutralizing antibodies and T-cell responses specific for the s-protein and the n-protein. The vaccine defined was implemented specifically to induce an expanded immune response to better combat and clear infections regardless of the circulating SARS-CoV2 variance.

This vaccine is the first step in the worldwide goal to provide a vaccine that gets ahead of the variance versus having to chase the variance. If successful, this vaccine will reduce reliance on the repeated administration of booster doses of existing vaccines. We believe that multi-punch approach, such as this, has the potential for providing a more robust and durable immune responsive protection than the current, authorized vaccines. We also believe that various, high-risk populations, such as immune-compromised individuals, will benefit from such a multi-prong approach.

In fact, in July, analysis of data from the phase I study of CM04S1, published in the peer review journal Eye Science showed that CM04S1 demonstrated potent and equivalent T-cell cross-reactivity against delta and omicron variants. These findings suggest that T-cell immunity, stimulated by CM04S1 may constitute a critical, second line of defense to provide long-term protection against SARS-CoV2 variants.

And I will repeat, these were based upon the analysis of data from the human clinical trial, phase I study of CM04S1, which was, indeed published in Eye Science. CM04S1 is currently being evaluated in two, phase II clinical trials. One trial is a comparative study of CM04S1 as the primary vaccine versus the current, FDA-approved Pfizer vaccine in people that have received or are undergoing specific blood cancer therapies associated with transplantation or CAR T therapy that suppress or severely reduce pre-existing immunity to COVID-19 vaccines.

Multiple, clinical evidence has demonstrated that such patients fail to respond optimally to the current generation vaccines and we believe that the CM04S1 will prove to be more potent because it is multi-antigenic, delivered using the MVA factor. We believe this will differentiate CM04S1 from the other vaccines by providing both a strong antibody response and a sustained, T-cell response in these patients who are still at high risk of severe COVID-19 due to their immuno-compromised status.

The other phase II trial underway is evaluating CM04S1 as a booster for healthy patients who have previously received either the Pfister or Moderna MRNA vaccine. We believe that providing a heterologous booster, rather than a continued, multiple shots of the same vaccine or similar vaccine, may provide more robust and durable immune responsive protection. Heterologous-prime boost immunizations are well studied in other fields, such as HIV, and are being evaluated in multiple countries using different COVID vaccines.

Finally, the ongoing GeoVax effort to develop an advanced, MVA manufacturing process, based on a continuously-growing A -- (audio gap) -- and cell line to increase production consistency and capacity will well mesh with the clinical development activities in full development schedule associated with the CM04S1 and the CM02 vaccines. We are not alone in recognizing the limitations of the current authorized COVID-19 vaccines.

The continued need for more durable immunity, the waning of protective response, insufficient protection among various, high-risk, immune-compromised populations, and other evident issues are well documented and of increasing concern. We applaud the federal government for realizing that significant, incremental funding is needed in support of next-generation COVID vaccines, providing the promise, such as our CM04S1 and our CM02, as well as other vaccines, therapeutics, and technologies.

This is underscored by the actions of the Senate Appropriation Committee’s recent FY’23 Health and Human Services Appropriations Bill, specifically targeting next-generation COVID-19 vaccine developments. We look forward to continued dialogue and discussions in support of CM04S1 and CM02 as we continue to advance the developments of these important COVID-19 or corona virus vaccines.

Recently, the WHO declared money pox a public health emergency of international concern. Nations worldwide are enacting procedures and policies in support of minimizing the health risk from money pox to their populations. Currently, there are two vaccines authorized in the U.S. for prevention of monkey pox, the primary vaccine being Modified Vaccinia Ankra, or MVA, which is also the vaccine factor utilized in numerous GeoVax vaccines, including our CM04S1 and CM02, which target COVID-19.

In addition, MVA is the vaccine vector used in our hemorrhagic fever virus vaccines against Zaire Ebola virus, Sudan Ebola virus, and Marburg as well as our development-stage Zika virus vaccine and even our MUC1 cancer immunotherapy. In fact, previous, peer-reviewed publications address the successful prevention of monkey pox and non-human primate models, following the administration of GeoVax MVA-based HIV vaccines.

Recognizing the global public health need in attention of monkey pox, evaluation is underway related to CM04S1 and the prevention of monkey pox. It is anticipated that the results will demonstrate successful protection, validating that CM04S1 is protective against both COVID-19 and money pox. We also anticipate validating our hemorrhagic fever virus vaccines as protective against monkey pox, potentially providing unique vaccines preventing both hemorrhagic fever viruses and monkey pox in a single vaccine.

This would be very important in certain endemic areas of the world. We look forward to reporting more on this topic soon. Now, I’d like to turn the presentation over to Mark Reynolds, GeoVax’s Chief Financial Officer, for a review our recent results and financial status. Thank you. Mark?

**Mark Reynolds**

Thank you, David. Starting with our income statements, I’m going to go through some of this brief -- pretty quickly. I know most everybody wants to get to the Q&A. But starting with the income statement, I’ll focus on the comparative figures. Actually, that’s our balance sheet showing up first. Okay. Here we go. Income statement. All right.

Grant revenues were $82,000 in a six-month period of 2022 versus $190,000 in ’21. That’s reflecting a wind-down of -- in both our grant from the NIH supporting the COVID-19 vaccine and the grant from the U.S. Army supporting our Lassa fever vaccine program. As of June 30, 2022, all the currently-available funds from these grants have been utilized. We do intend to seek additional, non-diluted (ph) funding for our development programs in the future, though.

Our R&D expenses were $2.6 million in 2022 versus $1.4 million in ’21, with the increase, as expected, primarily associated with new clinical trial activity for COVID-19 and the cancer programs and that includes manufacturing costs for clinical trial materials. The increase is also reflective of higher personnel and consulting costs as we stacked up for an overall higher level of activity.

G&A expenses were $2.1 million in ’22 versus $1.8 million in ’21, with the increase also associated higher personnel, consulting, and higher patent costs, so in there, also (ph). So overall net loss for the first six months of ’22 were $4.7 million, or $0.47 per share, versus $2.9 million in ’21, or $0.49 per share. Again, with the increase primarily associated with ramp-up of organizational infrastructure and other costs associated with CM04S1 and Gedeptin clinical trials.

I’m going back to the balance sheet. Our cash balances as of June 30, were approximately $31 million, as compared to $11.4 million at the end of ’21, and as David mentioned earlier, the change in the cash balances were reflective of $8.2 million used in operating activities, offset by proceeds from our stock offerings in January and May, with combined, net proceeds to us of nearly $28 million. And these numbers, I’ll point out, also do not reflect the additional $5 million that came in just this week, from warrant exercises. So current cash stands at about $35 million.

Funding our three, ongoing, phase II clinical programs and preparing for the next stages of development are the most significant uses of our cash and are our top financial priorities. And as I noted, we just received $5 million through (inaudible) warrants and based on that, our outstanding shares now stand at $24.7 million. That’s a current number. So, in summary, we are well positioned to accelerate and advance our clinical programs with a cash runway sufficient to fund our operations and priority programs for the end of next year. And I’ll be happy to answer any other questions during the Q&A, but I’ll turn, now, the call back over to David.

**David Dodd**

All right. Thank you, Mark. My colleagues and I will now answer your questions. Again, joining us for the Q&A session are Drs. Mark Newman, Kelly McKee, and John Sharkey, our Chief Scientific Officer, Chief Medical Officer, and Vice President of Business Development, respectively. I am, therefore, turning the call back to Andrew for instructions on the question-and-answer period.

**QUESTION AND ANSWER**

**Operator**

We will now begin the question-and-answer session. To ask a question, you press \* then 1 on your telephone keypad. If you are using a speakerphone, please pick up your handset before pressing the keys. To withdraw your question, please press \* then 2. At this time, we will pause, momentarily to assemble our roster.

The first question comes from Jason McCarthy with Maxim Group. Please go ahead.

**Jason McCarthy**

Hey, guys. Thanks for taking the questions. Can you guys talk a little bit about the dynamics around the needs for a monkey pox vaccine? Because we know MVA works. You would be, I think, the most advanced, U.S.-based MVA player in the states, but then we’re seeing some of the MRA companies try to nose in -- Moderna today coming out and saying their stock is up sharply. Can you give us a little bit of color around those dynamics -- what that space could shape up to be or, is it really just MVA and guys could be significant players there?

**David Dodd**

I’ll start and then we’ll see if any of my colleagues would like to. First of all, Jason, thank you for your question. Appreciate your interest in the company. We do recognize that we, more than likely, are the leading MVA company, certainly in the United States. We all know that there is a single-source supplier for money pox, currently. It’s out of Denmark.

We think it’s very important for there to be a supplier out of the United States that addresses this, for numerous reasons, not only to reduce the total dependence on a single supplier. I have no idea to the degree to which Moderna, with their MRA, may or may not be successful in producing a monkey pox vaccine. You know, time will tell on that, but we certainly recognize that MVA, which as we know, is the basis for so many of our products, is approved for preventing monkey pox, so that provides us an opportunity and we validated that in previous, you know, in previous peer-review publications that I mentioned in my comments. Now, I don’t know if Kelly McKee would like to add anything else to that, but I’ll as if he would. Kelly?

**Kelly McKee**

Yeah, hi. I mean, I -- David, I think you, sort of, summarized the, you now, the sort of overriding considerations. I, you know, MVA is -- or, at least Vaccinia-based, or Vaccinias, in general, are really the only proven preventative measure for monkey pox at this time. And, you know, the regulatory pathways for new re-entrants, I think, is yet to be decided. So, you know, how much Moderna or others will, or will be able to play in this -- I’m not sure anybody really knows at this time. You know, what -- as we look to how we would position ourselves for monkey pox, you know, we’ve got deal with some regulatory questions, as well. So, it’s kind of a wide-open field right now.

**Jason McCarthy**

So, do you take a multi-prong approach? Meaning, you have what looks like a really good COVID vaccine that could also, potentially cover monkey pox. But you also have Sudan and Marburg and Ebola and monkey pox might be more of an issue in other countries. Would consider doing something here in the States and maybe something in, like West Africa? We saw another group announce they’re going to something in Kenya, just this week.

**David Dodd**

The answer is yes and I’ll as Kelly to elaborate a little bit about our outreach to Africa and the concepts there, and also the difference in monkey pox and the strain of monkey pox that we see in Africa. Kelly, would you like to address that?

**Kelly McKee**

Sure. So, yes, I mean, you -- you’re thinking aligns very well with ours, as well. You know, the potential is to offer, sort of, a two-for, is certainly there for us. And we have made some preliminary inquiries with -- to individuals in some of the sub-Saharan African countries to explore interest in some sort of a co-development program. I’m not at liberty to sort of disclose any -- and the nature of those discussions but suffice to say the potential is certainly there.

You know, the strains of money pox -- there are two strains -- predominant strains of monkey pox, there are (ph) types of monkey pox, that have been recognized. The one that’s causing sort of the global epidemic right now is the West African strain, while the Central African strain of monkey pox, which is predominant in Central African Republic and sort of neighboring countries, is a much more virulent -- it seems to be much more virulent than the West African strains. And so, I think there is a lot more concern in these potentially endemic countries for having a, you know, access to an effective vaccine and the opportunity to offer protection against both monkey pox and another endemic virus, be it COVID or one of the hemorrhagic fever viruses, it is a -- is certainly an appealing prospect.

**Jason McCarthy**

And just a last question -- what about interest from pharma groups like BARDA, who have a stock piling, could be. Because, I mean the monkey pox virus, the MVA one that they supply, you know, as you know, I mean it’s their smallpox for immune-compromised people. Like, does that make your COVID vaccine for immune-compromised people that has cross protection against monkey pox particularly attractive to a government agency like that?

**David Dodd**

I would say, we think it does, potentially. You know, we know that various federal government agencies are recognizing that multi-antigenic approach for COVID-19 is something to seriously be evaluating and reviewing. So we know that from discussions, et cetera. And we also believe, based, you know, similar to what you’ve just raised, that the -- having that, and -- which is of increased, as we see, it will at least continue limitations of the current, authorized vaccine related to COVID-19, but also then having the added benefit of being able to address monkey pox could be very important to the stockpile program, as well as to NGOs who are looking at, you know, other endemic areas.

**Jason McCarthy**

Sounds good. Thank you for the questions -- taking the questions, rather.

**David Dodd**

Thank you.

**Operator**

Again, if you have a question, please press \* then 1. The next question comes from Jeff Kraws with Crystal Research. Please go ahead.

**Jeff Kraws**

Thank you. Jason asked several of my questions, but on that same wavelength, if you will, the combination -- there were stories around this week talking about the military, talking about military in Africa as well as talking about our military. We have already had grants -- (inaudible) grants -- Army grants. Is that something where one, you would be able to actually supply that and something you would pursue?

And secondly, have you talked with the miscoes (ph) down the pharma line, obviously, even companies like Pfizer and Modern, with the COVID vaccine, were not able to supply -- (audio gap) -- have you been able to move far enough down that line to be comfortable that, with these going through or, even the monkey pox one that I -- that you would be able to supply?

And the last question is, str -- (audio gap) -- wise, obviously if you have a combination vaccine, that’s great, as long as the government, or the regulatory bodies want to put through a combination vaccine. Are you thinking about doing it -- offering it separate as a way -- as well as combined?

**David Dodd**

To answer the second one, as has been commented on -- there, you know, there’s a complex -- I would say this. We are reviewing -- it’s a very complex development, regulatory pathway regarding to MVA as an alternative to the existing MVA that’s out there. So for us to go forward and bring that forward. What we recognize is that our MVA-based vaccines have that added benefit of preventing monkey pox.

So if we have an MVA VLP or an MVA-based Zika-virus vaccine and we were to further that in development, let’s say in a collaboration relative to the southern hemisphere, South America, we all -- we know that, for instance, in Brazil, that monkey pox is fairly common and is also a threat. So there, we would be able to meet the needs, not so much from a, I’ll call it dual indication, but from the recognition that the MVA-based vector brings the benefit of also preventing monkey pox.

So that’s sort of the approach that they were looking from that. From the standpoint of manufacturing, I’ll as if Dr. Mark Newman would comment on that, because as I mentioned in my comments, we can continue progress on moving towards a system that would enable us to meet the demands in a much faster rate than in the traditional chicken -- chicken eggs -- or chicken embryo fibroblasts. Mark?

**Mark Newman**

Yeah, sure. So, you know, right now, we manufacture using a process based on chicken embryonic fibroblasts, which is the same thing that Bavarian Nordic uses. So it’s primary cell line and that has limitations. Limitations in that you start with eggs. We are -- we have an active program, looking to getting -- it’s a continuous cell manufacturing -- cell-based manufacturing. And this would be more comparable to what the adeno vector. So if you think of the J&J or the AZ COVID vaccines. Those are with these continuous cell lines. And so that’s ongoing.

Now our focus has been on our vectored vaccines, particularly CM04S1 and then some of the other products, they’re at the research level. We actually haven’t looked at just producing MVA without one of these inserts in it. So, to go to your other point, would you make something that was MVA specific? That would be the easiest path. I have no doubt. There is a lot of data out there to suggest there are multiple cell lines that can produce, or support, the production of MVA. Where we run into a little bit of our difficult situation is when we have these combo vaccines, where you’re incorporating an insert, you gotta make sure that insert --

**Jeff Kraws**

Right.

**Mark Newman**

-- stays in there while you’re producing it. So that’s a -- just to make an MVA vaccine with a cell line would probably be the easiest path. And we have (inaudible) --

**Jeff Kraws**

Yeah, that’s why I asked, because -- right? -- that’s why I asked because, from a regulatory path -- (audio gap) -- directly the FDA has had some issues when you try to do things combined and I think you’re data is very clear and very convincing effort and I just think might be easier for you to get the -- (audio gap) -- even though, yes, you know, doing it combined and all the benefits of working against this one or working against that one and the whole platform. Great. I’m just thinking about what would be easiest for -- (audio gap) -- out there and simplest for someone to understand.

**David Dodd**

Exactly.

**Mark Newman**

Yeah, no, I think you’re right. If it’s an HIV vaccine, you’d have to get it approved for HIV and then you’d expand your claims show that it also --

**Jeff Kraws**

Right.

**Mark Newman**

-- worked against monkey pox. Yeah, I think that’s --

**Jeff Kraws**

Perfect.

**Mark Newman**

-- what we would face. So, yeah.

**Jeff Kraws**

Okay. Great.

**Mark Newman**

Those are all things that are being discussed.

**Jeff Kraws**

Okay. Thank you very much for the answers.

**David Dodd**

Thank you, Jeff.

**Operator**

The next question comes from Kumarguru Raja from Brookline Capital Markets. Please go ahead.

**Kumarguru Raja**

Thanks for taking my questions and (inaudible) to oncology. What are you seeing in in terms of (inaudible)? And also in terms of the animal studies that are being conducted in North Carolina? When can we get an update and what kind of information can we expect from that studies?

**David Dodd**

Kumar, thank you for your interest, et cetera. Could you repeat your first question and then we’ll address the North Carolina one?

**Kumarguru Raja**

Yeah, the first question is just the details about the implement (ph) is going, what you was seeing very important, we expecting some updates.

**David Dodd**

So I’ll ask Kelly to discuss the, you know, the Gedeptin, and all, and then I’ll ask Mark Newman to pick up on the development programs, including the UNC Charlotte. Kelly?

**Kelly McKee**

Yeah, hi. Yeah, we probably shouldn’t really talk about the enrollment dynamics at this time. You know, the -- we transitioned this trial to take control, I mean we in-licensed it, you know, the Gedeptin product a number of months back and we’ve been in the process of transitioning to the IND and expanding the trial to -- from a single site to a multi-site study.

And that has resulted in sort of a pause in the initial enrollment. And we anticipate accelerating in in short order. As David indicated in his introductory remarks, we hope to have, you know, the current trial completed some time next year. Beyond that, we need to be talking to the regulators to see, sort of, what they want us to present to them to -- for further studies or, you know, a regulatory pathways for an accelerated approval.

**David Dodd**

Good. Thank you. And again, I would just underscore that, you know, once we took over full sponsorship, we then are in the driver’s seat to initiate for those types of discussions and to focus on the acceleration across the multi-sites. And that’s where we are right now, so as Kelly says. So, Mark, do you want to pick up on the University of North Carolina, Charlotte work that’s going on?

**Mark Newman**

Yeah, sure. I can do that. So, we’re working with Pinku Mukherjee, who is a, you know, a world expert and, you now, pancreatic cancers and things related to MUC1. And she has a fairly unique animal model, or an animal model resource. Where we are right now, is we’re validating the animal model for our use, in her lab. And what we’re doing is a little bit different than what she has going on every day. So, that’s been moving along at an acceptable pace. All these things take longer than you want.

But we are anticipating, once the study -- once the mode is fully validated and we’re comfortable with repeat -- repeatability, the in-life portion of the study -- it’s got two pieces. The first data will be coming out by the end of the year. And then, we have follow-ups as, you know, the second piece, depending on what we see with the first. So that would be during Q1 and Q2 of next year. But I think we’ll have -- we’ll be talking about progress later this year, then Q1 next year.

**Kumarguru Raja**

So the expectation is that the data would be presented at the medical meetings? And also, with regarding therapy, where do (inaudible) come from drug (inaudible) for clinical trials? Thank you.

**Mark Newman**

The drug substance for the cancer trial?

**Kumarguru Raja**

That’s right. Yes.

**Mark Newman**

Okay, well so, what we’re envisioning with the MUC1 program, you know, I mean, I quick presented this before. It’ll be a combination vaccine of the MVA-vectored vaccine, which is ours, and then we’ll be boosting it with peptide anagemin (ph). So, the questions you’re asking right, with the mouse model, is do we start out with a peptide and then boost with the MVA? Do we start out with the MVA and boost with the peptide?

And it would be beyond the scope of this call to explain to you the different logics of what we’re looking for. But we think we can fine tune the immune response, you know, to a more CDA response or more antibody, through these different immunization routines. Now, how would be move that into a clinic, in terms of drug substance?

So, first of all, the peptide is available right now. We’re using a GMP product produced at the bio-facility, University of Pittsburgh, and that would be our partner, moving in through the National Cancer Institute. That material is available. We have a liposomal-encapsulated, toll-receptor agonist as agiment (ph). That’s already produced GMP and we’ve got the supply agreement in place through a company -- a partnership with a company called OncoVeer (ph).

The MVA would then have to be produced and we have a number of potential players or partners that we could manufacture. Now, we would manufacture only in CEF cells, this would be a primary cell, you know, go fast, we would not do anything experimental with this. And then, based on experience, like for example, with 04S1, we’ll probably take, between five and six months to manufacture a lot of material to support phase I and phase II testing.

Now, just the caveat being that is early-stage phase test A -- early-stage, phase I and II testing. So all of these products, at least the peptide and the MVA, and then we would, assuming good-looking results, then we would scale that and increase the quality control and everything, you know, go with the real CDMO for production of, you now, really cement the product. But we don’t have to have that in place until we’re taking phase III.

**Kumarguru Raja**

This is very helpful. Thanks so much.

**David Dodd**

And Kumar, we’ll -- the data results will be presented, you know, as they’ve been validated, et cetera, at scientific meetings. So -- and we’ll issue press releases, notifications of all of that. Thank you. Were there any other questions --

**Operator**

(Inaudible)

**David Dodd**

Go ahead, Andrew.

**Operator**

Oh, not at all. Seeing no further questions, this concludes our question-and-answer session. I would like to turn the conference back over to David Dodd for any closing remarks.

**CONCLUSION**

**David Dodd**

Thank you Andrew. And thank you, everyone, for participating in this corporate update call and sharing in our achievements, progress, and outlook. Your interest in greatly appreciated. Our focus is on execution and reporting updates and progress for Gedeptin, CM04S1, CM02, and other development programs, such as the ones we were just talking about with the MUC1, as well as the expansion of our capabilities and resources.

Our goal is to build shareholder and stakeholder value. I want to acknowledge and thank the GeoVax Board of Directors, our GeoVax staff, and the many other parties that continue to support, assist, and advise us towards achieving success. For all of us, it is a great pleasure serving our shareholders and stakeholders and being a part of this team. We wish you a safe and enjoyable day and thank you. We look forward to speaking with you at the next conference call.

**Operator**

The conference has now concluded. Thank you for attending today’s presentation. You may now disconnect.