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BioSig Technologies, Inc.
ViralClear Pharmaceuticals, Inc. Conference Call
Phase II Human Trials for Broad-Spectrum Oral Antiviral Candidate for
Treatment of COVID 19
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Presenters

Andrew Ballou - VP, Investor Relations, BioSig Technologies

Nick Spring - Chief Executive Officer, ViralClear Pharmaceuticals

Steve King - Chief Operating Officer, ViralClear Pharmaceuticals

Jerry Zeldis, MD - Executive Chairman, ViralClear Pharmaceuticals

Ken Londoner - Chairman, Chief Executive Officer, BioSig Technologies

Operator

Greetings and welcome to the ViralClear Pharmaceuticals conference call to discuss phase 2 human trials for broad-spectrum oral antiviral for treatment of COVID-19. At this time, all participants are in a listen-only mode. A brief question and answer session will follow the formal presentation. If anyone should require operator assistance during today's call, please press “*0” on your telephone keypad. As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Andrew Ballou, Vice President, Investor Relations of BioSig Technologies, Inc. Thank you, sir. You may begin.

Andrew Ballou

Thank you, operator. Good morning and welcome to today's ViralClear Pharmaceuticals management call to discuss upcoming and recent developments for phase 2 human clinical trials of merimepodib, ViralClear's broad-spectrum oral antiviral candidate for treatment of COVID-19.

On today's call we have Nick Spring, ViralClear Pharmaceuticals Chief Executive Officer; Steve King, ViralClear Pharmaceuticals Chief Operating Officer; and Jerry Zeldis, ViralClear Pharmaceuticals Executive Chairman. Additionally, Ken Londoner, BioSig Technologies Chairman and Chief Executive Officer, will be available to answer questions during the Q&A portion of the call.

I will remind everyone that on this call the presenters may make forward-looking statements. Such statements may be preceded by the words intends, may, will, plans, expects, anticipates, projects, predicts, estimates, aims, believes, hopes, potential, or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions, and are subject to various known and unknown risks and uncertainties, many of which are beyond the company's

control and cannot be predicted or quantified, and consequently actual results may differ materially from those expressed or implied by such forward-looking statements.

Such risks and uncertainties include, without limitations, risks and uncertainties associated with, one, the geographic, social, and economic impact of COVID-19 on our ability to conduct our business and raise capital in the future when needed; two, our inability to manufacture our own products and product candidates on a commercial scale on our own or in collaboration with third parties; three, difficulties in obtaining financing on commercially reasonable terms; four, changes in the size and nature of our competition; five, loss of one or more key executives or scientists; and, six, difficulties in securing regulatory approval to market our products and product candidates.

More detailed information about the company and the risk factors that may affect the realization of forward-looking statements is set forth in the company's filings with the Securities and Exchange Commission, SEC, including the company's annual report on Form 10-K and its quarterly reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's website at www.SEC.gov. The company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events, or otherwise.

I'll now turn the call over to Nick Spring. Go ahead, Nick.

Nick Spring

Thank you much indeed, Andy. Good morning, everyone. Thank you all for joining today's ViralClear business update call. Our last call was on April 29th, and so much has happened at ViralClear and the broader space since then.

For instance, two days after our call, the FDA granted Emergency Use Authorization, also known as EUA, for the investigational antiviral remdesivir to treat COVID-19. The EUA facilitated broader use of remdesivir to treat hospitalized patients with severe COVID-19 disease, enabling access to remdesivir at additional hospitals across the country.

That EUA had a ripple effect, changing the therapeutic landscape for hospitalized patients. We had to change our hospitalized patient trial protocols to incorporate remdesivir. The FDA cleared our IND application for merimepodib for a phase 2 protocol that added merimepodib or placebo on top of remdesivir therapy.

In addition, we raised \$10.8 million at the ViralClear subsidiary level. We expanded on ViralClear's Board of Directors, adding strong healthcare and capital markets expertise, submitted compelling *in vitro* data for the antiviral effects of merimepodib alone and in combination with remdesivir,

expanded our clinical trial to include more enrollment sites, and expanded the intellectual property portfolio.

As I've mentioned before, we're not alone in developing a solution, but merimepodib is a platform drug that can and will be used in combination with other antiviral or immunomodulatory drugs. As you can see, we have strong momentum and are very much looking forward to helping provide a treatment solution to this and future pandemics.

Now, I'll hand over Steve to talk about manufacturing and other related subjects. Over to you, Steve.

Steve King

Thank you, Nick, and good morning, everyone. Today I'm going to give an update on the CMC, the chemistry manufacturing controls, and drug product supplies. The goal of the CMC group is to provide a robust oral formulation for commercial launch. We are continuing to use a virtual drug development outsourcing model with a team of expert consultants.

As I've mentioned, ViralClear has sufficient merimepodib APIs to see us through both phase 2 and phase 3 pivotal trials. The material has been used to make solution for the phase 2 studies. It has also been used in our ongoing formulation development of ultimate dosage forms, including an IV and solid oral dosage form. This formulation development is moving in parallel with the production of clinical supplies and the dosing in the phase 2 trials.

The data from phase 2 will be very important as we learn more about how the drug works in the body for the treatment of COVID-19. Based on this data, we will make supplies for the phase 3 study, which is expected to start in the fall. We have contracted one US-based supplier of API, and new material will be delivered in Q4 2020. This material will be used to manufacture the NDA registration batches.

Further materials from this supplier and another US-based API producer will be contracted in the next few weeks. This material will arrive late 2020, early 2021. Formulation development work will continue over the next few months, and animal studies are planned to test these new formulations. The goal is to make a robust powder that we can make into a capsule or tablet.

We believe COVID-19 treatment will be a combination of one or more compounds, as seen in hepatitis C and HIV treatments. By developing a powder, it gives us more options to develop a combination product and increase patient compliance and successful treatment.

The regulatory team is performing a gap analysis on the work which was conducted by Vertex in the late '90s, early '00s and, once identified, the necessary work will be completed. On the clinical side,

we have been working to sign on multiple U.S. sites for our studies, which Jerry will talk more about in more detail.

Many things have been achieved since our last call, and I'd like to recognize the team at ViralClear as well as the US-based outsourcing providers who have supported our efforts to provide material to the clinic.

With that, I will hand over to Jerry to discuss the clinical programs in more detail.

Jerry Zeldis

Okay. Thank you very much, Steve. As both Nick and Steve have alluded to, because of the Emergency Use Authorization of remdesivir, we've had to reconsider what our phase 2 trials should be to move as fast as we can into the clinic and out of the clinic to show that our drug has a meaningful clinical benefit in this disease.

I'll remind you that the mechanism of action of merimepodib is that it focuses on a host enzyme, which means that, as the virus changes, its ability to be affected by our antiviral won't change. We have changed the inpatient--we've now adapted an inpatient strategy, which should not lose any time to accrue and for us to interpret the results.

There are now two inpatient studies. The first is the standard of care for patients who are hospitalized, who require oxygen but are not yet intubated. The standard of care right now is supportive care with supplemental oxygen and remdesivir. These patients will be randomized to either placebo or our drug, merimepodib, and we will follow them. We'll give them 10 days of treatment unless they get better and are then discharged from the hospital, and we'll look at a variety of clinical parameters to see if they improve, as well as viral shedding.

The actual endpoints and the structure of the trial is accessible on ClinicalTrials.gov, and I'm not going to read through the whole document. What we've discovered, however, is that even though remdesivir is accessible to all sites in the United States, all hospitals in the United States, the availability of the drug is limited, and there are many places where we'd like to do clinical research who, at this juncture, do not have access to remdesivir.

We therefore created another hospitalized patient study, which is identical to the first study, except these patients are not going to be treated with remdesivir. They'll be given supportive care, and they'll be randomized to either our drug or placebo. Both trials will enroll 40 patients, half of whom will get placebo, the exact same endpoints between the two studies.

We believe that now that we've expanded the number of sites, potentially we'll have eight sites going in the United States, some of whom we're beyond contracting and IRB approval, so we'll be initiating the sites very, very soon. We think they'll both accrue rapidly so we can get a readout on both trials no later than August of this year, perhaps sooner than that.

Okay. Nick, back to you.

Nick Spring

Thanks a lot there, Jerry and Steve. That concludes our prepared remarks. Operator, please remind participants how to poll questions.

Operator

Thank you. We will now be conducting a question and answer session. If you would like to ask a question, please press “*1” on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press “*2” if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the “*” keys. One moment, please, while we poll for questions.

Nick Spring

Hey, operator, this is Nick here. While we're waiting for the first question to come in, let me just tee up one question I know that a number of people have already, prior to the call, asked. So, the first question actually, and I'm going to ask Jerry to comment on this, is when do we expect first patients in the trial? Over to you, Jerry.

Jerry Zeldis

As I said, at some of our sites we already have IRB approval and we're--we've had site initiation visits. And there's a few minor things that need to be taken care of, but the actual therapy is being shipped to the sites, and then patients will be screened to see if they meet entry criteria. And if they do, they'll be enrolled, and we'll start treating.

So, we expect the first patients will go into the trial imminently. I can't tell you a specific date or time because it depends on who's hospitalized and who meets entry criteria, but we expect this will happen very, very soon.

Nick Spring

Thanks, Jerry. Okay, operator, have you got the first question, please, from the callers?

Operator

Our first question comes from the line of Yale Jen with Laidlaw & Company. Please proceed with your question.

Nick Spring

Good morning, Yale.

Yale Jen

Good morning and thanks. Hi. Good morning. How are you? And thanks for taking the questions and congrats on the rapid progression of the trial--.

Nick Spring

--Thank you--.

Yale Jen

--The developments. Just wanted to be clear a little bit in terms of the trials, these study--the two trials. One is with the standard of care, and then you have placebo versus -your drug. And is the second one also the same or slightly different, and what was the total patient size for each of those studies?

Nick Spring

Thanks very much indeed for that question, Yale. I'll toss that over to Jerry, please. Could you let Yale know the answers to those two questions?

Jerry Zeldis

Simplistically, they're identical trials. Each trial is going to bring in 40 patients, half of whom will get placebo and half will get merimepodib. In some hospitals, they do not have access to remdesivir. So, the--it's essentially standard of care plus or minus our drug, in other words, placebo or our drug. In those hospitals which do have--which does have access to remdesivir, it's the same thing. It's standard of care, which includes remdesivir with placebo or with our drug.

As you know, we've already published in F1000 Research that we're seeing synergy between remdesivir and our drug. So, we anticipate, or we hope that this will translate into a very meaningful clinical response. But the beauty of both these trials is that one trial will tell us what our drug can do by itself, whether you really need to add another drug on top, and we also think that the combination of remdesivir with our drug, we should get as good if not better clinical response. So, we'll find out.

Nick Spring

Thanks a lot--.

Yale Jen

--Okay--.

Nick Spring

--Jerry. Okay. Any supplementary, or next question, operator?

Yale Jen

Sure.

Nick Spring

Operator?

Operator

Our next question comes from the line of Scott Henry with Roth Capital Partners. Please proceed with your question.

Nick Spring

Good morning, Scott.

Scott Henry

Thank you--.

Nick Spring

--What's your question, please--?

Scott Henry

--And good morning. I guess first, just to follow up with what you just stated, that you've seen synergy between MMPD and remdesivir, can you talk about that? I mean, should we think of, you know, one plus one equals two or maybe a little better than that, or just, you know, just as long as we're getting some improvement after--over remdesivir, and how we should think about the two agents working together?

Nick Spring

Okay. Thanks very much indeed. I mean, one general comment I'd make is that we've always viewed MMPD as being either a mono or a combination therapy. So we, as we go forward, see that, you

know, there's going to be multiple solutions to this issue. But I'll hand over to Jerry for more specifics on that.

Jerry Zeldis

Yeah. Hi, Scott. If you go to F1000 Research, you'll see what we published. But essentially, at pharmacological concentrations that both drugs will achieve, we get zero viral production. So, it's one plus one equals 1,000 is the synergy that we're seeing. It's truly remarkable. And in fact, you have to get to very sub-therapeutic concentrations before you see any viral replication.

So, what happens in a human being we don't know. This is why we do clinical research. But we're very hopeful that what we've seen in this tissue culture system will translate into something very meaningful in humans.

Scott Henry

Okay. Thank you.

Nick Spring

Okay. Scott, any further questions? Okay.

Scott Henry

Yes.

Nick Spring

All right. Thanks, Scott. Next question, please? Operator, next question?

Operator

Our next question comes from the line Aaron Grunfeld, a private investor. Please proceed with your question.

Aaron Grunfeld

Good morning.

Nick Spring

Morning, Aaron. What's your question this morning?

Aaron Grunfeld

As--first of all, as a shareholder of both BioSig as well as ViralClear, I'm very impressed with what management has achieved so far in each of the different lines of business. When we were

proceeding with the investment, we were--we understood that there would be a registration statement filed and that the company would ultimately be listing on NASDAQ.

So, I have two questions. One is when will that registration statement be filed as far as people currently are contemplating it? And two, how long will the amount of money raised in the private placement last before a need for another financing?

Nick Spring

Thank you very much indeed for those very relevant questions, Aaron. I'll hand this over to Ken. Ken, would you like to answer Aaron's questions?

Ken Londoner

Yeah. Hi, Aaron. Thank you for your question and your comments. The registration statement is in the final process. We're in the third or fourth draft, and you can expect to see that filed shortly. I couldn't give you the day, but it's soon.

And as far as the spin-off that we've discussed, everything is still moving forward. Obviously, filing the registration statement's the next step, and then we have to get through comments with the SEC. We are hearing from our corporate counsel that, because, I guess, of the heightened activity of the pandemic, SEC is clearing comments very rapidly. So, let's hope that accrues to us. And then as soon as comments are cleared, you'll be hearing more about the contemplated transaction.

Nick Spring

Okay. Any other comments there, Ken?

Ken Londoner

Nope.

Aaron Grunfeld

I have one additional item. There on the--.

Nick Spring

--Um-hmm--.

Aaron Grunfeld

--On how long the proceeds would last before--roughly before--.

Ken Londoner

--Oh, I--yeah, I apologize. Basically, what I'm comfortable in saying is that the company has enough proceeds to comfortably get them through the phase 2 readout. And once the phase 2 readout is in hand, the company believes it'll have a multitude of options for additional capital at higher valuations. Thanks, Aaron.

Aaron Grunfeld

Okay.

Nick Spring

Does that help you, Aaron? Thank you very much indeed for your question. Operator, next question, please?

Operator

Our next question comes from the line of Gary Zwetchkenbaum with Plum Tree Consulting. Please proceed with your question.

Nick Spring

Morning, Gary.

Gary Zwetchkenbaum

Good morning, Nick. Good morning, Nick, Dr. Zeldis, and Ken.

Nick Spring

Yeah.

Gary Zwetchkenbaum

Thanks for the update. I really appreciate it as a shareholder of BioSig and also ViralClear.

I have a two-part question, for--one for you, Nick, and one for Dr. Zeldis. First for Nick, with your vast experience with Merck seeing viruses and the drugs, what gives you your high level of confidence that this drug will be accepted into the marketplace? And for Dr. Zeldis, importantly, please tell us why you chose to sell your antiviral drug to BioSig Technologies and Ken Londoner as opposed to Sorrento and other places. And then I have one short question for Ken regarding ViralClear and what percentage BioSig shareholders own currently. Thank you.

Nick Spring

Um-hmm. Thank you very much indeed, Gary. Yeah, I'll pick up on that first. So, you might remember from previous conferences--and by the way, thank you for being a shareholder in both companies.

When we really started this venture back in March, there were some compelling sort of drivers that drove me to really drop everything, as did Steve King and also Dr. Zeldis, to really jump in, you know, feet first into this particular opportunity. And really for me, the compelling elements, and I'll answer your question about why I believe this is a winner so much, you know, second is, you know, anything coming into the market needs to be safe, effective, and in this case it's got to be available to the patient rapidly.

So, when Jerry and I were originally talking about this on the safety side at that point, and still true, you know, over 400 subjects have been tested in phase 1 and phase 2 for hepatitis C product development way back in the Vertex days. So that, for me, checked that box. It was seven phase 1s and five phase 2s. So, that was a very, very compelling.

The second point was at that time--and now this has been developed even further and Jerry can probably talk in more depth. At that point, a Vero cell culture study had been done, and it was already demonstrating that merimepodib, or MMPD, was over 90% efficacious against dropping viral load of COVID in cells--well, to virus. So, you know, it was looking really, really good.

And then the third thing was that we could really get into clinical trials very rapidly. And, you know, one of the major achievements we've got under our belt already, and if you remember from previous conference calls, we talked about focus and speed, and I'd probably add agility to that in the company as well, it was getting an IND within something like 60 days. In my career, which has spanned over 35 years, I never heard of that. So, that gave me compelling faith in the actual drug and the product.

In terms of its actual activity, we've now had further cell culture tests that have shown as a monotherapy it gets over 98% drop in viral load. And as Jerry was just alluding to, in combination with remdesivir--and that's just one of many antivirals that there could be out there or--you know, we want this to be a platform drug. It will probably be used in combination, as we've seen in controlling other diseases. So, that gave me a lot of confidence.

The other thing that I really love about this particular product is it's oral. And if you look at remdesivir, for instance, it's IV so it can only be used in an inpatient situation, whereas this can be used both in inpatient and outpatient. And in fact, ultimately the biggest market for prevention and

cure is going to be the outpatient market, not the inpatient market. So, these all were very, very compelling evidence to me.

The final thing is, and I think it's--you know, at the end of the day, we're not really in a competitive type of situation. We're more as a collaborative, across the whole of the healthcare industry, to conquer this. But, you know, when you look at it, although there is a lot of talk about a lot of therapeutics out there, you know, a lot of vaccines, and vaccines are really a long-term play, not a short-term play, the thing that really also led me to believe that this is going to be a real winner is there's only a handful of drugs right now in phase 2 or phase 3 trials in the USA, and we're one of them.

So, when you add that all together, it looks like we've got a very compelling argument to say that this product is not only going to be a winner-- against COVID-19 disease and the pandemic and the echoes and it's going to be there for the stockpile, but it's also going to be one of the front leading drugs too--in this therapeutic category. So, that gave me a lot of confidence, and it still gives me a lot of confidence, which is why the team got together and we're doing what we're doing.

In three very short months, we've made huge strides forward. And we're imminently going to be in the clinic. And very shortly we'll have results from that, which I'm pretty confident are going to be very positive. And we--over to you, Jerry, for the other questions.

Jerry Zeldis

Okay. When we did this, the initial--when I was--at the time we looked at the Vero cell assay for the SARS-CoV-2 virus, the cause of COVID 19, I was not only the chief medical officer of Sorrento Therapeutics, but I also was the sole board member of Trek Therapeutics, which owned the asset merimepodib. At the time, I know that Henry Ji and Sorrento were going to use their monoclonal antibody and the genetic engineering expertise to address this.

I told Henry that I was going to do this, and he was not interested in small molecules. So, that would, of course, rule out anything that I did. And when we got the signal that the drug was quite active in the Vero cell--Vero cell assay, I went to Henry and said, Henry, this is so compelling that I think I--we can do something very meaningful. And since you're taking a different direction than I am, I'd like to resign from Sorrento. And he wished me lots of luck, I wished him lots of luck, and I resigned from Sorrento.

I then approached Ken Londoner, who I had known for 14-plus years. And together, we had been involved with some startup companies. And his expertise is finance and management, and I asked Ken, I need--I basically told him I need to raise money so we can do this. And Ken was very affected

by what was happening, and this is the early days of the pandemic, and he said if I can help you I will. He said let me think about this.

And then he came back to me a day or two later, having talked to members of his board, of which-- I'm also on his board, but of course I wasn't part of those conversations, where an offer was made that they would allow us, if we wanted, to move into a subsidiary of BioSig to allow us to move very quickly. And it was on that basis that we made the decision that that's what we would do.

And so, as documented, we sold--Trek Therapeutics sold merimepodib and another asset to NeuroClear, which was the name of the subsidiary. The subsidiary changed its name to ViralClear, and from there they raised money. And to this day, I'm--and probably beyond, I'm very, very grateful to Ken and the BioSig board for having the vision to allow us to move forward.

And as Nick said, in record time we went from ground zero doing--you know, to saying, okay, we know we have the asset, to actually putting our arms around the asset to getting the active pharmaceutical ingredient, formulating it, submitting an IND, getting the--allowed to proceed. And as I said a little while earlier to another question, we expect the first patient will be coming into our study imminently.

Ken Londoner

And Gary, the answer to your question is currently BioSig owns 69.3% of ViralClear.

Nick Spring

Okay, Gary. That's a lot of answers--.

Gary Zwetchkenbaum

--I want to just--.

Nick Spring

--To lots of questions there. Is that okay, or another one?

Gary Zwetchkenbaum

I just want to--what you guys have done in 64 days as a team is amazing, what a collaborative effort. I really appreciate--.

Nick Spring

Thank you very much indeed, Gary; appreciate you and your support.

Okay, operator, next question, please?

Operator

Our next question comes from the line of Mark Moran, a private investor. Please proceed with your question.

Nick Spring

Good morning, Mark.

Mark Moran

Yes. I was wondering--good morning.

Nick Spring

What's your question, please?

Mark Moran

Are you still proceeding with the outpatient trial at the Mayo Clinic, or are you--?

Nick Spring

--Jerry, would you like to comment on that?

Jerry Zeldis

Yes. What happened because--when remdesivir became the standard of care, the FDA wrote to us and basically--first of all, we anticipated that sites would not want to do a monotherapy trial because they'd want to combine it with remdesivir. So, as we were watching this Emergency Use Authorization was about to happen, we wrote our protocol in anticipation of the FDA coming back to us and asking if we could combine it with remdesivir, especially since we had preclinical data to show that we had synergy, which they did.

And so, that's what was approved by the FDA for us to go forward. The difficulty we ran into was that many of our sites said they can't get access to remdesivir, and therefore they couldn't do the combination study. Other of our sites said don't worry about remdesivir. We have it and you'll be able to enroll.

So, what we decided to do was to basically make a cookie-cutter protocol, same thing except standard of care is without remdesivir, and actually offer this to both--all sites. So, I'll make this up. A site this week has adequate remdesivir, they go into one trial. But next week they're not allocated any remdesivir, they can put people into the other trial, that type of thing. And because of our resources, we decided to delay the outpatient study.

And I--and when we thought about this some more, we realized that the problem with the outpatient study is that these people are at home. They're quarantined. They're remotely being monitored. And we thought it'd be better if we could see what well-monitored people can do on our drug, which would be hospitalized patients.

But our intent is very strong that we want to move into the outpatient setting as soon as possible. And we anticipate triggering an outpatient study sometime in the near future. It could be before the phase 2 trials are over. It could be immediately after these phase 2 trials are over. We just have to play it by what we're seeing in the clinic.

Nick Spring

Yep. Thanks, Jerry. And I think just one other comment I'd make is that I think the brilliant thing about the new study design is the fact that we get, in a very controlled environment, results both for using MMPD as a monotherapy as well as in combination. So, you know, it's a double whammy. So, that's great.

And the next question, please?

Operator

Our next question comes from the line of Todd Ammons with Norwood Capital. Please proceed with your question.

Nick Spring

Morning, Todd.

Todd Ammons

Yes.

Nick Spring

What's your question?

Todd Ammons

Morning. Morning. So, how much did Trek sell MMPD for to BioSig?

Nick Spring

I'll let Ken answer that question.

Ken Londoner

Yeah, we disclosed that in an 8-K. They received 7.5% of the equity of the subsidiary, and approximately \$3.9 million. There was money in the subsidiary that they moved into, and there was cash consideration for the asset.

Todd Ammons

Great. Thanks. And then--

Nick Spring

--Thanks, Ken.

Ken Londoner

There are two assets, not just merimepodib, but there's a second drug as well.

Nick Spring

Okay. Okay, Todd. Thank you very much. The next question, please?

Operator

Our next question comes from the line of Robert Constantino, a private investor. Please proceed with your question.

Robert Constantino

Hi, guys--.

Nick Spring

--Hello, Robert. What's your question--?

Robert Constantino

--Great progress. Great progress in the last three months; unbelievable.

Hey, I have a question. So, the former NeuroClear subsidiary is now ViralClear. Last year, we had several press releases about assets acquired or licenses acquired from Mayo that were going to be in the NeuroClear subsidiary before this deal. So, now that NeuroClear is ViralClear, where are those assets? Where are those Mayo licenses?

And second question is on CTAP. Is the CTAP approved and are you allowed to dose patients under CTAP outside of the trial?

Nick Spring

Okay. Well, there are two separate questions there. So, the first one is really financial, so I'll ask Ken to answer that. And then the second one I'll toss over to Jerry at the appropriate moment. So, Ken, would you like to comment on the first part of that question?

Ken Londoner

Yeah, Rob, the NeuroClear assets are back inside of BioSig, the parent. And we are proceeding ambitiously with that program. As you know, and what may have been clouded by the coronavirus environment, we signed an agreement with the University of Minnesota and Dr. John Osborn to start conducting proof of concept clinical trials in his lab in Minnesota.

And we are the--we've designed the trial. We're waiting, actually, for that center to open. Unfortunately, with the riots, it's pushed them back a few more weeks. But we have a very nice protocol and we actually have prototype development going on with our manufacturing partner. So, you'll be hearing more about the whole NeuroClear developments as we go forward into the back half of the year.

Nick, you can take the rest.

Nick Spring

Thanks very much indeed, Ken. Yeah, Jerry, do you want to comment about CTAP and our approach to the FDA, etc.?

Jerry Zeldis

As you know, CTAP was a mechanism to rapidly get clearances to allow patients to be treated with whatever you're developing. The difficulty is that they got swamped. And we found that the mechanism, by the time we put in our application to CTAP, it was very, very slow. And we felt that we can get a much faster turnaround if we went straight to the review division.

And so, therefore, we withdrew from CTAP and went straight into the review division, and we got a--and you have to understand, they're being swamped as well. This woman told us that they had 800 INDs they were adjudicating. And so, I'd say in record time, in under 20 days, they gave us permission to proceed. And so, we can now treat people on our protocols.

If we had gotten the CTAP approval, we would still treat people under the same protocols. So, from a regulatory perspective, it doesn't--it didn't change anything.

Nick Spring

Thank you very much indeed, Jerry. So, I think that answers those two questions. Next question, please?

Operator

Our next question comes on the line of Lawrence Beroza, a private investor. Please proceed with your question.

Nick Spring

Morning, Lawrence.

Lawrence Beroza

Hello.

Nick Spring

What's your question?

Lawrence Beroza

Good morning. I was wondering about the question, if a vaccine comes onto the market and is found to be effective, where will the need for MMPD come from? And in general, same question really. How would an effective vaccine affect your product?

Nick Spring

Yeah, that's a very interesting question. I'll answer that. So, really, we've always seen this as a multifaceted approach to controlling COVID and, you know, got to remember future possible pandemics. So, I'll deal with this in various areas. By the way, as background, we didn't go through our background at the beginning of this, I used to lead at Merck the worldwide live viral vaccines franchise, so I'm very, very familiar with vaccines.

So, we see a role for everything. There's really three major areas of therapeutics and vaccines together. There's antivirals, immune modulators, and vaccines, so I'll just deal with the vaccines here. So, normally a vaccine, as you know, would take something like 10 years to develop because you've got to produce something both safe and efficacious. So, right now the current programs in place are highly ambitious, even cutting it down to a year, or you've got this Operation Warp Speed which is trying to say you might have one by the end of the year. Who knows? So, I think that there's significant technical aspects to developing a vaccine very rapidly.

The other thing you got to remember is that vaccines are relatively difficult to develop, especially against coronaviruses. In fact, if you look at SARS or MERS, which were, you know, two other

possible epidemics/pandemics that never really developed that far, a fully functional vaccine was never actually developed for either. So, you've got to question whether you can get there.

But even if you did, there's other things you have to think about with a vaccine. The first thing is you've got to scale, which means you've got to produce enough to inoculate the population. Then you've got to go out and you've got to actually inoculate 80%, 90% of the population so you start to get herd immunity so the vaccine's effective. So, all that's going to take time. Let's say 18, 20 months or two years away.

The other thing you've got to remember is that vaccines are very specific, usually, to one particular organism or disease. So, even though you may develop a vaccine that's effective against COVID-19, who says it's going to work against COVID-20 or 21 or whatever else comes down the line? So, there are the sort of parameters around a vaccine, although a vaccine definitely has a part to play in the armamentarium against this disease.

So, coming back to the role of antivirals and immune modulators, if you think about it, no country in the world is going to allow the economy to be brought to its knees again for a virus. So, always your first weapon against viruses is going to be a broad spectrum, preferably oral, proven antiviral. And that's where we really come in and other antivirals will come in and immune modulators, because let's not forget people aren't necessarily just dying from the virus with this disease. They're dying from the effects of the virus. They go into the ICU. Their immune system goes into collapse. They have a thing called a cytokine storm. So, that's what's, you know, causing the endpoint.

So, our role in this is going to be, Lawrence, that not only can we be highly effective right now, and there'll be echoes to this pandemic. It's been proven throughout history. If you look at the history, say, of the great flu epidemic way back a century ago, you'll have seen wave after wave after wave. We're already seeing it now with people coming out of lockdown, and you're seeing, you know, the numbers of cases beginning to spike in certain states again. So, you need an antiviral that's effective against those waves.

Then also, and if you read the report from Leerink the other day talking about Gilead, in fact, that also there's going to be a huge need for a stockpile, for governments to have antivirals available as a first line of defense before they have the ability to develop any vaccines against not only coronaviruses but other viruses that could threaten us going forward in the future.

So, that for us is why this becomes a very sustainable business model, because it isn't just today, it's tomorrow as well. So, our view is that vaccines, immune modulators, and us and anti--other antivirals all have a part to play in containing this virus in future pandemics. Does that answer your question?



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Lawrence Beroza

It does.

Nick Spring

Okay.

Lawrence Beroza

Thank you.

Nick Spring

Thank you very much. Okay, next question, please?

Operator

Our next question comes from the line of Rene Delambert, a private investor. Please proceed with your question.

Nick Spring

Good morning, Rene. What's your question?

Rene Delambert

Good morning. Thanks for taking my call. So--there is so much money out there. When you think of the Bill Gates Foundation, some of these other foundations are just throwing around millions and millions of dollars.

Nick Spring

Um-hmm.

Rene Delambert

Has ViralClear either been approached or are they going after any of these massive piles of money to help fund perhaps the future development of phase 3 and onward?

Nick Spring

Yes, I mean, it's a very good question. The answer to that is definitely yes. Obviously, we can't openly talk about it, but we are investigating a number of different avenues of non-diluted--non-dilutive financing very actively. You know, we've been around for 2.5 months, so we've been in discussions for a while, and hopefully something may develop. But yeah, that's definitely an area that we're investigating very actively. So, thanks for the question.

Rene Delambert

Thanks.

Ken Londoner

I'd like to add one other thing as well, Rene. If you notice, all the partnerships that are being, you know, achieved by other companies, you know, we are looking at a number of opportunities in that arena as well.

Nick Spring

Yeah, that's true. Thanks, Ken.

Rene Delambert

Exciting; thank you.

Nick Spring

Okay. Thanks, Rene. The next question, please?

Operator

Our next question comes from the line of John Brecht, a private investor. Please proceed with your question.

Nick Spring

Good morning, John. What's your question, please?

John Brecht

Good morning. My question is, it seems like some of these studies are being impeded by not having remdesivir available. Could not remdesivir be supplied along with the BioSig antiviral so that that wouldn't happen, or is that just too simplistic?

Nick Spring

A very good question; I'll throw that over to Jerry again because it's obviously something we've been looking at. So, Jerry, do you want to comment on that, please?

Jerry Zeldis

Yeah. And this is going to end the end of this month, but when remdesivir got the Emergency Use Authorization, a certain amount of therapy was given to the U.S. government gratis from Gilead, which was then distributed amongst the states based on the perceived need, and each public health department at the state level would then allocate the drug to various hospitals based on their perceived need.

Based on what I've read in the New York Times, Wall Street Journal, whatever, it sounds like that is going to be exhausted at the end of this month and Gilead will start selling the drug. We--again, I can't comment on specifics, but through a variety of avenues, we've approached a variety of institutions that might have access to remdesivir to see if we could get the drug, and so far we have not secured it. So, we're really dependent on the hospitals which have contracted with us to do our research as to whether they can get the drug.

This also, therefore, was an impetus for us to change our phase 2 trial so that we have a very good site which takes excellent care of their patients. They can participate with a monotherapy trial while they're trying to get remdesivir. And once they get it, then they can go straight into the remdesivir trial as well.

But that's where things are at the moment. I can tell you, if you talked to me a week ago, you'd get a different answer. If you talked to me three weeks ago, you'd get a very different answer. And I expect that--so, I'm giving you a forward-looking statement--a week from now and two weeks from now, it will be also a different story. But we're trying to be very agile to move this program forward as fast as we can.

Nick Spring

Thanks, Jerry. Thanks, John. Next question, please?

Operator

We have reached the end of the question and answer session. I would now like to turn the floor back over to management for closing comments.

Nick Spring

This is Nick here. I'd just like to say thank you to everyone who called in today and for your continued support and enthusiasm. Also, I'd like to thank our management team and especially BioSig, who have been very helpful in moving this whole project forward for something that has complete or very high national and international interest.

So, I did mention that the company originally--we used to use the motto focus and speed, and we've now extended that to focus, speed, and agility as we move forward. And as Jerry just alluded to, this is a changing environment. It's like a kaleidoscope.

But out of all the companies out there that are trying to defeat COVID, I think it's very important to note that we're one of the very few that has a broad-spectrum oral antiviral that actually is entering a phase 2 or 3 trial right now, which means that it actually could be here to effectively combat the pandemic in the not so distant future. And that's what we're all trying to do.



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So, thank you very much indeed for your time, and we look forward to having another call at some point. So, thank you, and good morning and stay safe.

Operator

Ladies and gentlemen, this does conclude today's teleconference. You may disconnect your lines at this time. Thank you for your participation and have a wonderful day.