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BioSig Technologies, Inc.
ViralClear Pharmaceuticals, Inc. Update Call on merimepodib
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Presenters

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Ken Londoner, Chairman and CEO at BioSig Technologies, Inc.
Nick Spring, CEO at ViralClear Pharmaceuticals, Inc.
Steve King, COO at ViralClear Pharmaceuticals, Inc.
Jerry Zeldis, Executive Chair at ViralClear Pharmaceuticals, Inc.

Q&A Participants

Yale Jen, Laidlaw & Company
Scott Henry, Roth Capital
Bert Hazlett, BTIG LLC
Gary Zwetchkenbaum, Plum Tree Consulting
Sanjay Kamani, Pathvis Financial
David Skibinski, SnapMD
Robert Carlson, Janney Montgomery Scott
Tony Fitzgerald, Private Investor
Jeremy Roe, Integra
Steven Alesio, Private Investor
Rene Delambert, Private Investor

Operator

Greetings. Welcome to BioSig ViralClear Update Call on merimepodib Conference Call. At this time, all participants are in a listen-only mode. A question and answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please press star zero on your telephone keypad. Please note, this conference is being recorded. I would now like to turn the conference over to your host, Andy Ballou, Vice President of Investor Relations at BioSig. Thank you, you may begin.

Andrew Ballou

Thank you, operator. Good morning and thank you all for participating in today's call. Our last ViralClear update call was three weeks ago, but so much has happened since that we wanted to update you all on our progress. On today's call we have Nick Spring, Chief Executive Officer of ViralClear, Steve King, Chief Operating Officer of ViralClear, Jerry Zeldis, Executive Chair of ViralClear, and Ken Londoner, Chairman and Chief Executive Officer of BioSig Technologies, the parent company.

Before we get started, 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 limitation, risks and uncertainties associated with, one, our inability to manufacture our products and product candidates on a commercial scale, on our own, or in collaboration with third parties, two, difficulties in obtaining financing on commercially reasonable terms, three, changes in the size and nature of our competition, four, loss of one or more key executives or scientists, and five, 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. And now I'd like to turn the call over to Ken Londoner.

Ken Londoner
Thank you and good morning, everybody. Thank you for participating this morning. BioSig Technologies continues to move ahead with its PURE EP system, and I'm encouraged to let you know that a number of our key hospital partners are opening their hospitals starting next week, taking in atrial fibrillation patients for procedures. Our team will be out in the field recommencing our field operations, and we look forward to getting back to full swing. But today, this is a time to review the progress that the team at ViralClear has made, and I am going to hand the call over to Nick Spring. Thank you.

Nick Spring
Hey. Thank you, Ken, for that introduction, and good day, everyone, and welcome. This is Nick Spring here, I'm the Chief Executive Officer of ViralClear, and I'm accompanied on this call by Dr. Jerry Zeldis, our Executive Chairman, and also Steve King, our Chief Operating Officer. Just

to kick us off, I'd just ask both Jerry and Steve to introduce themselves. So, Jerry, would you like to introduce yourself to everyone, please?

Jerry Zeldis
Sure. Thanks, Nick. As Nick said, I'm Jerry Zeldis. I'm the Executive Chairman of ViralClear, and I'm the co-founder of the company.

Nick Spring
Thank you, Jerry. Over to you, Steve.

Steve King
Thank you, Nick. Good morning, everyone. My name is Steve King, I'm the Chief Operating Officer at ViralClear. Nick?

Nick Spring
Thank you very much indeed, Steve and Jerry. So, I think as we mentioned back on April 7th, the three of us--although we've been running this company for about 40 days, in fact, between the three of us, we have over 100 years' worth of drug development experience in the pharmaceutical market. My background, as you may remember, is I've been a pharmaceutical executive for over 35 years. At my last major gig at Merck, I led the global live viral vaccines franchise, and then I founded my own company called Topaz Pharmaceuticals, which I then sold to Sanofi.

So, really, ladies and gentlemen, as an update, due to the extreme conditions created by the COVID-19 coronavirus, ViralClear management, as well as many other companies and government agencies, have been working tirelessly since we began this endeavor, to advance our antiviral therapeutic merimepodib, and develop our corporation. Our company is six weeks old, and so much has happened since our last call on April the 7th, it's quite breathtaking. Since then, we have published data on the action of merimepodib, and we've shown that it has something like a 98% reduction in viral load, and Jerry and Steve can talk to that a little bit more later on.

And we've added a new board member, we've executed agreements with the Mayo Clinic to conduct our phase II trials under the leadership of Dr. Andrew Badley, Professor and Chair of the Department of Molecular Medicine, and Enterprise Chair of the COVID-19 taskforce there. We've sourced materials of volume production of merimepodib, and submitted our IND to the FDA, in hopes of beginning in-human trials in the coming weeks. Also keep an eye out for Phase II Protocols, which will be posted on clinicaltrials.gov, and where you'll be able to see in-depth and detailed the work that we've done with the Mayo Clinic to craft the trials.

I have to say, that we have accomplished so much in the six weeks or so since launching this endeavor, and even more so in three weeks since our last update on April 7th. I am truly honored to be working with such a tight and experienced team. Together, we have over 100 years of experience, as I mentioned, in drug development, having launched some of the world's top-selling therapeutics that have cumulative sales in the billions of dollars. Jerry Zeldis has gotten nine drugs through the FDA; Steve King has been involved in 500+ small molecule programs in various stages, from preclinical through its commercialization. And I've been instrumentally in drug developments such as with human papillomavirus, with Gardasil, as well as my own company, Topaz, which I took from--formation of the company through phases I, II, and III, and a successful NDA filing.

I would like to note at the outset that merimepodib is not a new molecule, and in fact, over $100 million has been split invested in companies like Vertex and Trek Pharmaceuticals, which Jerry founded, in developing the product so far. So we picked up the mantle from there. Our mantra here at ViralClear is focus and speed. Our execution is being driven by the desire and urgency to get into and through the FDA trials as soon as possible, to help bring forward a solution to this epidemic, so that we all can get back to life with a level of safety that is absent at this time. So at this point, I'd like to hand it over to Steve, and ask Steve to give us an update on CMC and clinical supplies. Thank you. Over to you, Steve.

Steve King
Thank you, Nick. What I'm going to do is really talk a little bit about the history of the molecule, where we are today, and then how we're going to move forward in the future, which is in the next couple of months. So, VX497, or merimepodib, or MMPD, as we call it, was licensed by Trek, from Vertex, and then from Trek to ViralClear. The mode of action is an IMPDH inhibitor, which was developed in the late 1990s-early thousands for hep-C and also psoriasis. And as Nick mentioned, it was over $100 million spent on this program, so it's really not a new molecule as such, and really went all the way through phase II. There were seven phase I studies completed, and five phase II studies completed, with over 400 subjects, with around 100 in phase I and over 300 patients in the phase II studies in hepatitis, and one small study in psoriasis. Regarding the CMC, we have a soft gel formulation which has two-year stability, and we have a source of drug substance. The program was discontinued, as there are more effective products available for hep-C.

So, fast-forward to today, where are we? Well, in the last six weeks, we've really made tremendous progress. We've recruited a virtual drug development team of consultants in regulatory, formulation development, clinical, and quality. The team worked together very quickly, because all were used to being consultants and used to working from home, so didn't

really have that transition from going from an office to home working. In that time, we have made clinical supplies for the first phase II studies. One challenge we had was, the existing formulation was in a soft gel capsule, and there were going to be too many capsules for people to swallow. So we converted this soft gel formulation into a solution which can be easily taken in the hospital for the phase II study.

We have also worked on developing an IV formulation. So the good news is, we have drug substance, which will take us all the way through the phase II studies, and all the way through to pivotal. We are also working to develop other dosage forms at all stages of the diseases. Our drug is primarily an oral drug, and this oral bioavailability is important. We're also going to be looking at developing an IV formulation for the clinic, as we move forward to the future. Moving forward, we have secured alternative supplies of drug substance and drug product, so we should be able to look to develop other formulations from these supplies. Regarding clinical trials, we have three phase II studies planned; two in the hospital, and one in the outpatient area, and Jerry will go into some more details on these. Thank you, Nick.

Nick Spring
Okay, over to you, now, Jerry.

Jerry Zeldis
Nick, thank you. As I said in the last teleconference, merimepodib, or as I'll call it, MMPD, was in development for both chronic hepatitis B and C, as well as psoriasis. As Steve said, the activity of the drug was such that other better drugs, which were more potent, were developed, and therefore the development was discontinued. When we licensed the drug into Trek Therapeutics, we realized that this would not be part of a hepatitis C regimen. But if we succeeded in getting a hepatitis C regimen that would bring in revenue, we would be able to afford to approach other diseases, for which MMPD as ideal, that is to say, emergent viral infections, or where the virus is replicating rapidly in the acute phase. And to that end, we did research with the Galveston National Laboratory and looked at a variety of these diseases such as Ebola, Zika, Hanta, and a few others. And in every single case, the drug inhibited viral replication quite dramatically.

Fast-forward to this pandemic. We tested the drug, it was very active against the SARS-CoV-2 coronavirus, which is the virus that causes COVID-19. And we've been doing much work. Since the teleconference, we tested the drug substance that is going into our clinical supply, to our—I'd say, delight, we found that it was actually more active than the old legacy drug, which was sitting in a refrigerator-- freezer for over four years. We're looking at whether we can combine this with other agents, and you'll hear more about this over the next week or two, as the data matures and we can—we'll be ready to report this out in a variety of venues.

We also have gone through the regulatory gamut at the Mayo Clinic, and you'll hear soon as to when we anticipate our first trial in hospitalized patients will occur. We've also written a second inpatient trial, which you'll hear more about over the next two or three weeks, as well as, we're now putting the final touches into an outpatient trial, which will look at people who are less severely affected by COVID, but are now quarantined at home with the disease. And the hope would be that our drug would clear the viral infection faster, and allow people to heal faster.

So all these activities are going on, and we also submitted an IND to the FDA, which will allow us to go into the clinic. And we are now in an active dialogue with the FDA, and hopefully, soon, we'll hear whether we get permission to go into patients. I'll just say, by law, the FDA must respond within 30 days. So, if you're conservative, 30 days from when we announced the IND was submitted, is when we'll have an answer. But we believe in this time of crisis, the FDA will move more quickly. Nick?

Nick Spring
Thank you much indeed, Jerry and Steve, excellent overview. So, operator, please remind participants how to queue for questions, and while you're doing that, we'll start to frequently asked questions.

Operator
Thank you. At this time, we will be conducting a question and answer session. If you would like to ask a question, please press star one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star two 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 star key. One moment, please, as we poll for questions.

Nick Spring
Okay, so this is Nick Spring again here. So before we start the questions from the floor, Jerry would just like to say a couple of things.

Jerry Zeldis
Okay. I'd like to inform everyone that we submitted a manuscript for peer review entitled “The IMPDH inhibitor, merimepodib, provided in combination with the adenosine analogue remdesivir, reduces SARS-CoV-2 replication to undetectable levels in vitro.” We anticipate that the peer review process will occur, hopefully, within the next week. And once it's accepted for publication, it will be available online. I'd like not to discuss the particulars of this until it’s

published, but I did want to let people know that this manuscript has been submitted to a peer-reviewed journal.

Nick Spring
Thanks a lot, Jerry, for that news. Just before we take questions from the floor, we've experienced a couple of questions we commonly get. So, we thought we would put them up front and let Jerry and Steve tackle them. So, the first question is, that we get commonly is, how can a company like ours scale up with a supply chain to meet the potential demand for the product? So, over to Steve, could you help us out with that?

Steve King
Yeah. Thank you, Nick. As I previously mentioned, we currently have sufficient drug substance to take us through the pivotal trials. ViralClear has already engaged one US drug substance supplier, and two drug product suppliers as well. We have been pursuing further supplies in both the US and Europe to prepare for commercial launch for both drug substance and drug product, to enable us to have sufficient supplies to launch.

Nick Spring
Thanks a lot, Steve. And the other question we get commonly is, how quickly can we be in human clinical trials? So I'll hand it over to Jerry to answer that one.

Jerry Zeldis
Thank you, Nick. As I said earlier on, we've submitted an IND to the FDA, and right now we're actively engaged with answering their queries. We believe that once we've addressed those queries adequately, an IND will be granted. Other than that, we're putting the final touches on our trial to be started in the Mayo Clinic, and we think that literally, within a few days after we have the IND filed by the FDA, that we can begin treating patients. So hopefully sometime in the next few weeks, we'll get started.

Nick Spring
Thanks very much indeed, Jerry. Okay, I'd like to now ask the operator, Devon, if he could give us the first question from everybody calling in.

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

Yale Jen

Good morning, and congrats on the very speedy development. I have two quick questions. First one, Nick, the other day you mentioned that the drug has both antiviral as well as impact on inflammation. We're probably a little bit more familiar with the first one, so if you want, you can maybe elaborate a little more in terms of its impact on inflammation, that would be very useful. And I have another follow-up, after this.

Nick Spring
Okay. Well, what I said was, it has an antiviral and an immunomodulatory effect. Probably Jerry's the best equipped to answer that. So, over to you, Jerry.

Jerry Zeldis
Okay. Way back when Vertex conducted a pilot trial in patients with psoriasis, and it was a very small trial, however, a number of patients had a remarkable response. These were people with advanced psoriasis. And a PASI score means the percent of resolution of the lesions, and a number of people, PASI 75s, and PASI 50s, anything above a PASI 50 is considered having disease activity. Activity against the disease, since psoriasis is an immunologically driven inflammatory disease, and to our knowledge is not caused by an infectious agent, the conclusion will be--or is, that our drug does have immunomodulatory activity.

Nick Spring
Okay. Thanks a lot, Jerry. Hopefully that answered your question. What's your follow-up?

Yale Jen
The next question is that, given Gilead, this morning, has announced their sort of preliminary data, and what do you think of the activity of remdesivir, and what do you think of that impact on your drug development at this moment?

Nick Spring
Okay. Well, generally speaking, we are looking upon the whole life sciences industry as doing collaborative effort to conquer the COVID. But I'll hand it over to Jerry, again, for any comments he wants to make.

Jerry Zeldis
First of all, I was very pleased to learn that their trial is positive. As I said, we just submitted a manuscript, and if you want, I'll read you the title again, where we're seeing complete shutdown of viral production. Again, this will be published, and I don't want to go into it further. But clearly, there's the need for more than one antiviral agent in this field to break the back of this pandemic. And we're looking at other antivirals as well. As I stated in the previous conference, we view merimepodib not only as a single agent to attack COVID-19, but also as a

platform drug upon which you can add other drugs. So, hopefully you get synergy, and also to prevent resistant viruses from emerging. So, I think this is actually a very good boost for us.

Nick Spring
Yes, I'll agree with that. And a couple other points, that, you know, merimepodib is an oral drug, whereas others aren't. We've got two modes of action, and we also work on the host side of the equation, so there are important distinctions as well. Anyway, back to the operator. Next question, please.

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

Scott Henry
Thank you, and good morning. Just a couple questions. First, with regard to the delivery mechanism, whether it be--you know, typically an oral is almost always the preferred route, but in some situations, obviously, the patient can't tolerate an oral and needs an IV. Could you talk about this patient mix, and what percent of that target market could be served with an oral, which would obviously be the preferred route, if one could do it, versus what percent cannot?

Nick Spring
Yeah, thank you, Scott, indeed. I'll probably hand this over to Steve to handle. He's been looking at the formulations; he's an expert in that area.

Steve King
Thank you, Nick. We are certainly looking at an IV formulation that we can—but given the hospitals, that's going to be a few months to develop that and take that forward. As for the patient mix, I think I'll pass it on to Jerry.

Nick Spring
Jerry, you there? We may have lost Jerry. I'll just do an overview on it very quickly, then. We expect, over time, that obviously in the--hello, are you back in, Jerry?

Jerry Zeldis
Yeah.

Nick Spring
Okay.

Jerry Zeldis
Right now, the best estimate—I mean, you can basically break this disease down by those who are exposed to the virus but yet are not infected, those who are infected but are asymptomatic, and those who have quite a bit of symptoms, grippe-like illness, but they're not severe enough to be at high-risk for respiratory failure, those who have respiratory—who are hospitalized because they're at great risk for going into respiratory failure, those who are hospitalized who are in respiratory failure and end up going into intensive care units, and probably get intubated and go on PEP. That's the spectrum.

The evidence is emerging—and we'll know much more over the coming months, that probably over half the people who are infected with the virus are asymptomatic or have mild symptoms, and then, you can break it down from there. Most likely, over 70% of people will be—can be managed at home, even if they have a grippe-like illness, meaning high-fever, headache, loss of taste, and other symptoms. The beauty of our drug is that it's oral, which means that people can take this as outpatients, they can take it as inpatients. When we finish the development of an intravenous form, we can even give it to people on respirators without having to take the medicine via an NG tube, or a PEG or something like that.

So, I think we can address the whole thing. The issue is—and we will find this out once we go into the clinic, can we rapidly clear the virus? And you can imagine, that if we show this, that people's symptoms will also abate, and they'll be, obviously, not at risk for infecting other people. So, we think the promise of this thing is very large. But we have to get in the clinic, and we have to do our studies. And this is why we're trying to do this as fast as we can, both an inpatient trial, as well as an outpatient trial.

Nick Spring
Thanks a lot, Jerry. Hopefully that addresses--

Scott Henry
--Great, thanks for that--.

Nick Spring
--Your question, Scott.

Scott Henry
Yes, that is very helpful. And then, one other question, and I don't know how much you're going to address this question on this call, but can you give us an update on the timeline on when ViralClear may be spun out, as its own entity? And then, kind of a follow-up question, when it

becomes its own entity, are there other indications beyond COVID-19 that you expect to pursue with this molecule? Thank you.

Nick Spring
As far as speculation on a spin out, etcetera is concerned, we're not really going to address that sort of question today. On extra claims, I'll hand that back to Jerry. We are looking at extra claims, this is a broad spectrum antiviral, which is active against both DNA and RNA viruses. So, over to you, Jerry, on the second part.

Jerry Zeldis
You know, there's a variety of other infections, where during the acute phase of the infection, you have massive growth of the virus, and therefore we think that the drug will be very active. One disease of interest is dengue fever. Dengue fever virus is found between the Tropic of Cancer and the Tropic of Capricorn. It's a major economic disruptor in that region, and throughout the whole world.

And so, not now, but once we get beyond this pandemic, we'll probably be exploring that one. And even though in North America and in Western Europe this is not a major issue because of vaccines, measles, pneumonia, still is a major killer of people around the world. So, again, the question is, if we were to give this, could we shut down the measles virus? There are a variety of other infections, which we're considering, but that will be clarified in the future, as we go forward.

Nick Spring
Okay. Great question, Scott. Devon, next question, please.

Operator
Our next question comes from the line of Bert Hazlett with BTIG. Please proceed with your question.

Bert Hazlett
Yes, thank you for holding the call and thank you for taking my question. Could you please describe what you think would be the dose of this molecule, compared to what—how it was considered in hepatitis C? And as you think—if it's higher, could you talk about the—maybe the therapeutic window that you have with this molecule? Thank you.

Nick Spring
Thanks, Bert, for that question. Again, I'll turn it over to Jerry to answer that.

Jerry Zeldis
The highest dose that was given in phase II was 400 milligrams every eight hours. And we know we're way above the—based on the—way above the concentration that gives about a thousand-fold decrease in viral replication. So, we decided we wanted to go with that dose, a very high dose, and observe what happened, and then later we can back down on the dose, you know, as we move forward.

Nick Spring
Thanks a lot, there, Jerry. Bert, any other questions, or has that answered it? If so, we'll move onto the next question, please.

Bert Hazlett
That's helpful, thank you.

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

Nick Spring
Hi, Gary. What's your question?

Gary Zwetchkenbaum
Thank you. Congratulations, Ken, Dr. Zeldis, Nick, and Andy, first, on recent developments over the last 41 days since you've acquired ViralClear Pharmaceuticals. I'd like to ask you about—a two-parter. I'd ask you, how does the ownership of ViralClear Pharmaceuticals affect the BioSig shareholder, okay? And if you can, as a second part, discuss about distribution, the spin off later this year, and what it means, is there a dividend for the shareholder? Just kind of discuss that, if you would, please.

Nick Spring
Thanks a lot there, Gary. I'll turn those questions over to Ken, as they're both BioSig-oriented. Ken, could you comment, please?

Ken Londoner
Sure. Gary, as Nick said earlier, we're working through all the spin out activity, and we're not prepared to discuss the specifics. As for your first question, in an 8-K we filed, I guess towards the beginning of this asset purchase, ViralClear, BioSig owns 87.8% of ViralClear. And ViralClear owns 92.5% of merimepodib, and that's already been disclosed to the public. Thank you.

Nick Spring
Okay, Gary, hopefully that deals with your question. And next question, please, Devon.

Operator
Our next question comes from the line of Sanjay Kamani with Pathvis Financial. Please proceed with your question.

Sanjay Kamani
Yeah, hi--

Nick Spring
--Good morning, Sanjay--.

Sanjay Kamani
--Thank you very much for the updates. And my question is, let's say, you know, the clinical trial phase II, phase III are done, and you know, there's permission to go to production. And so, the question is, is this drug going to be, you know, taken by the, you know, COVID-19-infected patients, or it can be given prior to that, or how is it going to work? And what will be the approximate cost for a course for a patient?

Nick Spring
Okay. I'll address the cost issue, first, and then I'll hand it over to Jerry to discuss the regime. Right now, we haven't fixed our cost of goods, or any pricing strategy, except from a philosophical point of view, we're going to make sure that this particular product drug is accessible to everyone who needs it. So that's really the way we've gone into this whole thing, so, at the moment, no specifics. But over to you, Jerry.

Jerry Zeldis
Yeah, hi. I'm just trying to clarify the question, so I can give you a spot-on answer.

Nick Spring
Sanjay was asking about the dosing regimen that we might be looking at, for tackling the disease--?

Jerry Zeldis
--Right. Well, as I said to the previous questioner, for the moment, we're giving the drug as a solution three times a day orally, every eight hours. We anticipate—right now, as Steve King mentioned, we're working on a variety of formulation improvements. And we anticipate that

by the time we will be pivotal, that some of these will be ready for the clinic. Otherwise, we will go out the gate with this solution, which people can take.

A lot is going to be dependent on the early trials we're doing. We literally will be monitoring whether people are shedding virus on a daily basis in the first trial that we're going to do. And if we find out that, after so many days, people are no longer shedding virus, that may change the length of time which we're going to treat people. So, it's a fluid situation; no pun intended. And we'll give more clarity as we move along and get more data.

Nick Spring
Okay. Thanks very much indeed, Sanjay, for your questions. So, Devon, next question, please?

Operator
Our next question comes from the line of David Skibinski with SnapMD. Please proceed with your question.

David Skibinski
Good morning, my question revolves around a solution, what's the value of it? Is it shelf stable? And do you anticipate, going into solution, will you be required to do any kind of dose ranging studies, to continue to demonstrate its efficacy?

Nick Spring
Okay, I think that's a question both Steve and Jerry can answer. So, Steve, would you like to kick off, and then hand it over to Jerry, please?

Steve King
Yep. So, what we did, is we took the soft gel formulation, which was in the capsule, a 25 milligram capsule. And we took that formulation, diluted it down to a 20-milligrams-per-mL solution, so the patient will take 20 mLs three times a day. The formulation was based on the soft gel formulation that we have two-year stability on. And we anticipate the solution to also be stable, and we currently have it on stability now. Jerry?

Jerry Zeldis
(INAUDIBLE) on that is that--

David Skibinski
--And a follow-up to that, will you be required to do any dose ranging studies as part of the phase II or any follow-on?

Jerry Zeldis
We will get a few measurements of dose concentration, but as we develop new formulations, we will be doing dose ranging studies to compare the current formulation that is in the clinic, which Steve just described, as well as newer formulations that Steve is preparing as we speak.

Nick Spring
Okay. Thanks a lot, David, for your question. And Devon, next question, please.

Operator
Our next question comes from the line of Robert Carlson with Janney Montgomery Scott. Please proceed with your question.

Robert Carlson
Hi, guys, and again, congratulations. In listening to some of the other calls, that are of companies developing drugs, they have already started the production process in anticipation of approval. Are we doing anything along that line? And if so—I mean, it's a costly endeavor, how are we funding it and who might be producing it?

Nick Spring
Okay. Yes, we are active in that area, I'll hand it over to Steve who's our expert on product supply. Over to you, Steve.

Steve King
Yep. Yeah, so, what we're doing is, we already have one drug substance supplier lined up in the US, and they're currently in that process of producing drugs. Until we can really finalize the formulation, we're not moving forward with drug product. And once the pivotal trial comes through—or even the phase II trial comes through, we'll get a much better idea of where we need to be, whether it's a solution formulation, a soft gel, or whether we also have an IV as well. So, the key is for us just to have the drug substance supply, which we have one company in the US. We're also looking at another one in the US, as well as a potential European supplier as well. And we'll phase them in as we go through the phase II study.

Nick Spring
Thanks a lot there, Steve. So, we are gearing up in anticipation there, Robert. Next question, please.

Operator
Our next question comes from the line of Tony Fitzgerald, a private investor. Please proceed with your question.

Nick Spring
Good morning, Tony. What's your question?

Tony Fitzgerald
Good morning, gentlemen, and echoing the congratulations of all the participants in the call, the progress that you've achieved so far. Just a quick question, do you, as ViralClear, owe any license or royalties to any other party, to Trek, or anybody else for the commercialization of the compound?

Nick Spring
I'll let Ken handle that. Ken, could you comment to that, please?

Ken Londoner
Yes. Hi, Tony. Vertex Pharmaceutical does have a small royalty payment if we get through FDA. That's the primary one out there. Thank you.

Nick Spring
Thank you.

Tony Fitzgerald
So there's nothing else to Trek?

Nick Spring
No. We saw the end of the license, that's what's transferred across.

Operator
--Our next question comes from the line of Jeremy Roe with Integra. Please proceed with your question.

Nick Spring
Good morning, Jeremy.

Jeremy Roe
Hey. Hey, good morning. Hey, thanks for taking our call and answering our questions. I had a couple questions, before I get to whether you guys got to visit with Pence yesterday or not. If we have difficulty developing a vaccine, due to, say, like a mutation, like we see with the flu, does that affect our effectiveness? And, we've seen one of these symptoms with COVID can be

foot lesions. Due to our drug's effectiveness with psoriasis, does that possibly make this more suitable for certain patients?

Nick Spring
Thanks a lot for that question. I'll hand it over to Jerry to answer.

Jerry Zeldis
So first of all, some of the people who we're collaborating with at the Mayo Clinic were at the session with Pence. We were not mentioned by name, and we don't have cosmic understanding of all the work that's being done at the Mayo Clinic. So, when some of them refer to some of the antiviral studies they're doing, it's not known whether he was referring to us or another drug company.

As far as the foot lesions, well, what we anticipate is that this will be—our drug, merimepodib, will be a very profound inhibitor of viral replication, which will allow the body's immune system to eliminate the infected cells, and allow patients to turn the corner. It has not escaped us, nor you, that there's immunomodulatory activity as well. So, we don't know this right now, but I hope we will observe, that this will also decrease the amount of inflammation that is induced by having cells that are infected, but that's to be determined. So at this point, it's a hope, it's not a certainty, and we'll just have to see the clinical data.

Nick Spring
Thanks a lot, Jerry. And thanks, Jeremy, too. Next question, please.

Operator
Our next question comes from the line of Steven Alizio, a private investor. Please proceed with your question.

Nick Spring
Good morning, Steven.

Steven Alesio
Good morning, Nick, this is really just for you. It's a question about staffing the company. If you could just tell us, kind of where you are in terms of how many active people you have employed and engaged at the moment, and what do you envision kind of getting through the next two phases?

Nick Spring

That's a good question. So, this is a work in progress, is how I'd answer it. We've been together for about six weeks now. We have three full-time staffers; that's me, Jerry, and Steve, and we have a significant number of consultants as well, who we're working with, and we are staffing up as we speak, and also building a Board.

But it's probably a little too early for me to go into great detail on that, as and when we appoint staff, we'll certainly announce them. But we expect to have this company up and running and fully staffed within a month or two. And I'll be back on another one of these calls and be able to probably answer that question much more fully once we've made decisions. Okay?

Steven Alesio
Just related though, it does sound like you need to staff up for phase II and phase III, and that's something you're working on.

Nick Spring
Absolutely. I think, you know, when we came into this, our mantra internally is focus and speed. And I think one of the things we're proud about is, because we have such highly-experienced people and experienced consultants, without bragging too much, we've pulled off a significant amount of work in just over a month, that normally would've taken six months to a year, to normally have done. You know, to have got protocols in place, to have got clinical trials in place, supply chains in place, everything else that goes with it is very complex. But we know the people in the industry have been reaching out and working very well.

And it's also—I need to give a bit of a shout out to BioSig for supporting us so well, and Ken Londoner and his team, because we wouldn't have got to where we are without them. But also, you know, various vendors, suppliers, etcetera, consultants, have been very flexible, put us at the top of their priority list, and offered to work at reduced rates or even for free, in some cases, to help us.

But you know, a very high priority for us is to staff up with people who we know, and obviously to create an organization that's both not only here for today, but is a sustainable organization moving into the future. Because we believe this business is very sustainable, with a broad-spectrum antiviral. And as we move forward, we'll have other announcements. But that's a very good question, and it's something definitely on our minds at this point. Thank you.

Jerry Zeldis
Nick, can I just add one thing--?

Nick Spring

--Yep. Sure.

Jerry Zeldis
As far as conducting the phase II trials, we have study monitors, we have appropriate people to deal with the data as it comes in. And at this point, using our consultants, we feel we're fully staffed to do the phase II trials, at this moment. As far as—

Nick Spring
--Yeah, very important point--.

Jerry Zeldis
--Once we're done with the pivotal trial, once we talk to the FDA and figure out what needs to be done to get to an approval, then we'll update you.

Nick Spring
Okay. Yeah, come back and ask in a week or two, and we'll have more information. Okay, Steven. Next question, please.

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

Rene Delambert
Thank you so much--.

Nick Spring
--Good morning. What's your question, please?

Rene Delambert
Good morning, thank you. This is maybe more for Ken. Obviously, it's fantastic value that ViralClear is adding as a long-time BioSig shareholder. But I'm just wondering for Ken, has all of this—and it's great we're gearing up to return to the PURE EP working, but has it impacted sales plans at all for the year, in other words timing, and has it delayed the first sales to be rolling out?

Nick Spring
Over to you--

Ken Londoner

--Yeah, thank you for the question. We've adapted our sales approach; hospitals are now starting to reopen again. For example, Mayo Clinic is doing cases in both Minnesota and Florida. They're doing cases at TCAI in Austin, Texas. Our teams are going out next week with the appropriate protective gear, and we're getting back up and running where our systems are already installed. We have some new opportunities that have come to us, that I can't be too specific about.

There are larger companies very interested now in partnering with us, because as, let's take Johnson & Johnson, for example, we have heard in the industry, that they've lost about six to 800 million in lost revenues because of the shutdown. And as they come back, as the hospitals come back open again, they're looking for ways to recover and recoup some of that revenue. And PURE EP may be a solution in the mix, to help restart some of the larger companies' programs, because PURE EP is in demand. So you'll be hearing more about this over the next quarter or two. And you know, we're still optimistic about our ability to make placements this year. And you know, if the whole country opens up, we'll get back on track a lot faster, but we still expect commercial revenues this year.

Rene Delambert
Thank you, Ken.

Nick Spring
Thanks a lot, Ken. Alright, next question, please, Devon.

Operator
Our final question comes from the line of Yeo Jin with Laidlaw and Company. Please proceed with your question.

Nick Spring
Good morning--.

Yale Jen
--Thanks for taking the follow-up question. This is a very brief one, and given that you are changing the formulation from the gel to the solution, I think you mentioned a little bit earlier, the dosage. But should I consider that you will not need a bridging study for the PK and other stuff, at this juncture?

Nick Spring
That's a very good question, and I know that Steve's right on that one, so over to Steve.

Steve King
Yeah, I mean, we still have a soft gel formulation that we can use as well. So, we'll have a solution, and a soft gel formulation, and we will be doing some PK studies to bridge the formulations, for both the existing formulations and potential new formulations as well.

Yale Jen
Okay, great. Thanks very much, that's helpful.

Nick Spring
So, Devon, did you say that was our final question?

Operator
That was our final question.

Nick Spring
Okay. In that case, I'll just wrap up by saying thank you to everyone for joining us this morning, and we appreciate all your support, and especially your time. This management team is committed to moving forward with merimepodib, and doing the trials, and hopefully they're moving after that into a situation where we can get this to patients who need the product, and we can start to really tackle COVID-19, and beyond that.

So, with that, I would just like to leave us with our motto, which is focus and speed, it's what we're all about. And we hope to speak to you again in the not-so-distant future, and give you another good update, and hope to move the ball even further down the field. So, thanks very much indeed, and stay safe.

Operator
This concludes today's teleconference. You may now disconnect your lines at this time. Thank you for your participation, and have a wonderful day.