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Officers and Speakers
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Presentation

Operator: Good afternoon and welcome to the Soligenix conference call on the COVID-19 landscape and applications.

(Operator Instructions)

As a reminder, this is a timed conference call and is being recorded today, September 10, 2020.

Before we begin, I would like to caution that comments made during this conference call by management will contain forward-looking statements that involve risks and uncertainties regarding the operations and future results of Soligenix. I encourage you to review the company's past and future filings with the Securities and Exchange Commission, including, without limitation, the company's forms 10-K and 10-Q, which identify specific factors that may cause actual results or events to differ materially from those described in the forward-looking statements.

Furthermore, the content of this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, September 10, 2020. Soligenix undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this conference call.

At this time, I'd like to turn the conference call over to Dr. Christopher Schaber, President and CEO of Soligenix. Sir, please go ahead.

Christopher Schaber: Thanks, operator. Good day. Again, my name is Chris Schaber, President and CEO of Soligenix. Thank you for joining us for today's webcast call, in which we'll be providing a COVID-19 landscape and applications presentation, with specific focus on our CiVax vaccine program.

Before beginning, the forward-looking statements, which I will give you a moment to review. As many of you know, we are legally required to make you aware that everything we are discussing today is a best estimate of what we know today and has the potential to change in the future.

As we now move to the agenda for today's webcast, I will kick off the presentation with a high-level corporate overview, as we have some very important near-term catalysts that I will be

taking up to briefly review with you on today's call. I will then turn the call over to our external vaccine expert and collaborator, Dr. Axel Lehrer, Associate Professor at the University of Hawaii. Dr. Lehrer will be reviewing COVID-19 and providing a vaccine overview. Following Dr. Lehrer, Dr. Oreola Donini, Chief Scientific Officer of Soligenix, will be providing a CiVax program overview and will briefly discuss the potential for dusquetide as a therapeutic option in COVID-19. Dan Ring, Vice President of Business Development and Strategic Planning for Soligenix, will then briefly review the COVID-19 vaccine market potential before turning the call back over to me for closing summary followed by Q&A. Next slide.

So for those of you not familiar with my background, I've been in the pharmaceutical and biotech industry for over 30 years now, where I've spent the majority of my career developing drug therapies in orphan diseases in areas of unmet medical need. During this time, I've worked across a wide range of functional areas such as preclinical research; manufacturing; clinical, regulatory and quality; as well as commercial. Next slide.

So who is Soligenix? Soligenix is a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is currently an unmet medical need. We have two unique areas of focus: a specialized biotherapeutics business segment dedicated to oncology and inflammation, and a separate public health solutions business segment funded entirely by the government focused on vaccines and therapeutics for civilian and military applications. Next slide.

Here is a snapshot of our rare disease pipeline. Essentially, as I noted, all our programs are orphan and/or fast-track designated, and what jumps out at you here are these green-highlighted arrows. These are programs funded in part or entirely by the government, public health solutions funded entirely by the government. If the government is not funding it, we're not developing it. And what this funding has allowed us to do is not only move forward very good technology but really be able to build out a more robust pipeline than you would typically see for a company our size with multiple shots on goal to mitigate risk, a lot like a financial portfolio. This funding has also allowed us to manage our cash burn very effectively.

I'll focus now on the specialized biotherapeutics business segment at the top, where we have two Phase 3 clinical programs. The first is SGX301, our topical synthetic hypericin, in cutaneous T-cell lymphoma. With this Phase 3 program, we announced top line positive results in our primary endpoint earlier this year and are waiting for additional follow-on data that will occur and we will announce in the fourth quarter of 2020.

The second Phase 3 program is our SGX942, our new chemical entity dusquetide, in oral mucositis in head and neck cancer. This Phase 3 study has completed enrollment following a positive interim analysis and we now expect final top line primary endpoint results in the fourth quarter of this year as well, so some very near-term catalysts. As you would imagine, with a market such as oral mucositis, which is much larger, there is the potential for business development activity, and we are in a number of active discussions. I cannot provide any more detailed guidance at this time, but those discussions continue, and when and if we do have updates, I'll be providing them.

If we now transition to the public health solutions business segment at the bottom half of the slide, as I noted, we pursue nondilutive government funding here, and CiVax is no different. Here, we are in a number of -- in different various phases of pursuit of funding and believe that there is funding in our future for this program, but we will not and cannot announce anything until we actually have that official funding. But clearly, we are not looking to utilize our own monies to advance CiVax. If you're following the other COVID-19 programs, these are extremely large programs, very expensive, so we need that additional funding, that nondilutive funding, in order to advance this. And you'll hear more detail about our cutting-edge technology shortly. But I think the important thing to note here is that, again, we believe that we will continue to identify and secure funding moving forward, and we're confident and we'll continue to pursue as best we can to advance this.

I will briefly add that with over $11 million in cash as of our last 10-Q and with the other financial instruments at our disposal, like our nondilutive government funding, this allows us to reasonably get to those near-term catalysts that I spoke of such as the top line Phase 3 results in oral mucositis. Next slide.

With that, I would like to now turn the call over to Dr. Axel Lehrer, vaccine research and development expert across multiple disease areas with a specialty in emerging infectious diseases. Axel?

Axel Lehrer: Hello, and good morning or afternoon for wherever you are. I'm actually an Associate Professor in the Department of Tropical Medicine, Medical Microbiology and Pharmacology at the John A. Burns School of Medicine here at the University of Hawaii. I have over 18 years of experience in vaccine research and development, both in academic and industry labs, and have previously worked in a number of emerging infectious diseases, particularly in the field of filoviruses, as well as flaviviruses, and have, in the course of this, developed protein expression methodologies for efficient vaccine manufacture. Next slide, please.

A quick disease background on COVID-19: This is, as we all know by now, a respiratory illness that is caused by SARS-coronavirus-2. This is a virus that is similar to the original SARS coronavirus that caused the limited outbreak in 2003. As a respiratory virus, droplet transmission via the aerosol route is believed to be the major mode of transmission, particularly in enclosed spaces. These viruses use their spike protein, which is a trimeric glycoprotein that sits on the viral surface, for viral entry through the human ACE2 receptor, which is a receptor that is very prevalent in cells of the respiratory tract.

The main disease driver is that, basically, a dysregulated inflammatory response, particularly a more undefined innate immune response, drives, then, the pathology seen. Particularly inflammation can be caused from adaptive immune cells later on or from the death of certain types of immune cells. What is really important is that the inflammatory response enhances dramatically the damage to the lung tissue and other areas and this causes an acute respiratory distress, which is a primary driver of mortality. Next slide, please.

Treatment options, as it is a relatively young disease, focus is mainly on severe disease, so therefore, remdesivir that has been approved for emergency use can decrease the length of

hospital stay but does not seem to increase survival. And then another treatment is dexamethasone; that seems to decrease mortality. It is understandable that there is a huge focus on these acutely ill patients; unfortunately, that means that mild or moderate cases of COVID-19 disease -- these are patients that are hospitalized -- they basically just receive supportive care; thus, oxygen and standard treatment, and there is no treatment so far for patients that don't require hospitalization. Next slide, please.

As we all know, I mean, the vaccine development efforts for this disease are unprecedented and are using a variety of different vaccine platforms. I will just go over these real briefly because it really helps to answer some questions pertaining to the vaccine candidate that we are developing together with Soligenix.

There are -- the main driver for vaccine platforms is to be able to target all types of patient populations, and that's mainly driven by the safety profile of the individual platform. In addition, logistical requirements are different for different platforms. Particularly, storage and distribution are vastly different; could range from ambient temperature to ultra-low frozen temperature. Dosage requirement is something else that may change between vaccines; most of the platforms right now seem to require two doses. And then there's differences in the manufacturing requirements, mainly in terms of the facilities and in terms of the raw product required to manufacture the product.

Another thing that we don't know yet is the durability of the immune responses. This is also something that is different for different platforms and we also don't know yet based on the epidemic characteristics of the virus whether yearly or seasonal vaccinations may be required. Fortunately, we know already from some candidates that have advanced further in the clinical process that immune responses can be achieved in humans, solid immune responses, and Phase 3 trials that are ongoing right now will help us to really understand what immunogenicity measures can be used as correlates of protection, so this is really good news in this very rapidly evolving field. Next slide, please.

Let's briefly focus first on the different development platforms. Conventional vaccines typically use live attenuated viruses or inactivated viruses. Inactivated viruses are -- can be developed quite rapidly, so there's a few candidates actually in Phase 3 clinical trials already, mainly in China. However, live attenuated vaccines, as good as they are, typically take decades to develop, so this is probably an approach that is not very feasible for COVID-19.

Subunit vaccines can be produced both conventionally by purifying proteins from virus grown in cell culture or via recombinant method, and then there's further, more advanced recombinant techniques where the genetic expression of antigen is observed in the patient. Examples for that are the adenoviral, the vector vaccines, as well as RNA or DNA vaccine platforms. Next slide, please.

What's really important is that different platforms modulate a different type of immune response. As you can see on the right here, the best vaccine, the second one here, would be a live attenuated virus. A good example of that is the yellow fever vaccine; that causes very potent antibody responses and T-cell-mediated immunities, therefore offering lifelong protection with a

single shot. Other platforms will have lower -- characteristics that are modulated more toward one or other side. The emphasis for COVID-19 is particularly focused on potent total antibody response that can be raised, for example, by just a piece of the virus, such as a protein or just a subunit of a protein, and then what we know is that antibodies to the receptor-binding domain are particularly potent in inhibiting viral entry. What we're looking for as well is a Th1-balanced immune response that may lead to less potential for immunopathology, as well as potent neutralizing antibody responses. Last but not least, cell-mediated responses are necessary and is often associated with having intracellular expression of viruses. That's one of the benefits of the expression of proteins in the host cell. And cell-mediated immunity is required to form good cellular memory. Next slide, please.

This is a summary slide basically showing what all the different mechanisms are that are being addressed here. As you can see, as the second from the top here, as CV, that's the normal coronavirus infection that would go into a target cell. So live attenuated vaccines basically work the same as the live viral infection and inactivated virus is trying to mimic this same thing. DNA and RNA vaccines are expressing certain proteins in the target cell. Similarly, virally vectors -- viral vectors that are replicating or nonreplicating are also focusing on target cells. You see these all as these gray boxes here. And then finally, subunit vaccines will be given and hopefully present the antigen directly to the immune system. Here we come to the green antigen-presenting cell here. The antigen-presenting cell will incorporate the antigens from a live virus as well as from differentially expressed antigens, incorporated and then processed, and communicates with the other components of the host immune system. And what we see, then, is basically formation of CD4 and CD8 T-cell responses as well as B cells, hopefully ending up with the memory cells shown here in purple on the far right, and that is what all vaccines are trying to elicit. Next slide, please.

Just as a summary, these are vaccine candidates that have been tracked by the Milken Institute COVID tracker. As you can see, there's more than 200 candidates in development currently. Of those, about 30 are in clinical trials and six currently in the late-stage Phase 3 human clinical trials.

With this, I would like to pass on the conversation to Dr. Donini.

Oreola Donini: Thanks very much, Axel Lehrer. So yes, my name's Oreola Donini. I'm the Chief Scientific Officer for Soligenix. I've been with Soligenix for about eight years now. I've had about 20 years of experience in the industry, primarily focused on preclinical and early clinical development, including specifically in immune modulators, so this has been a very excellent collaboration we've had with the University of Hawaii and I look forward to giving you some of the further information on this program.

So again, we're really focused on an antiviral vaccine platform, and it's the platform we've chosen to emphasize as one that uses a protein and directly delivers the protein to the person you're trying to vaccinate so that they can generate an immune response, an antibody and a cell-mediated immune response, to the protein that is the marker of the virus you're trying to vaccinate against. And as Axel just outlined, we need both an antibody and, ideally, a cell-mediated immune response to be raised. And so often, the viral antigens that are on the surface

of the virus are actually glycoproteins, and they're actually multimeric, meaning they have more than one piece to them. And so we're really looking to use that kind of protein as the antigen to raise the immune response again.

And so this is where the collaboration with the University of Hawaii has been very productive. Of course, they have good knowledge of an expression system that can not only produce the multimeric proteins but also produce them with a stable glycosylation pattern, and that's really important from a production perspective to have very consistent product. We've also licensed the CoVaccine adjuvant, because it's been shown to stimulate both humoral, meaning antibody, and cell-mediated immunity. And then, of course, ourselves, we've worked a number of years now with a thermostabilization platform that enables co-lyophilized formulation so that any product we produce would be thermostabilized, and therefore you could ship ambiently, so we don't have to worry about fridges and freezers and things of that nature.

Ideally, our product then is produced as a single vial which has some white powder in the bottom of it, and the only thing that needs to be done to be able to vaccinate would be to add sterile water for injection immediately prior to use. And this process of generating that white powder in the vial actually produces something that's pretty thermostabilized, meaning that we've actually shown that we can have at least 12 weeks' stability at 40 degrees Celsius, or 100 degrees Fahrenheit. And in fact, in our RiVax program, we've actually seen that we can drive that to 12 months at 40 degrees Celsius, so the thermostabilization, we think, is a very important aspect of the overall program.

So then, as we push forward with our antiviral protein vaccines as distinct from our antitoxin vaccines, we focus really, again, on this protein platform. We like it because the protein platform is equally applicable to older populations and the immunocompromised, so it allows for the widest possible application. Protein vaccines have been used for a number of years now, so their safety and their characteristics are very well understood. As I mentioned, we have a good avenue for antigen production, and we've identified an adjuvant that allows us to get maximum potency out of a vaccine, having licensed this CoVaccine from BTG, Boston Scientific. And then again, we couple this with our thermostabilization platform, so we really feel like this is a three-pronged approach that provides a complete package to a very desirable target product profile.

So just to drive down a little bit on the adjuvant, clearly this is quite important, especially for a protein-based vaccine, because you do need to stimulate both the antibody response and the cell-mediated immune response. This particular adjuvant has been tested previously in Phase 1 and Phase 2 clinical studies, so we do know what its maximum tolerated dose is. We do know that it's safe to use in humans and we do know how to produce it at scale in a consistent manner, so all of that's sort of been taken care of already. We've also demonstrated that we can lyophilize the product, or thermostabilize it, in a very similar way to the way we thermostabilize our proteins, and so that means it's a very compatible adjuvant as well.

We've done quite a bit of work in collaboration with the University of Hawaii looking at nonclinical efficacy data, specifically in the context of viral vaccines using the CoVaccine, and we've seen very broad applicability here, so there's reported efficacy with pandemic flu strains, we've demonstrated efficacy with filoviruses like Ebola and Marburg, Axel has done previous

work with Zika and tick-borne encephalitis. So we have a very broad background in terms of efficacy. And so that's very good as we moved forward into the COVID-19 vaccine program. We've also demonstrated efficacy not only in mice, of course, but with many of these previous studies in nonhuman primates, so we know it's a very translatable technology platform. And then as I mentioned, we've demonstrated, with the CoVaccine itself, that not only is it stable after lyophilization, but it's equally potent after lyophilization, so that means that it's very compatible for use.

So just to give you a bit of that background, we're looking here at the work we've done with the Ebola and Marburg vaccines. So Ebola and Marburg are sort of cousins, if you like. They're in the same filovirus family and they produce the same general types of disease, which I think most of us are familiar with. So here, CoVaccine is the vaccine adjuvant and filovirus vaccine could provide 100% protection in a nonhuman primate model with Marburg virus, and not only can it protect Marburg virus, but we can make a combination vaccine that can protect Marburg and Ebola at the same time. So that's the kind of flexibility we think is really important in a long-term vaccine platform.

So we took this platform and we thought, back in January, we were looking at this, and we think, well, there's a lot of similarity here between what we've done with our filovirus program and what we would need to do in the context of a coronavirus or COVID-19 vaccine. So in the filovirus space, we were using glycoproteins from the surface of the filovirus proteins as the antigen. Obviously, in SARS-CoV-2, it's that spike protein, which is also a trimer, is what is of importance, and so that should be very translatable. We felt we needed both humoral, and so antibody, and cell-mediated immunity; again, we've demonstrated that with the filovirus. That should be very translatable as well, the antigen expression system, as I've mentioned. And we have been able to demonstrate that all of these things have transferred over, including the mouse immunogenicity.

Now in the filovirus space, that program's a little bit ahead in that we've been able to demonstrate primate immunogenicity and efficacy, and we hope to be able to do that soon for the COVID-19 platform, but clearly, to this point, we've had very good translation between the filovirus program and this new COVID-19 program.

So what are the benefits, then, of CiVax? Well, again, we've done some prototype work, and I'll show some of the slides, some of the data in the upcoming slides, which have really shown that we do get that important Th1 response that Axel referred to earlier. We get it not only in the antibody response but also in the cell-mediated response. And with our original prototype vaccine, we saw that antibody response produced very quickly, within 14 days of the first vaccination. So that means you get a partial protection relatively quickly after vaccination, which in an outbreak scenario can be really important.

So there are a number of advantages of protein vaccines over some of the other platforms. I'm sure most people are aware, but of course, RNA and DNA vaccines have what we would call a novelty risk, so in other words, there's a lack of regulatory precedent and a lack of understanding of vaccine durability with this type of a vaccine. Similarly, those viral-vector vaccines that Axel was referring to do have some contraindications for the immunocompromised, and they do have

some complexity around the fact that you're basically latching onto another virus to generate the vaccine, and you might get immunity to the carrier as opposed to the piece you want for the -- for SARS-CoV-2, so there's some complications there. And of course, as Axel mentioned, a lot of attenuated viruses, although very potent when generated, take a while to make, and part of that is because there is some reversion risk with them, so that requires some careful planning and testing.

So again, we're using the protein platform because we think it is well understood and we've made sufficient breakthroughs in terms of thermostabilization and using the appropriate adjuvant to push both potency and give us some real advantages in terms of logistical constraints in distribution. Again, we can manufacture with a stably transformed cell line. We've got good proof-of-concept data there and we've shown that we can use protein-specific chromatography to clean it up, so we get a very clean product at the end. We've actually now just recently completed some studies where we used not just a prototype antigen but a more representative full-length spike protein, and here we saw many of the same outcomes that we'd seen in our prototype. And here, in fact, we saw responses as early as seven days after the first vaccination. So again, we think these are really important attributes of the program.

So I've tried to give you a feel for where a protein platform sits in the context of some of the other vaccine approaches that are being undertaken right now. So you can see, here, a bit more of a comparison. We've tried to indicate some of the, I guess, top five Operation Warp Speed candidates here just to give a feel for how comparisons can be made across them.

Clearly, one of the emerging issues is the storage and shipment issue, especially as some of the candidates require not just freezing but freezing at minus 70 degrees Celsius, so that's a pretty extreme requirement, and it's hard to meet that requirement when you're shipping. And it's probably important to note that when you don't make your storage conditions, there's actually two downstream costs to that. First is the ones that you know didn't meet their storage conditions and therefore have effectively been wasted and have to be thrown out because they went outside their storage parameters. But the second cost is the ones you didn't know went outside their storage parameters, and now you're potentially giving vaccine to people that is not going to be as potent as it should be. So generally speaking, when you have these cold-chain requirements and you can't meet them, there's those two arms of the downstream impact that they can have.

Again, the protein vaccines tend to be really broadly applicable across a lot of different populations. There's no reason, a priori, to exclude any one population, so they have a pretty broad applicability. And they can be used over and over again. So this may be possible with the other vaccines; that's maybe a little bit less well known, but the protein vaccine has certainly [inaudible].

Nobody knows yet if we'll be able to do a single-dose regimen; we do believe that with some of the newer candidates, two doses is thought to be necessary. Scale-up and manufacturing, once everything is established, should be relatively simple for some of the candidates but less so for others. And again, that idea of a single-vial formulation, I think, is quite important from the point of view, again, of logistics. So it's one thing to have a supply chain for a single vial; it's another thing to have to ship two components and both have their own storage requirements. So that's the

sort of thing that needs to be thought of. And then, of course, there's that idea of the regulatory risk that I referred to earlier.

Another way of looking at a product or a potential vaccine is in terms of what does the World Health Organization think would be a good target product profile for a vaccine, and they think about this in two contexts: one in an outbreak context where they're trying to get a disease outbreak under control, and one in a more long-term context.

They clearly, of course, prefer thermostability, and the higher a temperature you can go to, the better, when you think about worldwide distribution. Preferably no contraindications, preferably a very rapid onset of immunity, especially in the outbreak scenario. Ideally, a single-dose regimen, but certainly no more than two. It gets very hard to track people down to have them come back and have more than two vaccinations. They'd like to have durability of at least a year; at a minimum, six months, because they don't think they can get back in to the same population over and over again in less than a six-month window, I assume. Again, they would prefer a nonparenteral route; again, with our product, we are going to have to go parenteral. I think most products will likely have to go parenteral. And I think, as indicated by the minimal requirements, that is expected. I do think for our product it might be possible to go with a needle-free approach; that might relieve some of the logistic constraints, but it still does have to be administered parenterally. And then in the long term, the WHO likes to be able to group vaccines together, and so co-administration with other vaccines, where again we have that potential for multivalency, is also a consideration.

So maybe just to take a step [inaudible] now some of the data. The data we're showing here was published in a preprint publication that we spoke of earlier. This is a proof-of-concept study where we used just a portion of the spike protein and combined it with the CoVaccine adjuvant, and what we were trying to see is that yes, indeed, the CoVaccine adjuvant would be transmittable to this new disease context. So we're very pleased with this data. We do see a strong antibody response even post Dose One. You can see that the other adjuvants -- so the other one is alum. It's very commonly used in protein vaccines, and you can see that after a single dose, the antibody response isn't as strong. It does improve after two doses, but you get more rapid protection with the CoVaccine.

Now, of course, our -- again, a lot of vaccines being developed right now, obviously. Part of that is to cover for the potential failure of any platform or type of vaccine, so you want to sort of spread your risk from that perspective, but also part of it is just understanding that in order to vaccinate the worldwide population, we're really going to need a lot of different vaccines to produce adequate coverage worldwide. And we're really going to need to have rapid distribution of that as well, and we believe that the thermostabilization we think our product will offer will really enable that. And again, the government has placed a lot of -- worldwide government has placed a lot of priority on these development activities.

So other -- we talked about some of the other criteria which were important for a vaccine. First one of these was that we get this Th1 response. And Th1 here is identified by the IgG2a and 2b isotypes. You can see here we're getting a strong response with the CoVaccine, much less so with the alum. This is particularly important here because we actually are using mouse that

doesn't do Th1 very much, so we're pushing Th1 in a system where they're not biased to Th1. So that was a very good proof-of-concept demonstration.

And then the other thing we talked about was both neutralizing antibodies and cell-mediated immunity, so the graph shows you that we get a strong cell-mediated immune response with CoVaccine. Again, we don't get much of one with alum, and that's expected. That's what known about alum. We also got a strong neutralizing antibody response. So when we measure neutralizing antibodies, we take the serum from the animal and we dilute it over and over again, and we ask, how many times can we dilute it and still have a neutralizing response? So you can see here we were able to dilute 1,600-fold and still have a neutralized response, so that's as good as some of the post-convalescent plasma data that's been out there. Now, clearly, we are testing the samples side by side, but the assays generally work the same way, and so it looks like we're very well within the [inaudible] of what will be needed.

So more recently, we've taken an additional step here and moved forward with a more full-length spike protein just to see if all the same behavior patterns hold. And we see here, in fact, that we can go as early as seven days. And the way we see this in that little graph on the right there, the first left-hand panel, you see the purple open circles and the purple full circles. And the open circles are what you get seven days after vaccination. The closed circles are what you get 14 days' vaccination. So you can see already at seven days we're developing a response. And again, that very rapid response is quite important in an outbreak scenario where you're trying to protect people rapidly. And then post Dose Two, you can see that we get the maximum response already at seven days, so those open squares and closed squares are overlapping each other. So also, when we're using the vaccine in the booster sense, the boost is happening very rapidly, very rapid onset of protection. So we think both of those attributes will be quite important in terms of broad use.

And again, the Th1 bias, as we mentioned before; here we're seeing the response in an outbred mouse model -- this just means mice that aren't trained to be, say, Th1 or Th2 but are more variable, genetically variable, more like what you might expect a human population to be. Again, though, still with strong Th1 response, which is what we want to see. And still a strong cell-mediated response; also, again, what we want to see. So again, very consistent with what we saw and published with the prototype vaccine, so we're very pleased with this more newly emerging data.

So I just wanted to take a moment here and take a step back. We've talked a lot about our vaccine program for COVID-19; many followers of our company will know that we do have another immune modulation program. It's our dusquetide program. This compound is an innate defense regulator, so it enhances the anti-infective pathways while modulating the anti-inflammatory pathways. And given that profile, you could certainly see how it might be of potential utility in COVID-19. And we've definitely had people ask questions about this particular potential.

And we agree; there is definitely potential here. We can see it being used in a couple of different contexts, potentially. So you could give it to hospitalized patients hoping to prevent progression to severe respiratory illness, or you could give it to more severe patients in the hope of controlling the inflammation and the infection in conjunction with an antiviral agent like

remdesivir. So there are a number of ways we could see using this particular compound. Obviously, from a commercial perspective, we are focused on oral mucositis because that program is so far advanced, and that is where this compound is being used right now, but we do continue to seek nondilutive funding to potentially advance dusquetide in the context of COVID-19.

Now, it's worth noting, though, that funding agencies to date have really been focused on repurposing approved drugs as opposed to evaluating drugs in clinical development. We think that maybe with our Phase 3 outcome coming up here and with oral mucositis in Q4 of 2020, and given the very benign safety profile, there may be additional avenues to pursue here, and we do continue to pursue them. So I'll just put that out there for people, since I know that's been a question we've had quite a bit.

And with that being said, I'm just going to take a moment here and we're going to switch back to vaccines. I'm going to hand it back to Dan, and he can talk a little bit now about some of the market and competitive profile that we see for COVID-19. So Dan, do you want to take it from there?

Daniel Ring: Great, thanks, Oreola. Good afternoon, everybody. I'm Dan Ring, the VP of Business Development here at Soligenix, and just by way of a brief background, I spent 17 years at Merck & Co. in the commercial and financial functions. The majority of my time was spent there in BD and corporate licensing, doing all sorts of strategic transactions. I then moved to a hospital-based specialty pharmaceutical company called Exela; I was there for five years heading up BD and built the U.S. commercial operations. And then I joined Soligenix just about a year ago. Next slide, please.

So what I wanted to do over the next two slides is just share our view of the commercial opportunity for CiVax, bearing in mind this is a -- this pandemic is a humanitarian crisis and playing a role in potentially addressing it is really what's most important to our team. So from a macro level, the total addressable market for the COVID-19 vaccines is estimated at about $23 billion. So to put that into context, the current global vaccine market is about $40 billion, so clearly a large opportunity here for the COVID-19 vaccines.

We believe that this pandemic response will require many different vaccines to provide worldwide coverage, as Oreola alluded to earlier. We also believe that there is value in the long-term revaccination of patients, similar to what we see with seasonal flu vaccines. And then just to provide just a little context around that, in the U.S., the flu vaccine market last year was roughly $2.6 billion and unfortunately resulted in 24,000 to 62,000 deaths, and so we all know that the COVID-19 virus is much more lethal than the seasonal flu. And then finally, we believe that the vaccines that are in development will likely require multiple doses over a number of years to achieve the herd immunity. So longer-term value is certainly an opportunity here.

With respect to CiVax specifically and the strategic rationale for why we're developing it, we see four key principals. Firstly, the size of the market; billions of doses will be needed to satisfy the global requirements, and there's clearly room for multiple suppliers.

We also believe that we have a distribution advantage. You've heard the team talk about the thermostabilization technology we have in ThermoVax, and you might have recently seen the Wall Street Journal article just a couple of days ago; that timing was impeccable from our perspective, but it talked about vaccines fueling the scramble for freezers. So we believe by having the thermostable technology, we'll simplify and broaden the distribution by avoiding the cold-chain burdens of -- that the other vaccines have.

We also think that the platform that we're employing, the gold standard vaccine platform, is tried and true, and again, as Oreola mentioned earlier, it's been tested and many of the vaccines on the market are approved. And in fact, many of the vaccines that are in development for COVID-19 are using the subunit technology as well, so we're on trend and we think that bodes well for FDA clearance and public acceptance.

And then finally, the notion of seasonal use. We believe that CiVax could be used as a booster on an annual or semiannual basis and can be used in conjunction with or in addition to whatever vaccine technology was employed for the first dose. Next slide, please. Oreola, next slide please?

Oreola Donini: It's just on a delay. If you just keep talking, it'll move forward soon, hopefully.

Daniel Ring: Okay, great. Thank you. So the next slide will talk about the first-generation vaccines versus CiVax, and as exciting and as promising as we see the first-generation vaccines are, we believe that CiVax has some distinguishing characteristics and some significant competitive advantages over those first-gen vaccines.

Here we go. So, namely, the potential to -- namely, these first-generation vaccines employ novel and less understood technologies, whether it's mRNA like the Pfizer and Moderna vaccines, or the viral vector, like AZ's. These are new and untested technologies, and we believe increase the regulatory risk of those.

Again, our tried-and-true subunit vaccine technology has established regulatory and safety precedent, and we -- when we couple that with the CoVaccine adjuvant, we believe we have a safe and efficacious product here. The CoVaccine, again, as Oreola mentioned, enhances the immune response, so you have that one-two punch, if you will, with our CiVax vaccine.

And then thirdly, this tried-and-true approach, we think, will address some of the hesitation that people have with these first-generation vaccines. Unfortunately, somewhere around only 30% of Americans say that they will take the first-generation vaccines, whether it's a function of the speed or the technology that's being used, and so we think we have more broadly accepted product here compared to the first-generation vaccines.

On the second bullet there, you've heard us talk about this, but I really don't want to underplay this too much. But the notion of obviating the cold-chain logistical constraints and burden is huge. The Pfizer and Moderna vaccines need to be transported at negative 80 degrees Celsius; that limits, obviously, distribution and places where you can go to get the vaccine. Right now it should be limited, from what we're reading; limited to hospitals, and if you've been in a hospital recently, you know there's not a whole lot of space on the floors, let alone in the basement. They

already lined -- the hallways are lined with all those sub-zero freezers that are being used for other things. So it'll be a logistical burden for sure. CiVax will not have that issue. Additionally, we don't anticipate being restricted, similar to the viral-vector vaccines not being used in the elderly or the immunocompromised.

And the third bullet here speaks to -- specifically to the viral vector vaccines. They have the potential to build immunity to the vector, thereby limiting the dosing to once or twice, and so CiVax, we think, as I mentioned earlier, would be able to be used as a booster in addition to whatever platform technologies were used for the first shot.

And then the fourth bullet and final point is this: The first-generation vaccines may identify correlates of immune protection, and this speaks to what we see as a potential for regulatory advantage for us, which would potentially allow for faster and smaller studies where we would only need to demonstrate the similar antibody generation to the threshold that was demonstrated by the first-generation vaccines that then confers the protection, so we wouldn't have to go all the way to demonstrating the outcome of protection. So again, leveraging their correlates of immune protection, we see as a competitive advantage of ours.

So that's just in summary how we see it commercially. I don't think we're late to the party; I say that we're fashionably late. We're able to bring some advantages over what the first-generation vaccines have and we see that there's definitely a role for CiVax going forward.

So with that, I'll hand it back to Chris Schaber.

Christopher Schaber: Thanks, Dan. I would also like to take this opportunity to thank Oreola for her work with today's call, as well as a special thank you to Dr. Lehrer for taking the time out of his very busy schedule to participate. It's very much appreciated. Next slide.

So we can get to Q&A very quickly, in summary, hopefully with this short webcast presentation we were able to provide a good update into the important work we're doing here at Soligenix. We have multiple products with orphan and/or fast-track designation. We have Phase 3 clinical assets with data readout fast approaching, cutaneous T-cell lymphoma with SGX301 that's already achieved its primary endpoint, where we'll have some follow-on data coming later this year in the fourth quarter; our Phase 3 study in oral mucositis in head and neck cancer with SGX942, our dusquetide new chemical entity, where we've completed enrollment in that pivotal study following a positive interim analysis, and we expect those top line primary endpoint results in the fourth quarter of this year as well, so some very near-term catalysts. With the oral mucositis being a large market opportunity, it has the potential to be transformational for the company.

So there is the potential for significant near-term value creation. We have collaborations with biotech, academia and government agencies, and hopefully additional to follow, as we're very active on the business development front in a number of important discussions. And then, as you've heard clearly today, our CiVax heat-stable COVID-19 vaccine in development, as well as the potential for dusquetide as a therapeutic option in COVID-19.

So with that, let's open up our webcast to Q&A. Thank you.

Questions & Answers

Operator: And ladies and gentlemen, with limited time remaining, we will now address questions that have been submitted electronically. Dr. Donini will moderate the Q&A session. Dr. Donini?

Oreola Donini: Thanks very much, and I'd like to just begin by thanking everyone for e-mailing their questions in. We've received a good number, and we're going to do our best to get to a few of them, at least, in the remaining time, as there is a bit of overlap in some of the questions. I hope that those we can't get to directly all have been addressed to a certain extent either by the discussion we've just had or indirectly with these questions.

So the first question we received was: When might you expect to have nonhuman primate data with CiVax? And I think I'll just take that one myself and say that we hope to have nonhuman primate data by the end of the year, although I'll note this would not be a prerequisite for starting a Phase 1 study.

Our second question was: How would you compare the RNA vaccines to the CiVax approach? So maybe Axel, if I could ask you to address this one?

Axel Lehrer: Sure. So RNA vaccines like those that are under development by Moderna or Pfizer [inaudible] have demonstrated the ability to yield an antibody response, though generally a strong response requires at least two doses of vaccine. That is known from the published literature already. Given the need to first incorporate the RNA, as I mentioned earlier, to have the host produce the protein, RNA vaccine can take longer to generate that initial immune response. Although previous studies with RNA vaccines in clinical studies have demonstrated short-term safety and immunogenicity, the assessment for long-term safety and durability generated by this two-dose regimen is also still pending.

Of course, CiVax has not been tested clinically yet, but protein subunit vaccines are very well known and have been used for many years, as they are generally considered to be safe and the immune response can be very durable, depending on the adjuvant selected. And as we can see from the early preclinical data that we have generated already, the immunogenic response is rapid. This means that CiVax can not only be used as a primary vaccine but, as Dan has mentioned, can also have a significant value as a booster vaccine that could be used six to 12 months after the primary vaccine, most importantly, of any other developer has been given. And we've shown that this platform generally is compatible with multivalent formulations; that means also we could potentially adapt it in the future to protect against different strains of coronavirus, as an example.

Oreola Donini: Great, thanks, Axel. The next question we received is: How would you compare the AstraZeneca or Janssen vaccines to the CiVax approach? So I think I'll throw this one back at you as well, Axel.

Axel Lehrer: Oh, sure. So as this question rightly points out, the AstraZeneca and Janssen platforms use viral vectors to develop their vaccine, so they use a nonreplicating virus that then will express the spike protein in the host cells. This intracellular expression, as I mentioned earlier, helps to induce the right kind of immune response to this spike protein, particularly strong cell-mediated immunity.

The AstraZeneca vaccine, as an example, uses chimpanzee-originating adenovirus, while the Janssen vaccine uses a human-infecting adenovirus. In both cases, humans can develop immunity to the vector. That's one of the problems of using viral vectors for vaccine delivery, which then makes further injections with the vaccine candidate ineffective, as the body will mount an immune response to the adenovirus and then no spike protein can be expressed.

Another problem with the adenoviruses, or any viral vectors, is that they typically have to be, also, stored at frozen, minus 20 or minus 70 degrees, and it is certainly also a possibility that a protein vaccine like CiVax could then be used as a booster, as has been demonstrated, for example, in filovirus vaccines in the past.

Oreola Donini: Great, thank you. Maybe another one or two we'll try and squeeze in here. So how does the AstraZeneca clinical hold affect vaccine development in general? So maybe Axel, any comments there?

Axel Lehrer: On this, there are many potential reasons for the clinical hold that was just announced this week. They may or may not be related to the actual vaccine, and until further facts are known, I think we should not comment on this further. Clarity will likely emerge in the near future, as it's of utmost importance for the further development, and depending on the reason for the hold, there may be something to learn for this specific vaccine candidate or for COVID-19 vaccines in general, or, unfortunately, could also be said it is a more personalized question for the patient that experienced this.

Oreola Donini: Great, thank you. Well, I think at this point we've run out of time, so I'll just hand this back to the operator.

Operator: And ladies and gentlemen, we have used all the time allocated. Soligenix would like to thank everyone for their participation and for submitting questions. An audio recording of the Q&A will be posted on the Soligenix website. You may now disconnect. Thank you; have a good day.