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Officers and Speakers
Jonathan Guarino; Senior Vice President and Chief Financial Officer
Christopher Schaber; Chairman, President and Chief Executive Officer
Richard Straube; Senior Vice President and Chief Medical Officer
Oreola Donini; Senior Vice President and Chief Scientific Officer
Adam Rumage; Vice President, Project Management & Regulatory Affairs
Daniel Ring; Vice President, Business Development and Strategic Planning

Ellen Kim; Dermatology Clinic, Perelman Center for Advanced Medicine; Medical Director
Brian Poligone; Rochester Skin Lymphoma Medical Group; Director
Susan Thornton; Cutaneous Lymphoma Foundation; Chief Executive Officer
Michael Young; Cutaneous Lymphoma Foundation; Board Member

Presentation

Operator: Welcome to the Soligenix corporate update conference call.

(Operator Instructions)

As another reminder, this is a timed conference call and is being recorded today, March 19, 2020.

I would now like to turn the conference over to Mr. Jonathan Guarino. Please go ahead.

Jonathan Guarino: Good morning. This is Jonathan Guarino, Chief Financial Officer at Soligenix. Thank you all for participating in today's call. With the difficult and uncertain environment we all find ourselves in, I hope you and your families are well.

Joining me from Soligenix are Dr. Christopher Schaber, President and Chief Executive Officer; Dr. Richard Straube, Chief Medical Officer; Dr. Oreola Donini, Chief Scientific Officer; Mr. Adam Rumage, Vice President, Regulatory Affairs and Project Management; and Mr. Daniel Ring, Vice President of Business Development and Strategic Planning.

Also joining us for today's call are Dr. Ellen Kim, Medical Director, Dermatology Clinic, Perelman Center for Advanced Medicine and overall principal investigator for the FLASH study; Dr. Brian Poligone, Director, Rochester Skin Lymphoma Medical Group and the lead enrolling investigator in the study; Ms. Susan Thornton, CEO of Cutaneous Lymphoma Foundation, the largest patient advocacy organization for cutaneous T cell lymphoma; and Mr. Michael Young, Board Member of the Cutaneous Lymphoma Foundation and commercial consultant in cutaneous lymphomas and other cancers.

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, March 19, 2020. Soligenix undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this conference call.

With that said, I would like to turn the call over to Dr. Schaber. Dr. Schaber?

Christopher Schaber: Thank you, Jonathan. Good morning, everyone, and thank you for joining us. Given the very exciting news release this morning regarding SGX301, containing synthetic hypericin, and the pivotal Phase 3 FLASH clinical trial for the treatment of cutaneous T cell lymphoma, or CTCL, we thought it would be beneficial to our shareholders for us to provide a corporate update, including more information on the just-released top line results from the Phase 3 trial and the path forward, as well as a brief update on the status of our oral mucositis Phase 3 clinical trial that is also approaching top line results later this year.

I must caution you up front, however, that we are limited to what we can say at this time beyond what we have disclosed in our press release, as we only have the aggregate top line results for Cycle 1 from the CTCL study and remain blinded to individual patient treatment. Actual patient treatment assignments will only be unblinded when the last patient completes cycles 2 and 3, as well as their six-month followup visit.

So with that, I will get right into the subject at hand. As many of you have probably seen, we announced positive results for the double-blind Cycle 1 portion of our pivotal Phase 3 FLASH study for the treatment of CTCL, an extremely important milestone for our company and hopefully for patients. As you've seen in our press release and to our pleasure, Cycle 1 data consisting of SGX301 or placebo treatment of three index lesions administered twice a week for just six weeks demonstrated a statistically significant response, a p of 0.04, in the primary endpoint for the study. This endpoint was defined as at least a 50% cumulative reduction using the composite assessment of index lesion severity score, otherwise referred to as the CAILS score, in three predefined index lesions at the eight-week study time point relative to the baseline assessment. Importantly, there were no safety concerns noted.

As we now wait for the open-label cycles 2 and 3 of the study to complete, our focus remains to complete the study, and we'll continue to report data after the treatment cycles' database is locked. Internally, we will be informing the FDA of the findings so that we can set the stage for our pre-NDA meeting once the study is fully completed. During this time, we will begin preparation activities for our NDA so we are able to file as soon as possible.

Just a reminder to everyone: CTCL is a rare cancer in an area of unmet medical need as validated by the FDA, and for which we have been granted orphan drug designation as well as fast-track status, which carries with it the potential for priority review of an NDA with the FDA. In conjunction with these development efforts, we look to advance potential partnership discussions while also, in parallel, continuing to execute on our own strategy -- commercialization strategy, excuse me, in the U.S. By doing in this parallel, it will allow us to better assess where the greatest value may be for our shareholders moving forward.

And even though this call is about the preliminary positive top line results for SGX301 in the treatment of CTCL, I would be remiss if I didn't make note that we are advancing towards top line results with our other pivotal Phase 3 clinical study with SGX942 in the treatment of oral mucositis in patients receiving chemoradiation for their head and neck cancer. We look to report top line results for the primary endpoint of this trial, which we refer to as the DOM-INNATE study, midyear this year, 2020.

Before turning the call over to Dr. Richard Straube, our Chief Medical Officer, to review the clinical program in a bit more detail, a brief note on our financials. Current cash as of this morning is currently approximately $7.6 million, which does not include the approximate $1 million we anticipate receiving from our New Jersey NOL tax credit and U.K. tax incentive credit program. Some of you may recall that our cash burn is offset by nondilutive funding from the government, which gives us a minimum cash runway through the end of 2020. So our current

plan is to use this cash runway and wait until top line results for the oral mucositis Phase 3 study. This will allow us to better evaluate potential partnership before even contemplating the need for any larger equity raise. Keep in mind that we also have an ATM in place with B. Riley FBR, which we can use to supplement cash if and when the need arises and/or stock price and volume permit.

With that said, I will now turn the call over to Dr. Richard Straube, our Chief Medical Officer, who will review the Phase 3 CTCL study. For those of you not familiar with Rick's background, he has had a long and distinguished career of more than 30 years in both academia and industry, most notably with the University of California at San Diego, Centocor and INO Therapeutics. He is a board-certified pediatrician with deep research background in orphan disease development, oncology, immune modulation and infectious diseases, with a number of successful clinical trials and drug approvals under his belt. Rick?

Richard Straube: Thank you, Chris. As Chris noted, we're extremely pleased to have achieved statistical significance with a p equal to 0.04 in our primary endpoint of the study. Although all personnel who interact with the clinical sites, including myself, remain blinded to the individual patient treatments, we're also encouraged by the results emerging from the second cycle of treatment in our study. This cycle treated all patients' index lesions with SGX301, and in which we're seeing an enhanced response rate of approximately 35% based on current blinded data. This suggests that longer treatment with SGX301 is enabling even better responses for our patients, and we look forward to reviewing the final Cycle 2 data, with results currently expected in June of this year.

As a background to the detailed discussions concerning the results of this trial, I think it's important to understand the truly difficult nature of this disease. CTCL is a rare type of non-Hodgkin's lymphoma and is specifically caused by malignant T cells that are attracted to the skin. There is about 25,000 to 30,000 people living with CTCL in the U.S., and there's no cure for this lymphoma. Further, there's no approved front-line therapy for the disease, making it an area of unmet medical need.

With no cure available for CTCL, disease management and preserving the immune system are the key objectives of medical care in this chronic disease setting. For most patients and doctors, managing CTCL is about managing the discomfort of the lesions, which can be very painful, itchy and are cosmetically unbecoming.

The problem is that the current therapies themselves are not benign. Cancer treatments are obviously meant to kill cancer cells, but there is often collateral damage, including damage to otherwise healthy, normal tissue. This is particularly true in CTCL, where most of the current treatments themselves are mutagenic agents; that is, they kill tumor cells by mutating the DNA. This can cause DNA mutations in the normal skin cells as well, and this significantly raises the risk for secondary cancers such as melanoma. Thus, patients and their caregivers are faced with trying to treat a less lethal but difficult disease with treatments that raise their risk with extended treatment of potentially developing a more lethal cancer. Aside from the risk of cancer, there's also significant skin damage, which can cause premature aging, as well as allergic and local irritation associated with several of the second-line skin-directed treatments.

In contrast, SGX301 is a combination product, a topically applied ointment containing synthetic hypericin, which is activated by safe, cost-effective fluorescent light. This activation causes the release of free radicals, including superoxide, which in turn induces apoptosis, also known as programmed cell death of the cancer cells. Importantly, this path to cell death is not caused by DNA mutation, and therefore, hypericin is not mutagenic. Moreover, the light source is fluorescent light, which is not carcinogenic. Damage to the healthy tissue is minimized, moreover, by applying the ointment only on the cancerous lesions themselves, and by the selective and preferential uptake of the drug by malignant T cells compared to the healthy cells. So compared to other CTCL therapies, SGX301 is uniquely positioned, as it's not expected to be associated with the increased risk of malignancy or long-term skin damage.

So building off the Phase 2 trial with this drug, the Phase 3 FLASH study was a highly powered, adapted design that enrolled 169 patients with stage IA, IB or IIA CTCL. The trial consists of three treatment cycles, each of

which are eight weeks long. Treatments are administered twice weekly for the first six weeks, and then the treatment response was assessed in the eighth week after each cycle.

Treatment responses, as mentioned before, was measured by the CAILS score, with success defined as having reduced the CAILS score by at least 50% across three index lesions. The CAILS score is a composite score of four attributes, including: one, the size of the lesion -- we measured this as surface area; two, the amount of erythema or the degree of redness; three, the amount of scaling; and four, plaque elevation or thickness of the lesion above the surface of the skin.

In the first treatment cycle, 116 patients received SGX301 treatment with ointment containing 0.25% synthetic hypericin and 50 patients receiving placebo treatment for their index lesions. Again, I'm very pleased to announce that the study demonstrated a statistically significant response at the p equal to 0.04 level, with 16% of the patients receiving SGX301 responding, compared to only 4% of the patients receiving placebo, over the twice-weekly six-week treatment course. It's also important to note that the treatment was extremely well tolerated with minimal side effects reported.

In the ongoing second cycle, all subjects received SGX301 treatment of their three index lesions. That means some patients received a total of 12 weeks of SGX301 treatment and some received only six weeks because they received placebo in Cycle 1. While we remain blinded to the study treatment, as I mentioned earlier, we are seeing increased response rate in Cycle 2 of more than 35%, suggesting the continued treatment with SGX301 is increasingly beneficial to this patient population, as we were expecting.

In the third, optional cycle, all patients received SGX301 treatment of their three index lesions plus all other lesions that they wanted treated. The majority of the patients enrolled have elected to continue with this optional open-label component in the study, with approximately 70% of all patients opting into Cycle 3. In this arm of the study, we also evaluated the systemic availability of the drug, demonstrating that it does not penetrate into the bloodstream. This is very advantageous from a safety perspective and is consistent with the observed and anticipated general safety of this topical product.

Subjects were -- are being followed for an additional six months after completion of the last treatment cycle that they participated in. The second and third open-label cycles and the subsequent six-month follow-up remain ongoing, and the results will be further announced as the final patients continue to complete their designated visits, the patient data is monitored, and that data is subsequently transmitted for statistical analysis and quality audit. The data from cycles 2 and 3 will be handled in a similar manner as Cycle 1, and our focus now is to complete the open-label Cycle 2, where we hope to be able to announce high-level findings in June.

Again, to briefly note, all personnel who interact with clinical sites, monitor the data, prepare it for presentation to the statistical group for analysis will continue to remain blinded to individual patient assignment for the duration of the study. This is because it's necessary to keep the blind in place to ensure the safety data is adequately assessed in patients receiving longer or shorter SGX301 treatment; that is, whether or not they had drug in Cycle 1 or not. This is particularly important because we anticipate physicians will be especially interested in the data from SGX301's longer-term use. Therefore, data analysis remains ongoing. In addition, the data will be submitted for presentation and publication in medical settings, and we obviously don't want to jeopardize these submissions with too extensive public disclosure of the details of the results.

In summary, with positive, statistically significant results in the study's primary endpoint, we have achieved an important regulatory hurdle. We now proceed with preparing for further FDA discussion and NDA preparation activities to hopefully bring a safe and efficacious front-line therapy for clinicians to add to their CTCL treatment armamentarium.

To provide an independent expert opinion on just how clinically meaningful these preliminary Phase 3 results are after a short course of treatment, and the potential role for SGX301 in the future, I will now turn the call over to

Dr. Ellen Kim, who is the Medical Director at the Dermatology Clinic at the Perelman Center for Advanced Medicine, who is acting as lead investigator for the FLASH study. Ellen?

Ellen Kim: Thank you, Rick. It is a truly, really exciting time for me, as well as Dr. Poligone, who is also on the line, the clinicians participating in the FLASH study, and especially for the many patients and families struggling with this chronic and highly symptomatic cancer. I cannot overstate how important and clinically meaningful the preliminary Cycle 1 findings are from the trial discussed today. As a clinician, I've been treating CTCL patients for over 18 years. I unfortunately get to see firsthand just how difficult this cancer can be for patients and their families.

CTCL can be an isolating disease. Beyond the disturbing appearance of the lesions and tumors, many patients experience skin shedding and severe itching. Stress and anxiety related to the risk and fear of disease progression is also a significant concern. As Rick noted, there is no cure for CTCL. It requires long-term treatment and management over years, and oftentimes decades.

Therefore, our goal is to improve patient quality of life. This includes management of the appearance, itching, scaling and the patient's ability for normal life activities; maintain the disease in its early stage, avoiding disease progression; of course, choose treatments that are affordable and sustainable; and finally, and maybe most importantly, minimize long-term cumulative side effects/toxicities such as secondary skin cancer and photodamage.

As this disease is chronic and therapies have to be continued long-term or often rotated, safety is just as important, if not more so, than efficacy. We can't have treatments that are worse than the condition we are trying to treat. Unfortunately, traditional phototherapy is associated with increased skin cancer risk and photodamage. Many skin-directed therapies for CTCL have short- and long-term side effects that may affect their use. We need full-body skin-directed therapies that are safer and have less long-term side effects.

SGX301 as first-line therapy truly fits this unmet need. It is a photodynamic therapy that has efficacy without expected bystander mutagenesis in the normal skin, and will be a very important treatment option for patients, especially those with a history of skin cancers. This makes up a large percentage of the population, since skin cancer is the most common cancer in the world. The light source used in this study is visible, safe fluorescent light, not ultraviolet light. Further, the response rate seen is comparable with other therapies we are using.

SGX301 is positioned nicely in the treatment paradigm as a potential first-line therapy in early-stage CTCL. I would expect it to be used in roughly 30% to 50% of my patients and would imagine it would be generally used roughly the same, if not at a higher percentage, at other medical centers that treat CTCL.

I could continue talking, but I will stop here for the sake of time. Needless to say, I'm very excited about the news today and hope I provided the listeners with a better perspective on what clinicians and patients must contend with in treating this difficult disease. With that, I will turn the call back to Dr. Schaber.

Christopher Schaber: Thank you, Ellen, for that overview. Before going to Q&A, I wanted to briefly provide some concluding remarks. As hopefully you can tell from this morning's call, we are all very pleased with the preliminary results from the Phase 3 CTCL study. The biologic activity of SGX301 is quite apparent in this difficult-to-treat chronic cancer. It's a gratifying time for the company after many years of hard work on this trial, but it's not over yet, and that work continues.

Over the coming weeks, we will look to analyze the Cycle 1 data in more detail with our medical advisory board while we continue to collect the data from open-label cycles 2 and 3. I would expect our NDA preparation efforts and FDA interactions to pick up, as well as our potential partnership and commercialization discussions. As always, we will continue to keep you all updated as key information becomes available.

This is the first of two important and potentially transformational near-term milestones for Soligenix. As many of you know, we have another important pivotal Phase 3 clinical trial in oral mucositis and head and neck cancer, where we currently expect data readout by midyear, as well as a number of active programs in our public health solutions business segment, which are being funded by the U.S. government.

Now, prior to going to Q&A, I would also like to again caution everyone that at this time, we are unfortunately limited in what we can say regarding the Phase 3 data. With that, we will now take your questions. Operator?

Questions & Answers

Operator: (Operator Instructions)

Jonathan Guarino: This is Jonathan Guarino again. Let's begin our Q&A, as we've received quite a few questions. We will clearly not be able to address all questions, but we'll look to address as many as possible in the time remaining.

The first question: Congratulations, very exciting news. Can you remind us of your current cash position? Will the cash on hand allow you to get top line results for SGX942 Phase 3 oral mucositis study?

Christopher Schaber: Thanks, Jonathan. Thank you for the congratulations. So Jonathan, why don't you take this question?

Jonathan Guarino: Great. Yes, the current cash as of this morning, not including the approximate $1 million of NOL and tax credit funding expected from the New Jersey and U.K. government, is approximately $7.6 million. This does not include our nondilutive government funding, where we have an NIH contract award of up to $24.7 million.

This currently gives us a minimum cash runway of at least four quarters. Keep in mind that we also have an ATM in place with B. Riley FBR, which we can use to supplement cash if and when the need arises. So again, yes, with our current cash resources, we anticipate getting to oral mucositis Phase 3 top line readout.

The next question: This question's for Dr. Kim. What is the prevalence of CTCL, and what has been your experience with SGX301?

Christopher Schaber: Ellen, this is one of the questions addressed to you, so please, the floor is yours.

Ellen Kim: Thank you. Although the number of patients with CTCL remains imprecise, because the disease is often misdiagnosed, often for quite some time, before definitive diagnosis is made, it is generally accepted, however, that there are at least 25,000 to 30,000 patients in the U.S. diagnosed with the disease, with the vast majority of these patients having an early-stage diagnosis. Early-stage patients may not have progressive disease and may live 20 to 30 years or more after diagnosis.

By all current indications, SGX301 appears to be safe, well tolerated and effective. It does not carry the same increased risk of secondary skin cancers that are associated with UV treatments. This would be a very important therapeutic option for patients. It would be a preferred first-line option for early-stage patients.

Compared to other treatments, the main differentiating factor is the potentially superior long-term side effect profile, since, as was discussed previously, hypericin is not systemically absorbed; the mechanism of action does not cause genetic mutation, unlike traditional phototherapy; and there is no known increase in long-term risk of skin cancers or melanoma.

The treatment procedure is similar to traditional phototherapy; it requires the patient to apply SGX301 prior to light exposure, so coordination is required. However, it is convenient to have a treatment used only a few times a week instead of daily. It has also been extremely well tolerated and photosensitivity is less of a problem than what is typically seen with traditional phototherapy.

Jonathan Guarino: Great. Thank you, Dr. Kim.

Next question: Do you think the coronavirus will have any impact to your operations moving forward?

Christopher Schaber: That's a good question, a topic that we've been discussing internally quite a bit. As you know, it's difficult to say with any certainty just how much coronavirus will ultimately impact operations. However, given the concern over the spread of coronavirus, I think you need to evaluate what can potentially occur and try to account for it as much as possible.

In the coming days, weeks, we'll continue to assess the potential impact to our operations. If we believe it may impact or add potential undue risk to our programs, we will provide update accordingly.

Jonathan Guarino: Thanks, Chris.

The next question: How are the participant -- partnership discussions going, excuse me. I would expect them to start heating up. Is there anything you can tell us about the timing of announcing a deal?

Christopher Schaber: Dan, why don't you take that question?

Daniel Ring: Sure. Thanks, Chris. Good morning. As you can imagine, we're getting a lot of interest from potential partners in this de-risked, near-term commercial asset, but we can't make guarantees about a partnership and can't disclose anything right now. What I can say is we have a number of confidential discussions ongoing with potential partners, and we'll see where those discussions go. And of course, if and when there's something to announce, we certainly would share that with you all.

Jonathan Guarino: Great, thanks, Dan.

Next question: Congratulations on the positive response. Can one of the physicians on the phone today provide their expert perspective on the Cycle 1 response rate of 16% for me?

Christopher Schaber: We have not heard from Dr. Brian Poligone as yet. Brian, would you take this question?

Brian Poligone: Sure. So in short, the response rates we see at six weeks are very promising. Most treatment plans are carried out over a much longer time period, so seeing positive results at six weeks is excellent. Importantly, we would expect the response rates to increase with longer treatment times, as we have observed with the preliminary data for the end of Cycle 2. CTCL patients have variable disease presentations, but it's our general practice to continue treatment as long as symptoms are being alleviated, and importantly, there is no risk -- no increased safety risk.

Skin-directed therapy treatments require more than six weeks to determine response. So for example, mechlorethamine was studied over a 12-month application window with some patients continuing to show response for the entire duration, and some patients continued to improve beyond this 12-month treatment period. So we expect similar -- sort of a similar increase in response over time in this study. And this is exactly why the trial was designed with Cycle 2 extended treatment and Cycle 3 optional treatments included, and I certainly look forward to seeing this additional data.

So it is also important to understand that the six-week Cycle 1 response is using a light-based treatment. And phototherapy and photodynamic treatment protocols are optimized to maximize the amount of tumor death, but also minimize the damage to healthy tissue. And this requires slow increases in the light dosing. So therefore, a six-week trial, part of the time is spent arriving at the correct optimized treatment dose. Indeed, this titration can take up to four weeks, and this should further boost outcomes, and means that the Cycle 1 response rate is only the beginning.

While it's easy to focus on these good results in the response rate, it can't be overstated how important management of side effect and toxicities are in this disease. The safety of SGX301 will allow us to optimize treatment dosing and ultimately augment the findings from this short six-week Cycle 1.

Jonathan Guarino: Great, thank you, Brian.

Can someone please explain what this news today means for patients?

Christopher Schaber: There's no better person on the line today to answer this question than Susan Thornton, with the Cutaneous Lymphoma Foundation. Susan, would you be so kind as to take this question?

Susan Thornton: Sure. Thanks, Chris. This is excellent news for patients. From the patient perspective, you want a treatment that is safe, effective and with the least amount of side effects. Many of the therapies available today either don't work for all patients or don't work for long periods of time, or can't be used by some because of the side effects, or are used off-label, creating access issues. As a leader of the patient organization and a patient myself, I know firsthand the importance of developing more therapies and options to support people living with this rare blood cancer.

Jonathan Guarino: Great. Thank you.

Next question: If you intend to commercialize the product yourself, what do you anticipate the intended cost to build the marketing sales force would be?

Christopher Schaber: Dan, please.

Daniel Ring: Sure, thanks, Chris. So at this time we're not publicly prepared to discuss the details of our commercial strategy, but we're working towards providing some more information to you all in the next 90 days. I can tell you that because CTCL is an orphan disease managed by a limited number of prescribers in the U.S., we anticipate that a small, focused commercial footprint would be required to reach these prescribers compared to other therapeutic areas. In addition, our introduction into the marketplace and physician education should be greatly assisted by the fact that a large portion of the leading prescribers and treatment centers in the country who treat CTCL have participated in the FLASH trial, and as such, have familiarity with the drug and its use.

Jonathan Guarino: Great. Thanks, Dan.

Given that the interim analysis seems to have dramatically de-risked the CTCL Phase 3 study, I would imagine that this fares well for your pivotal Phase 3 study in oral mucositis as well. What are your thoughts?

Christopher Schaber: Rick, I don't think you've had a question yet. Why don't you respond to that one?

Richard Straube: Sure. I think it's important to realize that with any clinical trial, there's always risk. However, the interim analysis did de-risk the trial to a certain extent, as the independent unblinded data monitoring committee was able to look at the actual data being generated in the Phase 3 data and provide blinded guidance to increase the sample size to maintain the high 90% statistical power. So we're confident.

Jonathan Guarino: Great. Thanks, Rick.

Next question: What are your expected U.S. peak sales for SGX301?

Christopher Schaber: Our commercial work is ongoing. We haven't provided public guidance on the sales of SGX301 at this time. What we can say is that we estimate the total addressable market for CTCL in the U.S. and Europe to be approximately $250 million, and we'd expect our novel therapy to garner a meaningful share of the market and perhaps even grow it.

Jonathan Guarino: Great.

You've mentioned this is a drug-device combination product, but we haven't heard much about the device. Can you provide more detail about it?

Christopher Schaber: Rick, can you take that one as well, please?

Richard Straube: Sure. The light source is an integral component of the treatment paradigm, as you've heard. As we mentioned, this will be viewed by the FDA as a combination product.

The light panel is a small portable unit. It stands about six feet tall and fits easily behind an office door. It doesn't require a dedicated room. It doesn't require special electrical hookups. And we're hearing that the physicians leave our light panel behind the door in many cases in the exam room for easy access. The device itself is manufactured in the U.S. under exclusive agreement we have with the manufacturer. Panels used in the clinical program are 510(K)-cleared by the FDA.

Jonathan Guarino: Great. Thanks, Rick.

Next question: Won't the device be a barrier to uptake, a commercial challenge?

Christopher Schaber: We also have Michael Young on the line, our experienced CTCL commercial consultant. I believe you're best to answer this question, Michael.

Michael Young: Thank you very much. In answer to the question, we don't believe so at all. I think that, first of all, most medical dermatologists are very comfortable with photodynamic therapy, light sources and systems. They've used light systems for psoriasis, actinic keratoses and other diseases for decades. So they have similar light systems in their offices right now.

As had been mentioned here, secondly, the device is very convenient to use and store. It doesn't require a dedicated room or a special electrical hookup. And in this clinical trial, we understand that many of the physicians actually stored the light panel behind the door in the exam room for easy access.

Finally, we see a commercial opportunity with the light panel because it can be strategically paired specifically with our drug, and this should provide for an additional barrier to later generic entry.

Jonathan Guarino: Great, thank you.

Christopher Schaber: Thanks, Michael.

Jonathan Guarino: What, if any, plans are you considering for ex-U.S.?

Christopher Schaber: Dan, please?

Daniel Ring: Sure. Thanks, Chris. So our current plans for the ex-U.S. markets are to identify partners with commercial capabilities and experience in this unique therapeutic area. We do anticipate receiving marketing approval in the U.S. first, and then we would aggressively pursue marketing authorizations in other key markets.

Jonathan Guarino: Great. Thanks, Dan.

Daniel Ring: Yes.

Jonathan Guarino: Our next question: Dr. Donini, who is on the line, is an inventor of SGX942. Can she speak again to why she has confidence in SGX942?

Christopher Schaber: Oreola , please respond.

Oreola Donini: Sure, thanks, Chris. So of course we've tested SGX942 in a variety of nonclinical settings and across multiple animal species, and the results have always been extremely consistent. And our Phase 1 and Phase 2 results were also very similar and very consistent with the previous animal studies, despite the fact that all of these studies were conducted over a number of years. So on the basis of all that, we're very excited to see the outcome of the Phase 3 study.

Christopher Schaber: Thanks.

Jonathan Guarino: Great. Thanks, Oreola.

Next question: Although I am pleased with the outcome of the CTCL Phase 3 study, I am in this stock because of the new chemical entity dusquetide, SGX942, in oral mucositis. Are there other disease indications you could develop this in, such as oncology?

Christopher Schaber: Oreola, please take this question as well.

Oreola Donini: Sure. Thanks, Chris. As we all know, dusquetide is an innate immune modulator, and this means that there's a variety of different disease contexts that it could have a significant impact on. For instance, in infectious disease, under our public health solutions business segment, we're evaluating dusquetide in specific models of bacterial infection with Category A priority pathogens, but we're also now exploring the potential of this technology in the context of coronavirus as well.

In the setting of our specialized biotherapeutics business segment, we have not yet made definitive plans, but I know that I've discussed with other investors potential studies in other inflammatory indications and in oncology, and as well as in many of our presentations.

So these exploratory clinical studies obviously await the outcome from our Phase 3 trial in oral mucositis, which is also allowing us to assess a variety of secondary endpoints such as infection risk in tumor clearance.

Christopher Schaber: Thanks, Oreola.

Jonathan Guarino: Our next question: Can you provide some examples of how the coronavirus may have an impact to your operations moving forward, especially as it relates to the Phase 3 oral mucositis trial?

Christopher Schaber: As I stated, it's difficult to accurately predict the extent in which the coronavirus will impact operations and what those operations may be. However, as you're going through the planning exercise, you evaluate and ask yourself a number of questions. For example, in clinical operations, is there the potential to have an increase in the number of patients dropping out of your trial, either because they get the virus or are afraid to travel? Is there the potential that the collection of clinical data will take longer because the clinical sites will not

allow your staff to get in as quickly as you usually would, or are there delays in staff travel to collect the needed clinical data? These are some of the issues we're examining when discussing internal timelines, as well as our current public disclosures.

If you look specifically at the Phase 3 oral mucositis study, such factors may have an impact, especially when you consider patients are required to receive radiation and chemotherapy for approximately seven weeks after being randomized into the trial, (indiscernible) for an increase in the rate of patient dropouts or data retrieval delays could occur; therefore, we are monitoring this very closely.

Again, if we decide to take this more conservative approach and -- to potentially modify disclosures to maintain the statistical integrity or quality of the pivotal study, we will obviously update our guidance accordingly.

Jonathan Guarino: Great. Thanks, Chris.

Are you still on track to submit your NDA by the end of this year?

Christopher Schaber: We have Adam Rumage with us, who is our Vice President of Regulatory Affairs. Adam, can you take that one?

Adam Rumage: Sure, thanks, Chris. We are certainly working towards that. We intend on engaging the FDA in discussions regarding the NDA submission as soon as possible, with the objective of gaining agreement that a rolling NDA approach can be utilized. Assuming the challenges related to the coronavirus pandemic are overcome near-term and we have received timely FDA agreement, we would anticipate being able to begin submitting pieces, or what's known as modules, by the end of the year. Again, this timing will be very much dependent on the impact of the coronavirus, something we cannot accurately predict for today.

Christopher Schaber: Thanks, Adam.

Jonathan Guarino: Great. Thanks, Adam.

I think we have time for one more question: When would you consider a partnership versus commercializing the product? Has there been interest from potential partners?

Christopher Schaber: Sounds like another question for you, Dan.

Daniel Ring: Sure, thanks, Chris. So we can't comment on ongoing discussions, but I can say that a number of companies are very engaged. They're in our data room conducting due diligence, and they have been anxiously awaiting this data to complete their review.

Regarding the assessment of commercializing versus partnership, I think that will come down to the experience of the partner and our assessment of their ability to successfully commercialize the product, at least as rapidly, efficiently and profitably as we could do ourselves. In addition, we'd want to look at their expertise and reputation in this unique therapeutic area.

Christopher Schaber: Thanks, Dan.

Daniel Ring: Thanks, Chris.

Operator: As we are coming to the end of the time allotted for this morning's call, I would like to turn the call back to Dr. Schaber for closing remarks.

Christopher Schaber: Thank you, operator. Hopefully many of you found the call helpful today. Again, it's an exciting and rewarding time for us, after putting so much time and energy into development of SGX301. As I noted, we will continue to keep you updated on the SGX301 program and all our development programs across our rare disease pipeline.

I'd like to conclude with a brief word about the worldwide pandemic we are unfortunately experiencing. As I stated during the Q&A, it's difficult to say with any certainty just how much coronavirus may ultimately impact our operations. However, we continue to monitor things very closely, and if we believe it may have the potential to impact or add undue risk to the quality and/or potential success of our programs, we will provide update accordingly.

Thank you for participating and taking the time for today's call. I would also like to thank Dr. Kim, Dr. Poligone, Michael Young and Susan Thornton for taking time out of their busy schedules to share their expertise and insights with us; it's very much appreciated.

With that, remain safe, and I hope everyone has a good day.

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