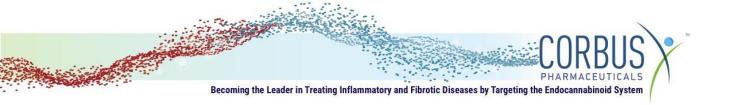


Corbus Pharmaceuticals Holdings, Inc.
Quarterly Update Conference Call
March-12-2019



**Operator:** Greetings, and welcome to the Corbus Pharmaceuticals Quarterly Update 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. As a reminder, this conference is being recorded. It is now my pleasure to introduce your host, Ted Jenkins, Senior Director Investor Relations and Corporate Communications. Thank you. You may begin.

**Ted Jenkins:** Thank you, Donna. Good morning, everyone, and thank you for joining us for the Corbus Pharmaceuticals Fourth Quarter and 2018 Year-End Update Conference Call and Webcast. At this time, I'd like to remind our listeners that remarks made during this call may state management's intentions, hopes, beliefs, expectations, or projections of the future. These are forward-looking statements that involve risks and uncertainties. Forward-looking statements on this call are made pursuant to the Safe Harbor provisions of the Federal Securities Laws. These forward-looking statements are based on Corbus' current expectations, and actual results could differ materially. As a result, you should not place undue reliance on any forward-looking statements.

Some of the factors that could cause actual results to differ materially from those contemplated by such forward-looking statements are discussed in the periodic reports Corbus files with the Securities and Exchange Commission. These documents are available in the <a href="Investors">Investors</a> section of the Company's <a href="website">website</a> and on the Securities and Exchange Commission's <a href="website">website</a>. We encourage you to review these documents carefully. Joining me on the call today is Yuval Cohen, our Chief Executive Officer, Sean Moran, Chief Financial Officer, Craig Millian, our new Chief Commercial Officer, and Barbara White, Chief Medical Officer. It's now my pleasure to turn the call over to Yuval Cohen.

**Yuval Cohen:** Thank you, Ted. Good morning, and thank you everyone for joining us today. My name is Yuval Cohen. I am the CEO of Corbus. 2018 was a transformational year for Corbus, and I want to take the opportunity today to review some of our key achievements, provide an update on our clinical programs, and walk you through some of the key themes for 2019. I will then provide a financial update before I will open the call for your questions.

In 2018, we made significant progress towards our mission of becoming the leading pharmaceutical company in the treatment of inflammatory and fibrotic diseases by targeting the endocannabinoid system, also known as the ECS, a master regulator of inflammation and fibrosis in the body. Our vision is important as it underpins everything we do, and it speaks to our long-term belief that the cannabinoid biology will become one of the hallmarks of medical advances in this coming decade.



Furthermore, as a pioneer in the development of small molecules that bind the cannabinoid receptors, we believe that Corbus is uniquely positioned to become the leading source of endocannabinoid system targeting therapeutics. Stepping back, "cannabinoids" is a term that is attracting a lot of interest, and I'd like to briefly remind you all of how Corbus fits into this landscape.

Endocannabinoids are the body's own endogenous cannabinoids signaling molecules that play a role in keeping our body healthy. Phytocannabinoids are chemicals found in the cannabis plant such as THC and CBD. They are extracted from the plant and are approved as therapy for significant medical problems such as severe childhood epilepsy, nausea and vomiting in people undergoing chemotherapy and the loss of appetite and weight loss in people stricken with cancer. But importantly, our compounds are neither endocannabinoid or phytocannabinoids. Our compounds bind the endocannabinoid system receptors in the body that do not exist in nature. In other words, they are artificial or synthetic cannabinoids.

There are several advantages to this strategy of rationally-designed small molecules to target the endocannabinoid system, including our small molecule drug candidates that can be designed for the treatment of specific diseases. Their chemical structure can be optimized to preferentially target the CB1 cannabinoid receptor or the CB2 cannabinoid receptor and to partially or fully activate or inhibit these receptors. Our compounds can be designed to specifically target the ECS in certain organs, such as the liver or the brain or, alternatively, avoid certain organs such as the brain.

Unlike plant derived cannabinoids, our synthetic ones benefit from composition of matter patent protection with all the market exclusivity benefits that accompany that. Lastly, this therapeutic approach of controlling activation or inhibition of endocannabinoid receptors has broad applicability to inflammatory and fibrotic diseases. Corbus now leads in the development of first in class drugs targeting the endocannabinoid system. We plan to be the first to market with novel therapeutics that target inflammation and fibrosis through the regulation of the ECS. Lenabasum, a CB2 agonist, is in pivotal testing for the treatment of rare autoimmune diseases, such as systemic sclerosis and dermatomyositis, and in late stage testing for the genetic inflammatory disease, cystic fibrosis, as well as in a first-in patient lupus study.

We believe we have the most innovative and largest pipeline of early stage drug candidates that target receptors in the endocannabinoid system. These include CRB-4001, a CB1 inverse agonist that is being developed for NASH, and a preclinical library of over 600 rationally-designed compounds. We have the largest patent portfolio protecting our compounds targeting the endocannabinoid system for inflammation and fibrosis, and we control the global commercial life for our compounds.



To summarize, with unique drug candidates from early all the way to late stage and strong intellectual property with patent protection and global commercial rights, we believe we are well positioned to capitalize on the large market opportunity for endocannabinoid system targeting drugs designed to treat a range of inflammatory and fibrotic diseases.

Over the past several quarters, we have achieved a number of significant corporate milestones. We now have a robust pipeline with multiple shots on goal and expanded targeted indications. Corbus has the exclusive worldwide rights to develop, manufacture, and market drug candidates coming from a library of more than 600 preclinical compounds that bind to the endocannabinoid system. CRB-4001 and the rest of this library are a strong foundation for our growth.

We also executed our first licensing deal to ensure lenabasum can reach patients worldwide. We licensed the commercial rights to lenabasum in systemic sclerosis and dermatomyositis in Japan to Kaken Pharmaceuticals. Kaken is an excellent partner for Corbus as we look to enter the Japanese market, which represents a significant opportunity for lenabasum with approximately 28,000 systemic sclerosis patients and 9,000 dermatomyositis patients.

Importantly, the agreement calls for a \$27 million upfront payment, and we are also eligible to receive up to an additional \$173 million in milestones and double-digit royalties after that. We view our Kaken deal as a model to pursue similar licensing deals for commercial rights to geographies that we cannot reach ourselves while providing near-term and future non-dilutive capital to the Company. Of particular focus next are South Korea and China. On January 30th, we closed on a \$40 million public offering of common stock. Our current cash reserve is adequate to support the Company through data in our two key clinical studies: the pivotal study in systemic sclerosis and the Phase 1b study in cystic fibrosis.

Another important milestone is the continued expansion of our leadership team. Recently, Craig Millian joined Corbus leadership as Corbus' first ever Chief Commercial Officer. Craig will develop and drive U.S. global marketing and commercialization strategies with an initial focus on our lead drug candidate, lenabasum. Craig brings 25 years of experience building therapeutic brands and leading commercial organizations in pharmaceutical companies. We are pleased to have Craig with us on the call today, and I'd like to hand it over to him for a brief introduction.

*Craig Millian:* Thanks, Yuval. Let me start by saying I am thrilled to join Corbus at such an exciting time for the Company. As a bit of background, I joined Corbus from EMD Serono, where I most recently served as Senior Vice President and Head of U.S. Neurology and Immunology. Prior to that, I held a number of commercial leadership roles at Vertex, Pfizer, and Sanofi. What attracted me to Corbus was, first of all, Yuval and the other talented members of the team, all



of whom share an inspiring vision and a commitment to excellence. I've only been on board for a short time, but I've already witnessed the truly collaborative team-oriented environment that's been cultivated here, and it's a true source of strength for the Company. I'm also very excited about the science underpinning Corbus' work. Synthetic cannabinoid development presents a significant opportunity.

As Yuval noted, this has the potential to be a truly ground-breaking therapeutic area in the coming years, and Corbus is at the forefront of developing novel synthetic cannabinoid medicines. I'm energized and excited to be joining such a talented team, and I look forward to help building the commercial strategy and infrastructure as lenabasum moves towards the completion of key registrational studies in 2020. While I'm currently head down as I get fully up to speed in my new role, I do look forward to meeting many of you in the coming months. And with that, I'd like to turn the call back over to Yuval.

**Yuval Cohen:** Thank you, Craig. Craig's appointment is an important milestone for Corbus, and we're confident that Craig's experience and leadership will drive a successful launch for lenabasum, which we expect to be in 2021. We'd like to now provide an update on our clinical pipeline, starting with lenabasum. With that, let me turn the call over to Barbara to provide an update on our clinical pipeline. Barbara?

**Barbara White:** Thank you, Yuval. Lenabasum, a CB2 agonist is our lead clinical asset. Lenabasum is currently being evaluated in Phase 3 studies for systemic sclerosis and dermatomyositis and in Phase 2 studies for cystic fibrosis and lupus. Patient enrollment and dosing in our Phase 3 RESOLVE-1 study for systemic sclerosis remains on track, and we anticipate the last patient by May. We are on track for study completion in the first half of 2020, and we anticipate NDA submission at the end of 2020.

We are optimistic that lenabasum has the potential to provide clinical benefit to patients with systemic sclerosis. Our optimism is based on the mechanism of action of the drug, benefitting animal models of the disease, consistent improvement in multiple efficacy outcomes in the double-blind placebo-controlled Phase 2 study of lenabasum and systemic sclerosis, as well as its open-label extension and evidence of improvement of inflammation and fibrosis biomarkers in skin of study subjects. We also remind you that lenabasum has Orphan Drug and Fast Track designations for treatment of systemic sclerosis with the FDA and Orphan Drug designation for treatment of systemic sclerosis with EMA.

Our Phase 3 DETERMINE study is a registrational study testing safety and efficacy of lenabasum as a treatment for dermatomyositis, our second potential rare autoimmune disease indication. Corbus has received input on study design from regulatory authorities in the U.S., Europe, and



Japan. This study is enrolling subjects. It will be the largest interventional study to date in dermatomyositis. We will keep you informed as key milestones occur.

Our Phase 2 study of lenabasum evaluating effects on the rate of pulmonary exacerbation in patients with cystic fibrosis is also ongoing and on track for data in 2020. The study is enrolling patients 12 years of age and above at high risk for pulmonary exacerbation without regard to CFTR mutation, pulmonary pathogens, or background medications. This study is funded in part by a Development Award for up to \$25 million from the Cystic Fibrosis Foundation that follows the \$5 million award we received in 2015. Lenabasum has Orphan Drug and Fast Track designations for treatment of cystic fibrosis with the FDA and Orphan Drug designation for treatment of cystic fibrosis with EMA.

The NIH-conducted lupus clinical study is progressing, and we look forward to its completion. With that, I'll turn it back to Yuval.

**Yuval Cohen:** Thank you, Barbara. Lenabasum presents a significant market opportunity for these three initial indications, with potentially up to \$5 billion and 350,000 patients in the seven major markets: This includes approximately \$1.4 to \$2.2 billion in peak annual potential sales for systemic sclerosis, with 200,000 patients in the U.S., Europe, and Japan. Approximately \$1 billion to \$2 billion dollars in peak annual potential for dermatomyositis, with approximately 80,000 patients in the U.S., Europe, and Japan. Approximately \$700 million to \$1 billion peak annual potential sales for cystic fibrosis, with approximately 75,000 patients in the U.S. and Europe.

Turning to CRB-4001, we continue to plan to initiate a Phase 1 study of CRB-4001 in 2019, expected to be followed by an NIH ("National Institute of Health") sponsored Phase 2 study in NASH. CRB-4001 is a second-generation inverse agonist targeting peripheral organ fibrosis with strong preclinical data.

In addition to lenabasum and CRB-4001, we expect to start one or two new clinical programs each year based in large part on the development and progression of drug candidates from our internal library beginning in 2020. We are very excited about the potential for our robust pipeline, and we look forward to providing an update with the first candidate, or candidates, we select later this year.

Now, let me briefly comment on our financial position. As we enter 2019, we have a strong balance sheet to help drive our operations through pivotal Phase 3 data for lenabasum. We ended 2018 with approximately \$42 million in cash, but this figure does not include the \$27 million Kaken upfront licensing payment, nor does that include the proceeds from our \$40 million recent public offering.



As a reminder, our partnership with Kaken alone will provide up to an additional \$173 million upon achievements of certain regulatory, development, and sales milestones, as well as double-digit royalties.

Before I turn the call over to question and answers, let me reiterate that 2018 was a truly transformational year for Corbus, and we are proud of what we have accomplished. We closed two significant transactions that expanded our pipeline and advanced our vision to become the leader in the treatment of inflammatory and fibrotic diseases by targeting the endocannabinoid system.

We've taken the steps to prepare for the commercialization and eventual marketing strategy for lenabasum following the completion of key registrational studies next year, including the hiring of our first ever Chief Commercial Officer, and continue to anticipate significant annual market opportunity for lenabasum of approximately up to \$5 billion.

Our registrational study of our lead compound lenabasum in systemic sclerosis is progressing well, with completion on track for the first half of 2020. Our Phase 2b study for lenabasum in cystic fibrosis is also expected to read out in 2020. With such significant milestones supporting us, we are confident that 2019 will be a very important year as we continue the clinical development of lenabasum, initiate the clinical development of CRB-4001, and select the first drug candidates to send to clinical trials from our large compound library.

In conclusion, we are proud of our achievements to date especially in light of the significant strides we've made as a company over a relatively short timeframe. From what was initially an entrepreneurial start-up over four years ago, Corbus has grown significantly. We have raised over \$168 million in equity capital, while successfully growing a high-quality institutional investor base and expanding our research coverage by top tier investment banks. We believe that cannabinoid innovation is one of the most meaningful scientific advances underway, and we are excited about the opportunities available to Corbus as a leader in this space. We are excited about the future of Corbus and the many opportunities we have to create meaningful solutions for patients, as well as drive value for our shareholders. We will now be happy to take your questions. Operators, please go ahead.

**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 keys. Once again, that is star one to register questions at this time. Our first question is coming from Liisa Bayko of JMP Securities. Please proceed with your question.

Liisa Bayko: Hi, good morning. How are you?

Yuval Cohen: Good morning, Liisa.

**Liisa Bayko:** I wanted to welcome Craig to the team and ask you kind of what are your plans you see now in commercialization, what are some of the key activities you'll be doing, and then maybe you can comment a little--you threw out some numbers for market size, which implies some idea about kind of price ranges--maybe you can ballpark that for us, as well. Thank you.

**Craig Millian:** Yeah, sure. Hi, Liisa, thank you for the welcome. I think I'll start by getting out and starting to meet with some of our KOLs and patient advocates and really getting grounded in the science and the current treatment patterns and the disease. We'll continue to define the commercial opportunity and certainly build on our market research. I think we want to continue to--Yuval gave a range of forecasts, I think we'll continue to refine that. I think it's a really good start.

Obviously, we'll be building out some initial launch plans and starting to think about a range of options in terms of our go-to-market strategy for our different markets and our different indications. We'll be thinking about our value proposition and thinking about the possibilities of our data and our label and the implications for that. So, we'll want to start thinking about that from a payer perspective. And, obviously, we'll start to identify some key capabilities and gaps in our staffing that we'll want to start to fill with some key hires. So, those are all some of the things I'll be focused on.

The numbers that Yuval quoted were from a fairly robust assessment--commercial assessment that was done by Health Advances completely kind of objective piece of analysis that they did, and was based on both published data, as well as some primary research they conducted with KOLs and payers in the U.S. and in Europe. I don't want to get into the specifics of the pricing at this point. I would say I think it was a fairly reasonable assumption that was built in, in terms of both the pricing assumption, as well as the penetration within the different indications to come up that range. But, again, I think it's a little premature at this point. So, we'll continue to dig into that and refine our assumptions, as I mentioned, and continue to acquire data and market research to validate those, and we'll share those in due time.

*Liisa Bayko:* Okay, great. Thanks. And then just one question maybe for Barbara, for your kind of foray into NASH, can you maybe talk about your mechanism? Is it primarily surrounding the kind of inflammatory component or do you see sort of other contributions, obviously, in the NASH as a complex disease with multiple different ways to target either through fat, fibrosis, through inflammation, where does your compound play?



Barbara White: Liisa, thank you so much for that question. CRB-4001 is a CB1 inverse agonist. That means that it inhibits CB1, and by doing that, we will have effects on multiple pathways that seem to be involved in the pathogenesis of NASH. First, we would anticipate having beneficial effects on metabolic pathways, and it's been shown that inhibiting CB1 can help with insulin resistance, with glucose metabolism, energy metabolism. It helps with lipogenesis, so, it helps restore a number of the underlying metabolic abnormalities that many patients with NASH have. Secondly, it's also been shown to have effects on both inflammation and fibrosis, which are the aspects of the disease pathogenesis that drive the initial aspects of liver damage, and then the final cirrhosis that can lead to the need for a liver transplant or even Hepatocellular carcinoma.

So, targeting CB1 to inhibit it has the potential to affect those three very important pathways, metabolic abnormalities, inflammation and fibrosis, and we think that's a therapeutic edge. Indeed, Johnson & Johnson also has put effort into targeting CB1--inhibiting CB1 in the treatment of NASH. They're doing it with a monoclonal antibody, which we think also is extra validation of the potential clinical benefit of this approach.

Liisa Bayko: Thanks a lot, guys.

**Operator:** Thank you. Our next question is coming from Brian Abrahams of RBC Capital Markets. Please proceed with your question.

**Brian Abrahams:** Hey guys, thanks so much for taking my questions and congrats on all the progress.

Yuval Cohen: Thanks Brian.

Brian Abrahams: My first question is around the ongoing clinical studies. With the RESOLVE systemic sclerosis study nearing completion of enrollment, I was wondering if you could maybe speak a little bit, I guess, qualitatively about the types of patients who've entered that study and the work that you've done to ensure that it's a refined population, and you've kind of eliminated the chance that patients with burned out disease are entering the study. And I guess as a corollary to that, I know it's kind of early days in the dermatomyositis Phase 3, but wondering if you could maybe talk a little bit about how the initial set up there is going? The types of patients and the mix that you're getting--enrolling in that study relative to expectations and whether you have any sense as to what this initial enrollment trajectory might mean for potential timelines there? And then I have a couple of follow-ups. Thanks.



**Barbara White:** Certainly, Brian, thanks. The first part of that just nudge me about it. So, first of all regarding the SSC Phase 3 study, that study and all the studies were all blinded to treatment assignment. So, all I can say is what does the group in general look like, and it looks like what we expected, and will look like many other studies that have been done in patients with diffused cutaneous systemic sclerosis. So, both in terms of age, gender, we've covered many geographies: U.S., many European countries, Japan, South Korea, Australia. We expect to have very representative group of patients so that clinical benefit can be determined again in a representative group of patients.

I would point out that there--that we have made reasonable attempts to identify patients who could benefit from treatments. And that's the way I'd like to couch our patient selection, folks who could benefit from treatment. And we've selected patients with--who have disease duration of no more than three years without any other requirement, because, in general, they're thought to be able to have a need for treatment, to be able to benefit whether it is in skin, lung, joints, whatever. There are multiple ways that those patients can benefit, and we will capture.

Similarly, we allow patients who have disease duration for three to six years, if they have a certain level of skin involvement. So, that, again, there's at least that component of the disease that is measurable--improvement would be measurable. So we're very, very comfortable with the type of patients that we've enrolled. There's been nothing unexpected, and we look forward to seeing the results and completing that enrollment very soon.

In terms of dermatomyositis study, again, it's an important question. How do you know you've got patients that represent those who have the disease and who can benefit? First of all, those inclusion criteria that we've selected allow us to include patients who represent the breadth of the disease, those with classic dermatomyositis, that is, muscle involvement and some skin variable degrees of skin but very definite muscle involvements through folks who have very definite skin involvement and minimal, if any, clinically apparent muscle involvement. So, that whole range has included the outcome that we have, the total improvement score is adequate to measure clinical benefit in that range of patients.

We have selected patients who have to have certain degrees of disease activity, and that is based upon the types of involvement they have. First of all the physician has to say they have active disease, so they have to sort of put in on a piece of paper, this patient is active, which is almost as good as anything, as well as they have to have a certain degree of muscle involvement, or a certain degree of skin involvement, have to have a certain degree of global abnormalities. So, again, I'm quite confident we've got the right patients, the right outcome, and the right inclusion criteria.



**Brian Abrahams:** That's very helpful, Barbara, thanks. And then we noticed that the structure of CB2 was recently published--just wondering how that might further facilitate the interrogation and development of additional CB2 and CB1 targeted treatments within the compound library that you now have as you look to bring some of these compounds forward next year. We'd love to hear about the types of compound profiles that you might be looking to pursue there.

Barbara White: Well, thank you. I'm just so happy to have that question. First of all, about the crystal structures--and I would say actually, an in silico model of how our CRB-4001, our CB1 inverse agonist, actually binds to CB1 has been published already, and we will do similar in silico models for our pipeline candidates as they move along, because it will help inform us about a number of potential properties. So, it's just a part of the data that we are building as experts in this field, the types of interactions we want with particular regions--the particular parts of binding regions. And we will do that for all of the compounds that we move forward into the clinic as part of our interrogation of their potential benefit. It allows us to actually tweak molecules, as well, as we develop our own set of internal compounds by determining just what we want to engage or not engage. So, very useful information for us, and we are using it currently, and we'll continue to use it in silico modeling.

**Brian Abrahams:** That's really helpful. Last question from me, maybe on the commercial front, perhaps a question for Craig. You spoke about some of the initial market-oriented activities that you'd be pursuing this year. How should we think about, as this commercial build-out and strategy sort of takes shape and new hires come on board, the potential impact to the cadence of SG&A expenses maybe over the course of this year as the year progresses and then in subsequent years? Thanks.

**Sean Moran:** Hey, Brian, Sean Moran here. So, we put out guidance for the cash resources we have, it's over \$100 million. So, we are funded through data into the fourth quarter of 2020. So, it covers all of those activities that Craig will be undertaking.

Brian Abrahams: Thanks so much.

**Craig Millian:** Yeah, I think for this year there'll be primarily strategic activities and fairly minimal amounts of hiring. Obviously, the cadence of hiring as we get the data out next year and as we approach filing our NDA, then those things will pick up, but not so much this year.

Brian Abrahams: Thanks so much.

**Operator:** Once again, that is star one to register any questions at this time. Our next question is coming from George Zavoico of B. Riley FBR. Please go ahead with your questions.



**George Zavoico:** Thanks. Good morning, everyone, and welcome, Craig, to Corbus Pharmaceuticals. Quick question about Kaken and its responsibilities in Japan and your responsibilities there and when we might expect the first milestones, including whether you anticipate any clinical trials that might have to be done specifically in Japan and how much--l guess the question, basically, is how much responsibilities Kaken actually have in Japan in overseeing both the development, the regulatory pricing, et cetera there?

Yuval Cohen: Hey, George. It's Yuval.

George Zavoico: Hi, Yuval.

**Yuval Cohen:** It's wonderful to see you last week, by the way. Kaken is our partner in Japan. On a very simplistic basis, our responsibility is to wrap up the systemic sclerosis study in Japan as well as, obviously, undertake the upcoming dermatomyositis study--Japanese study. The study has already started elsewhere but not in Japan.

So, in Kaken's responsibilities, regulatory responsibilities, they will be our liaison and, in fact, represents us from now on with PMDA end of course commercial responsibility. That means negotiating pricing with the Japanese authorities, as well as going out there and actually marketing and selling the drug. In terms of the milestones, they are, of course, confidential, but, George, you should think about them as fairly standard. They involve regulatory milestones, you can probably guess what those are, commercialization milestones and sales milestones very, very standard for this type of deal.

**George Zavoico:** And there's a set of milestones applied both to the systemic sclerosis and dermatomyositis, individually and parallel?

**Yuval Cohen:** The deal in Japan is for just Japan, which is interesting and just for systemic sclerosis and dermatomyositis. Yes. The answer is yes.

**George Zavoico:** Okay. Thanks for that. And with regards to NASH, you mentioned that it's NIH sponsored, the first trial. How do you expect to transition from NIH sponsorship, or when, I suppose, in the course of the clinical event with transition from NIH sponsorship to Corbus sponsorship?

**Barbara White:** So, I think that it is, again--I view it as a very tight partnership with the NIH. We will do typical Phase 1 testing. When we have the typical Phase 1 data available, we are working in collaboration with the NIH to develop the design of the next study or studies, which will look at blood-brain barrier penetration, and we'll also look at a number of biomarkers and perhaps even some liver imaging in patients with metabolic syndrome and with NASH. So, those designs



are not complete, but it will be done in very close discussions with the NIH. Thereafter, it's entirely up to Corbus what we decide to do. So, think of the NIH as extremely helpful in the interlude in determining impact on biomarkers in blood-brain barrier penetration.

**George Zavoico:** But it'll be NIH money they will run the first trial or Corbus?

**Barbara White:** We will run and pay for the Phase 1 study, SAD, MAD. They will run and look after and pay for internal project, the NIH. It's been a long-term interest of Dr. George Kunos. They will do the study of the biomarkers in the patients--Phase 2 patients with NASH metabolic syndrome.

**George Zavoico:** So, it's a shared funding, in other words? You both have defined responsibilities that you will be paying for then, right?

**Yuval Cohen:** So, for the Phase 1, George, it's on our dollar, and, of course, the nice thing about Phase 1 is that they're very affordable. And then, for the first in-patient Phase 1b/Phase 2a, the only obligation we have is to supply the drug for the NIH.

George Zavoico: Okay, that's good. That's a good arrangement.

Yuval Cohen: I'm very happy with it.

**George Zavoico:** Yuval, when you mentioned your market sizes, you talked about systemic sclerosis, for example, in very general terms, and yet the trial is really diffused cutaneous. So, can you break down a little bit what proportion of the total, what you call, systemic scleroderma eligible patient population in general and which ones are actually eligible for the trial and eligible, perhaps once it's approved for that indication?

**Barbara White:** I'm going to handle that. This is Barbara.

George Zavoico: Thanks, Barbara.

**Barbara White:** The proportion of diffused cutaneous systemic sclerosis varies from study to study, but I think 45% is reasonable--is a reasonable ballpark range. In terms of what the label will say, don't forget that's important. We don't have a label yet. You're absolutely correct that the study population is patients with diffused cutaneous systemic sclerosis. I do not know if the label will say systemic sclerosis or diffused cutaneous systemic sclerosis. So, I'm going to leave it at that.



**George Zavoico:** So, in other words, each one of these trials has a defined, pre-specified subgroups to take a look at that will define what the label eventually will say based on, obviously, the results for each of the subgroups. Is that fair to say for both scleroderma and DM?

Barbara White: I'm sorry. Would you mind just repeating that, George?

**George Zavoico:** Well, the question is whether you have pre-specified subgroups within the broader systemic sclerosis and dermatomyositis populations. And depending on those subgroups, some might perform better than others, and that might inform what the label will say eventually?

Barbara White: No, I'm going to say that they're always subgroup analysis--.

George Zavoico: --It's right, okay, good--.

**Barbara White:** --And that there you should expect the same with ours. I'm not going to speculate what the label will say at this time.

George Zavoico: Yeah, of course that's going to depend very much on the results, of course.

**Barbara White:** And I did want to point out what is the difference--for folks that might not know, what's the difference between diffused cutaneous systemic sclerosis and limited cutaneous systemic sclerosis. It's really defined, clinically, by what parts of the body the skin-the physician thinks the skin is sickened. In diffused cutaneous systemic sclerosis, it's upper arms, upper legs, or trunk. They have to be involved, and in limited less so. So, for example, if the physician thinks that the skin thickening stops just below the elbow, that would be limited. If the physician thinks the skin thickening extends just above the elbow, that would be diffused and the trunk.

**Craig Millian:** One thing I'll just add in terms of the market assessments that Yuval referenced, we did take into consideration, penetration rates and--based on disease severity diffused is first limited. So, we did actually, even in this piece of research, look at different segments and assigned penetrations accordingly. Again, we don't know, ultimately, what the label will be and what the data will readout but fairly reasonable assumptions, I think, for this point in time.

**George Zavoico:** Okay. Thanks and a final question regarding your 600+ compound library, and maybe this is part of the commercial strategy for--a question for Craig. I mean, there's a lot of opportunities there, more than likely too much so perhaps for a company of your size. Is there a licensing strategy that's going to be part of the commercial strategy?



**Yuval Cohen:** George, let me embrace that one with both arms. The answer is, resoundingly, yes. If you think about it, our vision really is to become the go to company for these synthetic, rationally designed compounds that bind to endocannabinoid receptors. Some diseases make perfect sense for us to go out and commercialize and market ourselves--particularly rare diseases, but there are many other inflammatory diseases--fibrotic diseases, where it makes perfect, perfect sense to actually partner with a Big Pharma. What I'd like to emphasize to you and all of our audiences is our conviction that this coming decade will be a decade where most, perhaps even all, Big Pharma will embrace cannabinoid biology.

We're already seeing that, and at that case, each Big Pharma has a choice. They can either develop their own cannabinoids, which will be expensive, lengthy, cumbersome, or they could partner with the leading Company that has, I believe, achieved a really unique position--almost a dominating position around our understanding of the biology, the depth of our pipeline, our medicinal chemistry capabilities, and also our patent strategy. I think the latter makes much more sense.

George Zavoico: And then, to that point, I presume that you're still growing the library?

Yuval Cohen: That is a very safe assumption.

George Zavoico: Okay, great. Thank you very much.

**Operator:** Thank you. This brings us to the end of today's question-and-answer session. Corbus Pharmaceuticals would like to thank you for your interest in today's conference. You may disconnect your lines at this time and have a wonderful day.