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On December 10, 2015, Relmada Therapeutics, Inc. held a conference call, a transcript of which is below.

Relmada Therapeutics, Inc. Conference Call
December 10, 2015

Operator: Greetings, and welcome to the Relmada Therapeutics 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.

I will now turn the conference over to Mr. Michael Becker, Senior Vice President of Finance and Corporate Development. Thank you, Mr. Becker. You may now begin.

Mr. Michael Becker: Thank you very much, and good morning, everyone. Welcome to Relmada Therapeutics' conference call to discuss the BuTab results. With me today is Dr. Sergio Traversa, Chief Executive Officer; Dr. Richard Mangano, Chief Scientific Officer; Dr. Lisa Nolan, Chief Business Officer; and Dr. Danny Kao, Senior Vice President of Pharmaceutical Development and Chief Intellectual Property Counsel.

Also joining us on the call is one of Relmada's scientific advisors Dr. Gavril Pasternak, Anne Burnett Tandy Chair in Neurology at Memorial Sloan Cancer Center and laboratory head in the Molecular Pharmacology and Chemistry Program within the Sloan-Kettering Institute.

During this call, we will review the BuTab program and then open up the call to a Q&A session. Before we continue, I'd like to remind you that this conference call may contain forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. Reference to these risks and uncertainties is made in today's press release. And they are also disclosed in more detail in our most recent filings with the U.S. Securities and Exchange Commission.

These statements speak only as of the date of this call, and Relmada undertakes no obligation to update or revise these statements. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. When evaluating Relmada's business and securities, investors should be careful--should give careful consideration to these risks and uncertainties.

As a reminder, this call is being recorded for audio replay. And in addition, I would like to point out that today's teleconference will focus solely on the BuTab study. And we ask that you limit your questions to today's topic.

And with that, I will now hand the call over to Dr. Sergio Traversa, CEO of Relmada. Sergio?

Dr. Sergio Traversa : Thank you, Michael. Good morning, everyone, and thank you for joining us on today's call. I am very pleased to report that Relmada has achieved positive results in a proof-of-concept pharmacokinetic study in healthy volunteer with BuTab, an investigational oral formulation of buprenorphine, an opioid that is broadly used to treat both chronic pain and addiction.

BuTab is designed to be delivered orally and reach safe and effective blood levels of buprenorphine through the gastrointestinal route of administration due to its modified release profile.

There are currently no commercially available oral formulation of buprenorphine. They are designed to be easily swallowed, like a traditional tablet or capsule.

We continue to believe that BuTab represents a first-in-class product, targeting the multibillion-dollar market for buprenorphine products.

The speed with which we completed this initial study, while also continuing to advance the other products in our pipeline, underscores our expertise and commitment to the existing pain therapy--exciting pain therapy field.

With our solid development pipeline, Relmada is in an even stronger position than when we entered 2015. Let me summarize what we accomplished to date.

We have performed and completed a Phase 1 proof-of-concept pharmacokinetic study for our novel version of a proven drug product, BuTab, for the treatment of both chronic pain and opioid addiction indication that will be discussed today.

We have progressed on our new chemical entity d-methadone, performing two successful clinical trials, a single ascending dose, or SAD, and a multiple ascending dose, or MAD. And we expect to start the Phase 2 proof-of-concept study in neuropathic pain in the first half of 2016.

We have received a patent from the U.S. Patent Office for our proprietary abuse-deterrent platform SECUREL, which we use in our LevoCap ER product candidate that is a novel version of a proven drug product for the management of pain severe enough for around-the-clock and long-term opioid treatment.

We continue to prepare for our Phase 3 development program for LevoCap ER. And we are planning to submit an end-of-Phase-2 meeting request with the FDA to discuss the final regulatory and clinical plans.

We also completed the formulation optimization work and the preclinical toxicology studies for MepiGel, a topical dosage form of the local anesthetic mepivacaine for the treatment of painful neuropathies, which have also been granted two FDA orphan drug designation. A clinical trial application, or CTA, is in preparation.

Processing a diverse portfolio of novel therapies for the treatment of chronic pain is an important element of Relmada's business strategy, as it minimizes the company dependence on any single program. This is especially prudent given the risk and uncertainties inherent in discovering and developing new therapies.

Throughout my more than 25 years' career in the healthcare sector, I've never been more excited about the opportunities we expect are achievable for Relmada and for BuTab. Relmada's business, it is an inflection point with significant value creation opportunities possible in the next 12 to 24 months.

At this point, let me turn the call over to Dr. Richard Mangano, Chief Scientific Officer at Relmada, for a review of our BuTab program and discussion of the top-line result. Dr. Mangano has extensive experience leading global R&D programs in both large and small pharmaceutical companies. He led the global registration programs for Sonata, Effexor, and Prishteet [sp] while at Wyeth and was involved in the NDA submission of enterecatatalor [sp]. Dr. Mangano?

Dr. Richard Mangano: Thank you, Sergio. Buprenorphine is a partial opioid agonist approved for two indications, chronic pain and addition. Buprenorphine suffers from poor bioavailability due to first-pass metabolism in the upper gastrointestinal tract and liver when swallowed. As a result, there are no currently available oral formulations of buprenorphine that result in meaningful gastrointestinal absorption.

The currently available dosage forms for buprenorphine are nonstandard and may be difficult to use for some patients. These include skin patches, sublingual tablets, and buccal adhesive films and patches. We believe that patients could benefit from a more convenient swallowable tablet, such as BuTab.

Relmada's BuTab is designed to be delivered orally and to reach safe and effective blood levels of buprenorphine through the gastrointestinal route of administration due to its modified release formulation. It's designed to bypass metabolism of buprenorphine by the P450 enzymes in the small bowel. Bypassing the metabolism by these enzymes has been shown to increase the bioavailability of several other drugs.

The BuTab clinical study conducted by INC Research, a leading global contract research organization, was designed to assess the safety, tolerability, and pharmacokinetics of BuTab in 32 healthy volunteers. The key objective of the study was to assess if buprenorphine can be delivered orally and reach safe and effective blood levels through the gastrointestinal route of administration.

In terms of study design, we used a five-period crossover design, evaluating three formulations of BuTab against sublingual buprenorphine and intravenous buprenorphine.

Important to note, the three BuTab formulations were not optimized and contained basic active pharmaceutical ingredient, or API. Due to the long half-life of buprenorphine, there was a two-week washout period between each of the five treatment periods.

We're pleased to report that, even using the nonoptimized prototype formulation, the absolute bioavailability of BuTab relative to intravenous administration exceeded published data with nonmodified buprenorphine.

In addition, buprenorphine blood levels with BuTab compared favorably with currently marketed transdermal patch and reached blood levels that are associated with clinical efficacy in chronic pain.

We are very encouraged by this result, and we will further develop an optimized BuTab formulations with an eye towards pivotal studies and NDA submission.

It's now my pleasure to turn the call over to Dr. Gavril Pasternak, Anne Burnett Tandy Chair in Neurology at Memorial Sloan-Kettering Cancer Center and laboratory head in the Molecular Pharmacology and Chemistry Program within the Sloan-Kettering Institute.

Dr. Pasternak's research focuses on opioid receptors and their mechanisms of action. He's demonstrated the importance of different sets of mu receptor subtypes and the actions of various opioid analgesics and identified a set of subtypes that offer a unique target for the development of analgesics lacking opioid side effects. Dr. Pasternak?

Dr. Gavril Pasternak: Uh, thank you, Dr. Mangano. Uh, basically, I would like to, uh, discuss the drug itself. Uh, I won't be specifically talking about the formulation, uh, the BuTab, but rather the buprenorphine as a, uh, molecular entity.

Buprenorphine has a very complex pharmacology within the opiate field. Unlike traditional drugs such as morphine, it interacts with a host of different opioid receptor subtypes, mu, delta, kappa, as well as even the, uh, ORL1 receptors. And this gives it a wide range of actions.

Uh, interestingly enough, although it does have analgesic actions that are mediated through the mu receptor, its activity at the delta and kappa receptors really are in the antagonist realm.

Now, this may have advantages. We can't be certain yet, but in the--in other types of studies, antagonists working through delta receptors can actually minimize the production of tolerance to opiates. And there's some suggestion that kappa antagonists may have, uh, advantages as well so that buprenorphine, by interacting with multiple targets, may actually come up with a superior profile compared to many of the traditional opiates.

The analgesic actions of buprenorphine are mediated solely through mu receptors. But, as was noted earlier, the mu receptors are a complex receptor class. Although there's a single gene, that gene generates well over two dozen different mu opiate receptors in people. Uh, similar patterns are seen in animal models.

There are two major classes that we feel are important in terms of understanding buprenorphine analgesia. The traditional receptors, which we refer to as full-length ones, mediate the actions of morphine, methadone, and the traditional opiates.

Buprenorphine has some activity through these receptors, but it also seems to act through a different class of receptor generated by the mu opiate receptor gene.

These receptors contain only six transmembrane domains. And I realize that many people may not be familiar with the, uh, molecular structure of the receptors, but just keep in mind that this is a different class of receptors, uh, structurally distinct from the ones that mediate morphine analgesics.

These receptors are very, uh, important in the actions of buprenorphine. If you remove these receptors from the animal, buprenorphine ceases to work. This is in distinction to morphine and methadone, which continue to work just normally, uh, in those same animals.

So, thus, the pharmacology of buprenorphine can be very clearly differentiated from that of the traditional classical mu opiate receptors, like morphine and methadone, codeine, etc.

So, in view of that, uh, the choice of buprenorphine to use for formulations I think is an excellent one. I think buprenorphine, uh, is currently used, uh, in Europe quite extensively for pain. And I think it has a great potential to, uh, add to the--uh, you know, the choices of clinicians here in the United States for pain management.

Uh, I'll now turn the call back over to the company.

Dr. Sergio Traversa : Thank you, Dr. Pasternak. At this time, I would like to invite Dr. Danny Kao, Relmada's Senior Vice President of Pharmaceutical Development and Chief Intellectual Property Counsel, to speak.

Dr. Kao has extensive formulation development experience. He has developed a number of marketed extended release opioid dosage products, including Opana ER and first-to-file OxyContin generic. He also has more than 20 issued or pending patents. Dr. Kao?

Dr. Danny Kao: Thank you, Sergio. This is Danny Kao. I have developed opioid formulations for 20 years at Endo Pharmaceuticals and DuPont Pharma. I was responsible for the Opana formulation development and oxycodone morphine extended release opioid formulation development.

As we know, oxymorphone is a molecule subject to a very high first-pass metabolism. It was developed and is now a very successful product. The annual sales is approaching 400 million for Opana.

Buprenorphine is also subject to a very high first-pass metabolism. Because of that, it has never been successful developed into an orally swallowable dosage form.

Now, for the first time, Relmada has demonstrated that it is possible to develop buprenorphine as a swallowable dosage form. The patient may no longer need to put their film in their cheek, under the tongue, or on their skin. They can just take the tablet and swallow it.

The current study shows that swallowable buprenorphine developed using our patented technology can achieve therapeutically effective plasma levels. Based on these encouraging study results, we will continue with formulation development so that we can provide the patients with the most convenient method of administration.

Thank you very much. Now, I turn the call over to Dr. Lisa Nolan, Relmada's Chief Business Officer, for discussion of the commercial landscape for buprenorphine.

Dr. Nolan has worked in the pharmaceutical industry in the United States and internationally for more than 25 years in specialty and large pharma companies, including AstraZeneca and Elan Pharmaceuticals, where she was Head of Strategic Marketing, and at Skyepharma, where she held a position of Vice President Global Business Development and closed a large number of partnering transactions.

Dr. Lisa Nolan: Thank you, Dr. Kao. When we think about the commercial opportunity, we have to think about two distinct markets, chronic pain and addiction. The key driver for the commercial opportunity in pain is the recent rescheduling of hydrocodone from Schedule 3 to Schedule 2. This makes it more difficult for physicians to prescribe hydrocodone.

Now, prior to the rescheduling, physicians wrote more than 100 million prescriptions per annum for hydrocodone products. That's a huge number of prescriptions, more than even Lipitor.

Buprenorphine is now the only Schedule 3 opioid in the U.S. So, there's a great opportunity for buprenorphine to replace hydrocodone as the first-line strong opioid. And BuTab will be the first and maybe the only standard tablet that's swallowed like nearly all other medications and, therefore, intuitive and easy for all patients to use.

We expect that the oral form will compete very well with the patch because it has always come with problems associated with the patch, such as adhesion site reactions that can occur in a high proportion of patients, limitations on dosing, patches falling off, and the need to carefully dispose of the patches to avoid accidental exposure of children or adults to the drug left in the patch.

So, an oral buprenorphine like BuTab is ideally placed to capitalize on that gap left by hydrocodone rescheduling and grow the buprenorphine market in pain.

The addiction market is a smaller market. But, it's currently valued at approximately $1.8 billion globally, most of it in the U.S., and all of it in unconventional dosage forms, such as sublingual films or adhesive patches that are fixed to the inside of the mouth and dissolve over 10 to 30 minutes. All of these forms require careful patient instruction and education on how to use the products.

The great thing about a standard oral tablet is that the patient knows instinctively how to take it. And the physician can be confident that the patient knows how to take his medication. Also, in Europe, the regulations require that the dosing of buprenorphine to addicts is supervised by a healthcare professional. So, an oral form that's instantly swallowed, as opposed to waiting for 10 to 30 minutes, can save a lot of time for the pharmacist and the doctor and also for the patient.

In fact, we have a lot of interest from companies that are already active in the addiction space in Europe and the U.S. And we will consider commercialization partnership for addiction and also for pain when the timing and economics make sense.

I will now turn the call back to Dr. Traversa.

Dr. Sergio Traversa : Thank you, Dr. Nolan. Uh, we hope that you have found this update to be helpful. And we will now conclude our prepared remarks. Operator, please open the lines for questions.

Operator: Thank you. We'll now be conducting a question-and-answer session. If you'd 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'd 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.

Our first question is from Ken Trbovich of Janney. Please go ahead.

Mr. Ken Trbovich: Thank you. Uh, I guess, uh, a couple of quick questions. The first one I think you've already touched on a little bit, but I just wanted to confirm what I was hearing, uh, with regard to the blood levels that were being achieved. Uh, was it specific that you were able to achieve a level that's consistent with the 100- to 200-picogram level associated with Butrans?

Dr. Richard Mangano: We're pleased with the results we have. They are showing that we are within that range, uh, and we have room for improvement with some optimization.

Mr. Ken Trbovich : Okay. And then, uh, another question was just whether or not there was anything specifically in terms of special measures that were required in order to achieve these blood levels. Was there any sort of prolonged fasting or, uh, an extremely low or very high fat diet that would be required in conjunction to--uh, to effectively reach these levels?

Dr. Richard Mangano : No. There were no special requirements within the protocol. Subjects were fasted just to standardize the pharmacokinetic measurements that we need to have to progress this program.

Mr. Ken Trbovich : Okay. And then just to better understand sort of the threshold here that you've crossed with being able to develop an oral formulation, uh, you know, I guess, you know, trying to better understand from the standpoint of, uh, you know, low bioavailability that has perhaps been known or established, uh, with buprenorphine specifically and how that might compare to Opana sort of prior to the formulation of--or oxymorphone prior to the formulation of Opana, can you give us a sense as to how similar or different those comparisons are?

Dr. Danny Kao: Uh, this is Danny. Uh, we used Opana just, uh, example because I was working on as a formulator. And, uh, for the competitive--the reasons we don't discuss the specific numbers, we can say that we are significantly higher than the Opana.

Mr. Ken Trbovich: Got it. Okay. I do appreciate it. I'll go back in the queue.

Mr. Michael Becker: Thank you, Ken.

Operator: Thank you. The next question is from Ed White of FBR. Please go ahead.

Mr. Ed White: Uh, good morning, everyone. Just, uh, a couple of, uh, big-picture questions. Um, can you just, uh, tell us what you think the next steps to development are? I know you had been--mentioned it before that, uh, you know, if the data was positive, there was a chance, uh, to either go straight directly to the FDA, but more likely that you were going to, uh, run, uh, Phase 3 trials. And so, I just want to know, you know, what is the path, uh, to--uh, to submission.

Dr. Richard Mangano: This was a proof-of-concept study to--based on the hypothesis that we stated earlier, bypassing metabolism in the upper GI would give us enhanced exposure. And we achieved that. We're very pleased with the results we have now.

Mr. Ed White: Okay. So, what are the next steps? Uh, are you--for the company? And this is a question more for Sergio.

Dr. Sergio Traversa: Yeah, hi, this is Sergio here. No, we just received the data. And we are working on--um, we will try to move as fast as possible. And, uh, clearly, the goal is to go to a Phase 3 trial, uh, as fast as possible.

Mr. Ed White: Okay. Um, and then, Sergio, obviously, this is a--uh, a--uh, potentially a very large product here. Um, uh, you know, uh, will Relmada, uh, commercialize it on its own, or are you going to partner? And you know, um, if partnering, you know, uh, would you be thinking of bringing a partner in during development or wait until after Phase 3?

Dr. Sergio Traversa: It's a great question for Dr. Nolan.

Dr. Lisa Nolan: Yeah, so, obviously, the considerations are very different for pain and also for addiction. So, you know, it's not our goal to be a commercialization entity in addiction. So, we will probably partner the product, maybe at this stage, maybe after further optimization for addiction. And we're already in discussions with a number of companies in that space.

For chronic pain, it probably makes more sense for us to add value and take it through the next stage of development. And then--you know, and then at a later stage, we consider--we could consider whether to commercialize it ourselves or to partner for commercialization.

But, it is a very large market opportunity. So, probably, you know, a partnership with a company with great expertise in this space would make some sense.

Mr. Ed White: Uh--.

Operator: --Thank you. Our next question is from Michael Higgins of ROTH Capital Partners. Please go ahead.

Mr. Michael Higgins: Thanks. Uh, good morning, guys. Congrats on the data. Um, just wanted to see, uh, here in your view, um, why'd you pick, uh, buprenorphine as a oral. Um, think we're all familiar with it, its unique abilities. Just looking for your--uh, your perspective as to why you're picking this, uh, program.

Dr. Sergio Traversa : Hi, Michael. This is Sergio here. Well, there are several reasons. One is that, you know, we had a discovery about, you know, the metabolism of--uh, of buprenorphine that make it where we can really have an advantage. We believe we--we believed we can do it. Now, we strongly believe it. We definitely can do it.

Uh, second one, of course, when we picked the buprenorphine, we didn't know about Vicodin being moved to Schedule 2. So, we got somewhat lucky, uh, in that sense. But, uh, the--uh, there is a need for some, uh, new, uh, with different mechanism of action, uh, products for pain.

So, it's a combination of, you know, having the opportunity and, uh, believing that the market for pain, it's very, very attractive.

Mr. Michael Higgins: Okay. Fair enough. Uh, second question would be what you believe would be your RLD for this, the, uh, BuTab, Buprenex, um, uh, the Subutex will--may be RLD for BuTab.

Dr. Danny Kao: Uh, this is Danny. The way we are evaluating the RLDs and the--we don't have the final answer for that yet.

Operator: Thank you. At this time, I would like to turn the conference back over to management for any additional comments.

Dr. Sergio Traversa : Thank you. In closing, I'm very pleased that Relmada has achieved positive results in a proof-of-concept pharmacokinetic study in healthy volunteer with BuTab. There are currently no commercially available oral formulation of buprenorphine. They are designed to be easily swallowed like any traditional tablet or capsule.

As Dr. Mangano discussed, the currently available dosage form of buprenorphine are nonstandard and may be difficult to use for some patients, such as skin patches, sublingual tablets, and buccal adhesive films and patches. We believe that patients could benefit for a more convenient swallowable tablet such as BuTab.

We are pleased that, even using a nonoptimized prototype formulation, the absolute bioavailability of BuTab relative to intravenous administration exceeded published data with nonmodified buprenorphine.

In addition, buprenorphine blood levels with BuTab compared favorably with currently marketed transdermal patch and reached blood levels that are associated with clinical efficacy in chronic pain.

We are very encouraged by these results, and we will further develop and optimize BuTab formulation with an eye to our pivotal studies and NDA submission. These result with BuTab could have been less favorable due to inherent risk and uncertainty of drug development.

However, we credit this success and our ability to deliver this significant milestone in Q4, as we promised to shareholders, to Dr. Mangano, his experienced drug development team, Dr. Kao and his extensive formulation development expertise, Dr. Nolan through understanding of the commercial marketplace and the attributes necessary to attract interest from prospective partners, and the many other important contributions from everyone else at our company.

We are enthusiastic about these results. And I want to reiterate that we believe this is just one of Relmada's significant value creation opportunities possible in the next 12 to 24 months. We are excited by these advances, and we continue to develop these treatments to benefit patients and drive long-term shareholder value.

On behalf of everyone at, uh, Relmada, we thank you, our valued stockholder, for your continued support. I look forward to keeping you updated on the progress of Relmada. And we continue to execute on our existing plan.

This concludes our conference call. Thanks, everyone. And I wish all the best for the rest of the day. Thank you.

Operator: Thank you. Ladies and gentlemen, this does conclude today's teleconference. You may disconnect your lines at this time. And thank you for your participation.