TITAN PHARMACEUTICALS, INC.

Moderator: Sunil Bhonsle
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3:15 pm CT

Operator: Thank you for holding, and welcome to the Titan Pharmaceuticals' First Quarter 2016 Financial Results conference call. At this time, all participants are in a listen-only mode. There will be a question and answer session following today's remarks. Please be advised that this call is being taped at the company's request and will be archived on the company's Web site starting later today.

At this time, I would like to turn the call over to Sunil Bhonsle, President and CEO of Titan Pharmaceuticals. Please go ahead, sir.

Sunil Bhonsle: Thank you, (Travis), and thank you all for joining us. Welcome to the Titan Pharmaceuticals call to review financial and operational results for the first quarter of 2016. Before we begin, I wanted to inform you that this morning we file our first quarter 2016 Form 10-Q with the SEC and the press release issued this morning provides a summary of the results and both of these can be found on our Web site at titanpharm.com.

Joining me on the call today from Titan are Dr. Marc Rubin, our Executive Chairman; Dr. Kate Beebe, our Executive Vice President and Chief Development Officer; and Brian Crowley, our Vice President of Finance. Before we get into the details of the financial results and provide an update on the company, I want to remind everyone that certain matters we will discuss today, other than

historical information, consist of forward-looking statements relating to, among other things, our expectations concerning our financial results, available cash, development programs, partnering arrangements, regulatory strategies and business plans.

The forward-looking statements are not guarantees of future performance and are subject to a variety of risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements. These risks and uncertainties are described in our Annual Report on Form 10-K filed with the SEC.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today. We undertake no obligation to update or revise the information provided in this call, whether as a result of new information, future events or circumstances or otherwise.

Having said that, as always, let's start with an overview from our Executive Chairman, Dr. Marc Rubin. Marc?

Dr. Marc Rubin: Thank you very much, Sunil. Hello, everyone. And as always, we are very appreciative of all of you joining us today on this call. And we're pleased to be here today to provide you with an overview of our accomplishments in the first quarter of 2016 and discuss the progress we're making in advancing our pipeline of product candidates based on our ProNeura continuous long-term drug delivery platform.

As many of you know, in January, the US Food and Drug Administration Psychopharmacologic Drugs Advisory Committee or PDAC voted 12 to 5 to recommend approval of Probuphine for the maintenance treatment of opioid addiction. During the committee meeting, questions were raised about the Risk Evaluation and Mitigation Strategy or REMS, and our development and commercialization partner, Braeburn Pharmaceuticals responded promptly with answers to those questions.

In February, the FDA extended its action date by three months to May 27, citing the changes submitted to the REMS section of the NDA as a major amendment requiring additional time for completion of their review. We've been working with Braeburn and the agency to finalize the REMS and the product labeling and we are eagerly awaiting the agency's decision.

If approved for the long-term maintenance treatment of opioid addiction in adults, Probuphine would be the first and only commercialized treatment for opioid addiction to provide continuous around the clock levels of buprenorphine for six months following a single treatment. Buprenorphine is currently available in the form of daily dose sublingual formulations with annual sales now approaching $2 billion in the United States.

The successful phase 3 program for Probuphine, coupled with the potential approval of Probuphine by the FDA, represent an important validation of our ProNeura long-term continuous drug delivery platform. If approved, Probuphine would also be Titan's first commercialized product based on ProNeura.

We've also made progress during the first quarter with the development plans for our Ropinirole implants for Parkinson's disease and/or implantable triiodothyronine or T3 product for hypothyroidism. We remain on track to submit an IND application for our Ropinirole implant by the end of the year and hope to secure a pre-IND meeting with the FDA to discuss our T3 implant development plan within that same timeframe. And in just a moment, Dr. Beebe will provide you with additional details on our product pipeline.

So the board continues to be enthusiastic about the prospects of the ProNeura long-term delivery platform. And while we are still in the early stages of product development with Ropinirole and T3, with the known associated risks in early product development, we are pleased with the progress Titan is making in advancing and expanding the pipeline.

And with that, I will now pass the ball and the call back to Sunil to review the financial results of the first quarter of 2016. Sunil?

Sunil Bhonsle: Thank you, Marc. Next, I will provide you with our first quarter 2016 financial results and Dr. Beebe will update you on the development activities during the quarter. And then to conclude, we will open up the call for your questions for the Titan management team.

So for the financial details for the first quarter. Titan reported no license revenue for the first quarter of 2016, compared with approximately $0.9 million for the comparable period in 2015. License revenue in the first quarter of 2015 reflected the amortization of the upfront license fee received from commercialization and development partner Braeburn Pharmaceuticals in December 2012 and the amortization finished last year.

Total operating expenses, consisting of research and development expenses and general and administrative expenses were approximately $1.8 million in the first quarter of this year, compared with approximately $2.5 million in the first quarter of 2015.

R&D expenses for the quarter ended March 31, 2016 were approximately $0.7 million, compared with about $1.4 million for the same period in 2015. While there were increases during the first quarter of 2016 in external research and development expenses related to the support of our Probuphine and ProNeura product development programs, employee-related expenses and other R&D expenses, these were offset by the reimbursement by Braeburn of expenses associated with Probuphine.

During the first quarter of 2016, external R&D expenses related to Titan's product development programs were about $0.6 million, compared with about $0.4 million for the same quarter in 2015.

G&A expenses for the quarters ended March 31, 2016 and 2015 remained consistent at about $1.1 million.

Net other expenses for the first quarter of 2016 were about $15,000 compared with about $3.3 million for the same period in 2015. Net other expenses consisted primarily of non-cash gains and losses on changes in the fair value of warrants, tax expenses, and interest income.

Net loss for the quarter ended March 31, 2016 was approximately $1.8 million, or about 9 cents per share compared with about $4.9 million, or about 24 cents per share, in the same quarter in 2015. At March 31, 2016 Titan had cash of about $5.8 million, which the company believes is sufficient to fund operations through the end of this year. This does not include the milestone payment of $15 million that we will receive upon the approval of Probuphine.

These financial results were as expected, and we're well positioned heading into the remainder of the year. As Mark said, we're all very much looking forward to the FDA's decision on Probuphine later this month, and seeing Probuphine available shortly thereafter as a new tool to fight the drawing academic of opioid addiction.

Now to provide you with an update of recent development activities, including our continued progress with our Ropinirole implant and development program for hypothyroidism, let me turn the call over to Dr. Beebe. Kate?

Dr. Kate Beebe: Thank you Sunil and hi, everyone. I'm very pleased to provide you with some additional details on our product development pipeline including Probuphine, and our Ropinirole implant for Parkinson's Disease and our ProNeura-T3 implant for hypothyroidism.

As Mark mentioned, PDAC committee voted 12 to 5 to recommend approval of Probuphine and we have an action date of May 27. And while the FDA completed to review Probuphine, we are assisting Braeburn and our contract manufacturer to prepare for product launch.

Also on the Probuphine front, in April Dr. Rick Rosenthal, who's a Professor of Psychiatry and Medical Director of Addiction Psychiatry at the Icahn School of Medicine at Mount Sinai and a Co-Lead Investigator of the most recent Phase 3 trial, presented a poster on results from the trial at the 47th Annual American Society of Addiction Medicine conference in Baltimore.

These data showed that participants who were clinically stable on sublingual buprenorphine at a dose of 8 milligrams a day or less maintained stability when transferred to Probuphine over the course of six months. And that they were more likely to a sustain from illicit opioids throughout the six months than participants who remained on sublingual buprenorphine. This was the first head-to-head comparison of Probuphine and sublingual Buprenorphine, demonstrating the efficacy of a long acting six month Buprenorphine implant.

Now we will also be presenting these data including some pharmacokinetic data about Probuphine in poster your presentations at the several upcoming medical conferences, including the American Psychiatric Association meeting in Atlanta, Georgia later this month, the College on Problems With Drug Dependence meeting in Palm Springs, California in June and the International Society of Addiction Medicine meeting in Montreal, Canada in October.

In addition, a manuscript describing these data is currently under review for potential publication in a major medical journal. The US market for addiction treatment has continued to grow and there are three proprietary daily dose formulations on the market along with a few generic versions.

Also worth noting, there are three injectable one month deeper formulations in clinical development, which really emphasizes the importance of longer term treatment. Probuphine with a six-month treatment option has the potential to be the first and only such product on the market. In addition to these important US efforts, we are evaluating opportunities for regulatory approval and commercialization of Probuphine outside of the US and Canada.

Having conducted initial discussions with opinion leaders and some regional pharmaceutical companies in countries where people knocking products are used for the treatment of independence and assuming approval in the US, our plan moving forward is to obtain additional regulatory guidance to confirm the path to product approval in these countries and to seek appropriate partnerships for commercialization of the product.

As we also mentioned we're very enthusiastic now about the prospects for our ProNeura continuous long-term drug delivery platform and its role in the treatment of select chronic diseases for which maintaining consistent levels of the medication in blood over extended periods of time may offer safety or health benefits.

We're very pleased with the progress we've made with our ProNeura based Ropinirole implant for Parkinson's disease following the submission of the FDA briefing materials in support of an IND for our Parkinson's disease program late last year.

In January the FDA provided written feedback on our initial development plan. And based on the FDA's feedback, we've begun the required non-clinical studies to support the submission of an IND application, which is currently targeted for the fourth quarter of 2016 to be followed by the initial pharmacokinetic and proof of concept clinical study.

Titan is pursuing a 505(b)(2) registration pathway for the product candidate. The Ropinirole implant is designed for the long-term continuous delivery of Ropinirole HCL for the treatment of

science and symptoms of Parkinson's Disease, including stiffness, tremor, muscle spasms and poor muscle control.

Ropinirole is a dopamine agonist that's currently available in daily or more frequently dose of oral formulations for the treatment of Parkinson's Disease symptoms and also for restless leg syndrome. The Ropinirole implant is designed to address some of the side effects associated with daily or more frequently dose oral formulations Ropinirole, such as motor side effects and disc nation.

About 1 million people in the US suffer from Parkinson's and that number is expected to double by 2030 due to the aging population, and this is according to the Parkinson's Disease Foundation. In addition to the progress we're making with our Ropinirole plant, we continue advance our implantable T-3 product for the treatment of hypothyroidism.

As Mark said, we remain on track to secure a pre-IND meeting with the FDA in the fourth quarter of 2016. Hypothyroidism is a disease affecting about 15 million Americans, mostly women. And based upon symptoms and blood tests, it is estimated as many as 15% to 20% of hypothyroid patients are not adequately treated with the standard therapy, resulting in a persistent efficiency in the primary active form of thyroid T-3. And so physicians typically add an oral T-3 regiment to the treatment the patient.

Once daily synthetic T-3, otherwise known as Cytomel, is an effective medication for hypothyroidism but it is also associated with potential side effects, including headache, nervousness, irritability, letting, cardiac arrhythmias. And this is driven by the peak and trough blood level fluctuations associated with a standard oil delivery.

On the other hand continuous delivery of T-3 by the oral or parenteral route is highly desirable but it has been difficult to achieve because of unique solubility characteristics of the compound. So

an implantable T-3 product utilizing the ProNeura platform could more closely replicate normal thyroid physiology and avoid the unwanted side effects associated with the current pulsatile release formulation and this would present a significant market opportunity.

We look forward to adding more potential product candidates to our portfolio and of course the potential commercialization of our first ProNeura based product candidate Probuphine. And now I'll turn the call back to Sunil. Sunil?

Sunil Bhonsle: Thank you, Kate. Thank you for that update. This brings us to be end of formal remarks. And now (Travis), we are ready to take question from the call participants.

Operator: Thank you. If you would like to ask a question, please signal by pressing star 1 on your telephone keypad. If you are using a speakerphone, please make sure your mute function is turned off to allow your signal to reach our equipment. Again, press star 1 to ask a question. And we'll pause for just a moment to allow everyone an opportunity to signal for questions.

We'll take our first question from (Scott Henry) with ROTH Capital.

(Scott Henry): Thank you and good afternoon. I guess for starters just a quick model question. Should I expect R&D to pick up as we go throughout the year?

Sunil Bhonsle: Hi how are you?

(Crosstalk)

Sunil Bhonsle: And...

(Scott Henry): Good.

Sunil Bhonsle: ...the answer is absolutely, yes. As we go forward through the rest of this year and what we indicated was the non-clinical development programs, you know, are funded through our current cash position. But as we get closer to the clinical studies, the expenses will pick up and that will be, you know, late this year. So, towards the end of the year really.

(Scott Henry): Okay and then, I mean, I ask this question every quarter, but has the correspondence with FDA anything unusual or, you know, just in line with what you would expect given the timelines that we have?

Sunil Bhonsle: Well, I will remember you asking that question every time (Scott), so - but clearly, you know, as we've indicated, the review was continuing. It's the labeling in the REMS that are being, you know, finalized. And, so far we feel very comfortable and confident with the outcomes.

(Scott Henry): Great. And final question which is more qualitative. There has been a lot of press about opioid addiction and I'm starting to see Probuphine start to make it into some of that press. My question is how do you feel about the awareness of Probuphine leading into potential approval and launch? It would seem like the awareness would be higher than you would have previously expected?

Dr. Kate Beebe: That's a great question, (Scott), and nice to talk to you. I think that the awareness is certainly increasing for all products used to treat opioid addiction and the recognition of the epidemic that we're in, particularly, with notable celebrities dying recently of opioid overdose or potentially opioid overdose, it's really an emergency situation.

And so, yes, Probuphine is getting picked up by the media and we are, as I mentioned, we are getting out there and presenting the data at as many conferences as we can. We're hopefully

going to be publishing a manuscript describing the data from the most recent study in the next few months.

So, yes, I believe that we are having an opportunity right now to really tell the story about Probuphine in anticipation of approval.

(Scott Henry): Okay.

Sunil Bhonsle: Just to add to that, (Scott), you know, it's sort of the first new treatment modality for addiction in a long time. And that, you know, certainly deserves some mention and then rightfully so I believe it's good to see that being picked up by the media.

(Scott Henry): Okay, great. Well thank you for taking the questions.

Sunil Bhonsle: Good, (Scott). Thanks.

Dr. Kate Beebe: Thanks, (Scott).

Operator: And once again just as a quick reminder, if you would like to ask a question please signal by pressing star 1 on your telephone keypad. We'll now take our next question from (John Vandermosen) with Zacks Research.

(John Vandermosen): Good afternoon, everybody.

Sunil Bhonsle: Good afternoon, (John). How are you?

Dr. Kate Beebe: Good afternoon, (John).

(John Vandermosen): I'm doing fine. First I just wanted to follow on (Scott)'s question and ask if, you know, all this media attention that we've been seeing has caused management to kind of increase their - your perception of how large the market can be for the products.

Sunil Bhonsle: But, you know, clearly the market and commercialization of this product is in the hands of Braeburn Pharmaceuticals. They see this as a key product in both the treatment for addiction as well as, you know, for building the addiction franchise that they have in mind as well.

Now having said that, ((inaudible)) obviously, I can't - they will provide projections as we get going and this product is approved. In the interim, what I can, you know, provide this color is that there is a lot of interest from physicians and Braeburn has been planning on the program to train physicians, which is a very important step before they can use this product.

And there is a large demand from physicians throughout the country to be - to get trained. And Braeburn has already started scheduling a training program meetings over the next few months. So, we're very pleased to see that and that kind of attention would imply certainly that there is awareness of such a product, a need for such a product, and I certainly hope it results in a very good product launch.

(John Vandermosen): Okay. Second question kind of following on that was with Braeburn. Can you give us kind of an update or current status of Braeburn pursuing pain indication for Probuphine?

Sunil Bhonsle: Sure. From prior discussions and what we had indicated, Braeburn first is focused on getting approval for the addiction indication. And once that is in place, and obviously the initial emphasis will be on product launch and getting this product out there in the market.

At the same time, they recognize the opportunity increasing pain, chronic pain specifically, and they've indicated, you know, their desire to pursue that as well. In terms of when exactly it falls in

place is something we'll have to wait and see. But maybe Kate can add something more to that as well.

Dr. Kate Beebe: Nothing ((inaudible)).

Sunil Bhonsle: Okay. So I...

(John Vandermosen): Okay.

Sunil Bhonsle: ...you know, clearly it's something they do intend to pursue. And the first focus is clearly on getting Probuphine out into the addiction market successfully.

(John Vandermosen): Okay. And, you know, to this point ProNeura has only been used with generic products. And I'm wondering if there is or there might be any opportunities for any on patent products out there that might be helped with this technology. Is that something that might be pursued?

Sunil Bhonsle: Absolutely, (John), I mean, a very good question. And when you think of, you know, ProNeura and its basis for treatment, basically providing a steady level of drug long-term typically something that is available only through IV therapy in hospitals that is somewhat restricted.

And something like a ProNeura implant, which can provide that same benefit while you are not restricted in a - in hospital setting is a major advantage. You know, obviously our first products have been in areas where there is already proven efficacy that provides a basis to show this technology works and we believe we've done that with Probuphine.

We are now moving into the next two products, both of which have a lot of promise. But once again, they are both products based on compounds that already have shown to be effective. Our

next step really is to expand that both with drugs that are known to be effective and offering this technology as a basis for development of other products that are proprietary to other companies.

And this includes products where, you know, potentially they see problem such as for as first pass metabolism, which we can avoid by delivering a drug in this manner. Peptides possibly that are not easily delivered orally can be delivered in this manner.

So there are many opportunities. And our goal now and strategy starts expanding to include these opportunities by working with other companies who have proprietary compounds. Kate is looking forward to that very much.

Dr. Kate Beebe: Yes, I'm jumping ((inaudible)).

(John Vandermosen): Okay. Thank you for the update there. And then just one last question, more of a financial statement question. It looked like cash burn was about $2.1 million in the first quarter. In the release, you indicated that current cash level should hold you until the end of year. Should that suggest that we'll see kind of a little bit lower cash burn as the year progresses?

And, again, I was assuming that this excluded any payments from Braeburn.

Sunil Bhonsle: Right. Right. You know, through the rest of the ((inaudible)) that when you look at our burn, it fluctuates, it typically drops off a little in the second quarter, it'll pickup because there are certain periodic expenses that happened in the first quarter.

I'll tell you one big one that always look at them and it's when I have to sign to sign the check and shocks me, it's the D&O insurance that you have to pay for things like that. So some of these expenses are up and down a little bit. So, it could be a little less in the second quarter may be a little more in the third quarter, but generally in the same levels.

(John Vandermosen): Thank you for answering my questions.

Sunil Bhonsle: Thank you very much, (John).

Dr. Kate Beebe: Thanks, (John).

Operator: That concludes today's question and answer session. Mr. Bhonsle, at this time I will turn the conference back to you for any additional or closing remarks.

Sunil Bhonsle: Thank you very much, (Travis). And thank you all for participating in this call. As you know this is a very important time in the company's development with potentially transformational news ahead of us, and we all thank you for your continued support.

We look forward to updating you again soon on Probuphine, as well as our other development programs. And as always, thank you for participating in the call today. Goodbye.

Operator: That concludes today's presentation. Thank you for your participation.

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