TITAN PHARMACEUTICALS INC.

Moderator: Sunil Bhonsle
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3:.05 pm CT

Operator:. Thank you for holding everyone and welcome to the Titan Pharmaceuticals' Third Quarter 2015 Financial Results Conference. Today's conference call is being recorded. 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 recorded 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 of Titan Pharmaceuticals. Please go ahead, sir.

Sunil Bhonsle:. Thank you, (Kelly Ann), and thank you all for joining us today. Welcome to the Titan Pharmaceuticals call to review financial and operational results for the third quarter of 2015. Before we begin, I wanted to inform you that today we filed our third quarter 2015 Form 10-Q with the SEC and issued a press release that provides a summary of the results, which 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 the 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 provided you with all of the legalities, now let's go and start with the call. As always, let's start with an overview from our Executive Chairman, Dr. Marc Rubin. Marc.

Marc Rubin:. Thank you, Sunil, and hello everyone. Thank you for joining us today, as always. We are very pleased today to provide you with an overview of our activities in the third quarter and to discuss the development of our pipeline of product candidates based on our ProNeura long-term continuous delivery technology.

On the product development front, as you know, in September we announced that the FDA accepted for review the resubmission of the NDA for Probuphine for the long-term maintenance treatment of opioid addiction and set an action date of February 27.

As many of you know, in June of 2015, Titan, and our development and commercialization partner, Braeburn Pharmaceuticals, reported positive top line results from PRO-814, the final Phase 3 trial of Probuphine. As we previously announced, the study met the pre-specified primary endpoint of non-inferiority as well as all secondary endpoints.

If approved, Probuphine would be the first commercialized treatment for opioid addiction to provide continuous around-the-clock levels of buprenorphine for six months following a single treatment.

We continue to believe that the successful development of Probuphine to date provides a strong validation of our ProNeura platform. In addition to Probuphine, we are aggressively advancing our development plans for ProNeura-ropinirole for Parkinson's disease. We are on target to submit briefing materials to the FDA in the fourth quarter of this year in order to support a pre-IND meeting.

As you may have seen, we also announced today the addition of a product development program using ProNeura implant containing triiodothyronine or T3, which is the active form of thyroid hormone in the body, for the treatment of hypothyroidism.

We believe the ProNeura platform's ability to provide low dose non-fluctuating levels of certain medications in the bloodstream over extended periods of time ranging from three months to a year holds great promise to the treatment of a number of selected chronic diseases and conditions. Dr. Beebe will share more details on the development of our pipeline momentarily.

While we continue to advance Probuphine and our other development programs, we also achieved a significant milestone with the uplisting of our stock to the NASDAQ Capital Market, a move that raises our visibility among a broader range of investors and potentially generates more

value for our shareholders. The Board is very enthusiastic about Titan's progress and prospects and we look forward to maintaining this momentum into 2016.

And with that, I will now pass the call back to Sunil to review the financial results for the third quarter of 2015. Sunil?

Sunil Bhonsle:. Thank you, Marc. Next, I will review our third quarter 2015 financial results, following which Dr. Beebe will update you on the development activities during the quarter. We will then open up the call for your questions for the Titan management team.

Titan recognized no revenue in the third quarter of 2015 compared with approximately $0.9 million of revenue recognized in the third quarter of last year, which consisted of license revenue and reflected the amortization of the upfront license fee received from Braeburn in December 2012. Essentially, we have now fully amortized the upfront payment, and so there is no ongoing revenue to be shown for that upfront payment.

Total operating expenses for the quarter ended September 30, 2015 were approximately $1.8 million, an increase of approximately $0.1 million over $1.7 million reported for the same quarter in 2014, and this was driven primarily by higher research and development expenses.

R&D expenses were approximately $1 million in the third quarter of 2015 compared to approximately $0.8 million in the same period of last year. This increase was primarily associated with increases in external R&D costs related to support of our Probuphine and the ProNeura-ropinirole product development programs, employee related and other R&D expenses.

General and administrative expenses were approximately $0.8 million in the third quarter of this year compared with approximately $0.9 million in the same quarter in 2014. The decrease of

about $0.1 million was primarily related to a reduction in professional fees and other outside services.

Net other expenses for the third quarter of 2015 were about $5,000, compared with net other income of about $1.5 million in the same quarter a year ago. Net other income and expense during these quarters consisted primarily of non-cash gains and losses on changes in the fair value of warrants.

Net loss for the 2015 third quarter was approximately $1.8 million or about 9 cents per share, compared with net income of about $0.7 million or approximately 4 cents per share in the same period in 2014. At September 30, 2015, Titan had cash of about $9.7 million, which the Company believes is sufficient to fund planned operations into the fourth quarter of 2016.

These financial results were as expected and our current cash position is sufficient to take us well past the FDA action date of February 27, 2016 for the Probuphine NDA and the potential approval of Probuphine which would generate a milestone payment to Titan of $15 million. We remain optimistic of the potential of Probuphine for the maintenance treatment of opioid addiction and look forward to an interaction with the FDA over the next several months.

As Marc mentioned, our Parkinson's program is well underway and we have now added another product candidate to our pipeline of products based on our ProNeura long-term continuous drug delivery platform. With our product pipeline progressing and the recent uplisting to the NASDAQ, Titan is well-positioned for growth and potential increase in value for our shareholders. We look forward to providing updates as we continue to advance these programs.

And now, to provide you an update of recent development activities, let me turn the call over to Dr. Beebe. Kate?

Kate Beebe:. Thank you, Sunil, and hello everybody. I'm very pleased to provide you with additional details on the development of our pipeline of product candidates based on our ProNeura technology, which includes Probuphine as well as our ongoing work developing ProNeura-ropinirole for Parkinson's disease, and as announced earlier today, our latest product development candidate, ProNeura T3 implant for hypothyroidism.

While the FDA completes its review of Probuphine, Titan continues to work with Braeburn and our contract manufacturer to prepare for its potential approval and commercial production. As we have mentioned, the final Phase 3 double-blind double-dummy clinical study of Probuphine met the pre-specified primary endpoint of non-inferiority as well as all secondary efficacy endpoints.

The overall safety and tolerability profiles for each treatment group were comparable, and the implantation procedures were generally well-tolerated and comparable to observations from earlier studies with Probuphine. We believe this study design was robust and provides a well-controlled evaluation of Probuphine compared with the current standard of care and this was in stable maintenance patients.

As a proprietary subdermal implant with patent coverage in the US to 2024, Probuphine has several advantages over the daily dosed formulations of buprenorphine, and new treatments that are safe and effective are critically needed for patients, their families and health care providers.

The US market for addiction treatment has continued to grow with prescriptions for buprenorphine products increasing by more than 12% last year, and there are currently three proprietary daily dosed formulations on the market along with a few generic versions. Also worth noting, there are three injectable one month depot formulations in early to mid-stage clinical development, which just emphasizes the importance of long-term treatment.

Probuphine, with a six-month treatment option, has the potential to be a first such product on the market. Additionally, Probuphine could play an expanding role in the treatment of opioid addiction as government officials call for greater access to evidence-based medication-assisted therapy and are considering a revision to the cap on the number of patients who can be treated with buprenorphine products by physicians.

We're also very excited about our ProNeura-ropinirole program for Parkinson's disease. During the third quarter, we made good progress to finalize the formulation of ProNeura-ropinirole and expect to submit the pre-IND data package in support of the product development plan sometime during the fourth quarter of this year. Our goal is to initiate a clinical proof of concept study in late 2016, following the approval of Probuphine.

About 1 million people in the US suffer from Parkinson’s disease and that number is expected to double by 2030 due to the aging population, according to the Parkinson's Disease Foundation. Dopamine replacement and dopamine agonist therapy, which is the current standard of care, is designed to replace dopamine in the brain of Parkinson’s patients, but typically stops working efficiently after several years and can trigger serious side effects. About one third of treated patients develop motor response fluctuations and/or drug-induced dyskinesia’s within three to five years of treatment.

Clinical and nonclinical research suggests that these motor side effects may arise from the pulsatile dopaminergic stimulation resulting from current oral treatment. In clinical studies, dopaminergic stimulation by continuous infusion has been shown to palliate these motor complications and to also delay or prevent the onset of dyskinesia’s for up to one year in Parkinson’s patients.

The ProNeura drug delivery system can offer a simple way of providing around-the-clock stable levels of medication, such as a dopamine agonist like ropinirole, in an outpatient setting and we

believe that this has the potential to alleviate some of the motor complications and offer another option in treating Parkinson's disease.

As I mentioned, earlier today we announced the addition of a product development program of an implantable triiodothyronine T3 product for the treatment of hypothyroidism. ProNeura T3 has the potential to offer significant advantages over once-daily oral delivery for patients who need T3 in their treatment regimen.

Hypothyroidism is a disease that affects about 15 million Americans, most of whom are women. Symptoms include chronic fatigue, weight gain, obesity, dry skin, impaired mental activity and depression. The majority of patients are diagnosed with standard blood tests and receive treatment typically consisting of synthetic prohormone thyroxine T4 given as a once-daily oral medication, otherwise known as Synthroid or Levoxyl and other generics, which in turn is converted in the body to active T3.

Based upon symptoms and blood tests, it is estimated that as many as 15% to 20% of hypothyroid patients are not adequately treated with this therapy, and this could be the result of a persistent deficiency in the primary active form of thyroid hormone T3.

Once-daily synthetic T3, Cytomel, is an accepted medication for hypothyroidism but is also associated with potential side-effects, including headache, nervousness, irritability, sweating and cardiac arrhythmias, which are driven by the peak-and-through blood fluctuations associated with standard oral delivery.

Continuous delivery of T3 by the oral or parenteral route is highly desirable, but has been difficult to achieve because of unique solubility characteristics of the compound. An implantable T3 product utilizing the ProNeura platform could more closely replicate normal thyroid physiology

and avoid the unwanted side-effects associated with the current pulsatile-release oral formulation, and this could potentially present a significant market opportunity.

I'm very pleased with our progress to date in the T3 implant formulation development and look forward to providing further updates as we advance towards the regulatory discussions for this potential product candidate. And now, I'll turn the call back to Sunil. Sunil?

Sunil Bhonsle:. Thank you, Kate. This brings us to the end of our formal remarks, and now Kelly Ann, we are ready to take questions from the call participants.

Operator:. Thank you. At this time if you do have a question that will be star 1 on your telephone keypad. Again, star 1 for questions and we'll pause for just a moment. And We'll hear first from Scott Henry with ROTH Capital.

Scott Henry:. Thank you and good afternoon.

Sunil Bhonsle:. Good afternoon, Scott. How are you?

(Crosstalk)

Scott Henry:. I'm doing pretty good, thank you for asking. A couple of questions. First, as far as correspondence with the FDA, you know, anything unusual at this point, can we assume there's no Ad Committee Meeting?

Sunil Bhonsle:. Scott, as you know, I mean the process is, you know, obviously FDA asks questions during this period. Most of them are typical wanting clarifications and looking for specific information in the NDA, and those are the kinds of things and interactions that we have had. Both Braeburn and Titan, we look at this as we have to be prepared in every way for whether there is

or isn't an Ad Com requested by the FDA, and we are proceeding in that manner. So, you know, once we know for sure, I'm sure both the FDA and we will make that known. Okay?

Scott Henry:. Okay, certainly fair enough. And as far as supplying, initial launch and the logistics of that, I mean how comfortable are you that could you launch right away or would this be a middle-of-the-year launch, just trying to get a sense into the logistics of that?

Sunil Bhonsle:. Sure. Very good question and certainly something that, you know, Braeburn is looking at closely and preparing for. We of course have been supporting the manufacturing from our contract manufacturer, DPT. We have made product at commercial scale that, you know, was part of the validation process and so on, and we're fully prepared to have the product ready at the time of approval, although as you know, the packaging and final labelling and so on is not really available till that final approval.

So that whole process takes some time, and it may take two, three months to be able to have everything in its final packaging and ready for commercialization, and that's what I would expect. So middle of the year is not a bad target at all, in fact maybe even sooner.

Scott Henry:. Okay, great. I appreciate the color on that. Final question I guess for Kate, the hypothyroidism product, sounds like a very interesting product. I'm just trying to get a sense of what exactly is the hook there. I mean is it really all about getting patients that are not adequately treated, is it all about that 15% to 20%, you know, or is it more patients that don't like side-effects? And I guess finally, that 15% to 20% that are not currently adequately treated, how confident are you that your product will be able to treat those patients?

Kate Beebe:. All very good questions, Scott. We're actually going for the full opportunity, but focusing on that 15% to 20% that are not adequately treated at this point because of their inability to

convert T4 to T3 or their inability to tolerate the existing oral T3 product. So at this stage, we're still continuing to work on formulation development.

We fully expect that we should be able to deliver T3 in much the same way we have shown delivery of other products like ropinirole, like buprenorphine, Probuphine. And at this stage, we can't really comment on anything other than that, but we're going to update you regularly as we continue to obtain more data and get closer to a point where we can have a discussion with the FDA and other regulatory agencies.

Scott Henry:. Okay. And I guess just a follow-up question, because obviously I haven't done the background work on this just yet, but as far as a patient that can't convert T4 to T3, you know, what percent of that 15% to 20% are those patients?

Kate Beebe:. Probably most of them.

Scott Henry:. Okay, great. Thank you for taking the questions.

Kate Beebe:. Thanks for asking.

Operator:. Again that is star 1 for questions. We'll move on to Nisha Hirani with Zacks Investment Research.

Nisha Hirani:. Hi there. Good afternoon. I hope you all are doing well.

Sunil Bhonsle:. Great. Thanks, Nisha. How are you?

Kate Beebe:. You too, Nisha.

Nisha Hirani:. Doing well, thank you. Can you please provide us with a quick update in regards to pursuing approval and commercialization of Probuphine outside of the US? Have you had any meetings with any of the European health authorities at this point or will those be taking place in the near-term?

Sunil Bhonsle:. Great question, Nisha. As we have mentioned in the past, for the regulatory authorities outside of the US, we started preparing all of the information using the NDA that was submitted recently and we expect to meet with those agencies in the early part of next year, and this would be primarily focusing on UK, possibly France, maybe Australia, where there are substantial markets that are of importance right now.

There is some debate on the merits of meeting before the FDA action date versus after, and so again, the regulatory experts have different opinions and we're going through that process now. But we're going to be well-prepared with all the information that is being put together, so in the early part of next year we can meet with the regulatory authorities.

Simultaneously, we have continued to proceed in contacting commercial groups who have an interest in the buprenorphine market in these countries and others around the world, and there are substantial numbers who have expressed an interest, but I think like everyone else, everyone wants to see how the FDA proceeds here and that makes it a lot easier to get commercialization and approvals elsewhere in the world.

Nisha Hirani:. Sure, that makes complete sense. I appreciate that update. And then just my only other question is regarding the T3 implant for hypothyroidism. Any thoughts on how quickly the preclinical program can move along, given that you've already studied the same technology in a Phase 3 setting?

Sunil Bhonsle:. Sure. You know, in this setting, there are two parts to - sort of as we've done with the program for Parkinson's, similarly with T3, one part has to do with optimizing the formulation itself and that's what we are doing currently. You think of the T3 program as being maybe six months or so behind the Parkinson's program in that process.

The second part, which is working out, you know, the details of what will be necessary for a pre-IND meeting and so on, I mean Kate can comment on that as well, but I expect by middle of next year we will be in a position where we can start that process with the FDA in the regulatory discussions.

So if you think of it overall, I would say, you know, we're maybe six months or so behind the Parkinson's program in getting this done and into the clinic as well. I would expect by middle of 2017 to be in that position, and maybe sooner if we, you know, have sufficient resources and push it faster.

Nisha Hirani:. Excellent, that's great. Thank you so much for taking my questions.

Sunil Bhonsle:. Sure.

Kate Beebe:. Thanks, Nisha.

Operator:. At this time, I'd like to turn things back to Mr. Bhonsle for closing remarks.

Sunil Bhonsle:. Thank you, (Kelly Ann). Thank you all for participating in this call. This quarter was a significant one for Titan with both the FDA's acceptance for a review of the resubmitted Probuphine NDA and our progress with the ProNeura platform, both with the ropinirole program and more recently the T3 program.

And last but not least, we are now trading on NASDAQ, which was a key milestone for us to accomplish this year as well. We look forward to providing you additional updates on our programs, and as always, we appreciate your support. Thank you for being on the call.

Operator:. Again, that will conclude today's conference. We thank you all for joining us.

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