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Officers and Speakers

- Sunil Bhonsle; Titan Pharmaceuticals, Inc.; President and Chief Executive Officer
- Jennifer Kiernan; Titan Pharmaceuticals, Inc.; Administration and Communications
- Marc Rubin; Titan Pharmaceuticals, Inc.; Executive Chairman
- Kate Beebe; Titan Pharmaceuticals, Inc.; Executive Vice President and Chief Development Officer
- Brian Crowley; Titan Pharmaceuticals, Inc.; Vice President, Finance

Analysts

- John Vandermosten, Zacks Investment Research
- Scott Henry, Roth Capital Partners, LLC

Presentation

Operator: Thank you for holding, and welcome to the Titan Pharmaceuticals Third Quarter 2017 Financial Results Conference Call.

(Operator Instructions)

Please be advised that this call is being taped at the company's request and will be archived on the company's website starting later today.

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

Sunil Bhonsle: Thank you, Amy, and thank you all for joining us. Welcome to the Titan Pharmaceuticals call to review financial and operational results for the third quarter of 2017 and recent business updates.

Before we begin, I wanted to inform you that this morning, we filed our third quarter 2017 Form 10-Q with the SEC, and the press release issued this morning provides a summary of the results and can also be found on our website at titanpharm.com.

Joining me on the call today from Titan are Dr. Marc Rubin, our Executive Chairman; Dr. Kate Beebe, Executive Vice President and Chief Development Officer; and Brian Crowley, our Vice President of Finance.

But before we provide an update on the company and the summary of financial results, Jennifer will review the required cautions regarding forward-looking statements. Jennifer, please?

Jennifer Kiernan: Thank you, Sunil. I want to remind everyone that certain matters that will be discussed today, other than historical information, may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to our product development programs and any other statements that are not historical facts. Such statements involve risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price.

Factors that could cause actual results to differ materially from management's current expectations include those risks and uncertainties relating to the commercialization of Probuphine; the regulatory approval process; the development, testing, production and marketing of our drug candidates; patent and intellectual property matters; and strategic agreements and relationships.

We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

And now, back to you, Sunil.

Sunil Bhonsle: Thank you, Jennifer. We will start the call with an overview from our Executive Chairman, Dr. Marc Rubin, followed by Dr. Kate Beebe, who will provide an update on our product pipeline, and then Brian Crowley will summarize the financial results. I will close with a brief recap before opening the call for your questions. So let's get started. Marc?

Marc Rubin: Thank you, Sunil, and thank you all for joining us today for a review of our business highlights for the quarter and an update on progress on our portfolio of products based on our ProNeura long-term continuous drug-delivery technology.

I want to begin by addressing the decline in Probuphine revenue for the quarter. While we did certainly anticipate that the adoption of Probuphine for the year or so post-launch would be a measured one, we were, however, very surprised and disappointed with the decline in its sales this quarter. Feedback from Braeburn, as well as feedback from key opinion leaders, indicates that patient access to Probuphine has been negatively impacted by issues related to the timing and level of reimbursement by third-party payers, as well as requirements of the risk evaluation and mitigation strategy, or REMS, programs as proscribed by the FDA.

And as an example of the former issue, it can take weeks or even months for an insurance provider to approve coverage from the time a preauthorization claim is submitted. This kind of delay in receiving a much-needed and a potentially life-changing treatment is frustrating to both the patient as well as his or her health-care provider, and it is especially disappointing in light of the ongoing national opioid epidemic.

I do want to take a moment to address the changing landscape of treatment options for opioid use disorder. In the next several months, two companies have PDUFA dates for depot formulations of buprenorphine. Indivior is a company with monthly depot formulations, and Braeburn with both weekly and monthly formulations, and both companies' products received positive advisory committee votes last week, as you probably know. If approved, these products should continue to shift the current treatment paradigm away from daily oral therapy and towards longer-duration, procedure-oriented treatments. We believe that this dynamic should have a positive effect on the acceptance and uptake of Probuphine as patients enter the maintenance treatment stage. Opioid use disorder is a chronic neurobiological disease requiring ongoing treatment, often for years, and so we strongly believe that patients can benefit from transitioning to Probuphine for maintenance treatment, and of course, we continue to believe in the long-term medical value of, and the prospects for uptake of, the product.

In light of the current sales of Probuphine to date, we do expect that we will need additional capital by the second half of 2018 in order to continue advancing our ProNeura development programs. We are evaluating alternatives and potential pathways available to us, including ex-U.S. partnering opportunities for Probuphine, possible collaborations for one or more of our ProNeura programs, and financing strategies.

Importantly, I want to assure you that in addition to these alternatives that I just mentioned, and in addition to our discussions with Braeburn and with treatment providers that are aimed at a fuller understanding of the impediments to the uptake of Probuphine, the board is actively assessing all operative and strategic business options available that can increase shareholder value. We will keep you informed.

I now want to turn the call over to Dr. Beebe to provide additional details on our development programs, including our efforts to secure approval and partnerships for Probuphine in Europe, as well as our ropinirole implant for Parkinson's disease and our early-stage programs for the prevention of opioid use relapse and overdose, chronic pain, type 2 diabetes, hypothyroidism and the prevention of malaria, as well as other chronic disease settings. Kate?

Kate Beebe: Thank you, Marc, and hi, everyone.

As you know, our portfolio is based on our proprietary ProNeura technology, which is designed to provide long-term continuous drug delivery for up to 12 months. We remain optimistic and committed to the prospects of ProNeura across a diverse range of chronic diseases.

First, let me start with an update on Probuphine outside of the United States. While Braeburn holds commercialization rights to Probuphine in the U.S. and Canada, many of you know that we retain rights to Probuphine in Europe and other territories. Our initial focus for Probuphine outside of the U.S. is in Europe, which is the second-largest market for Probuphine-based products, with sales representing about 10% of the $2-plus-billion U.S. market.

This week, on Monday, November 6, we submitted our Marketing Authorization Application, or MAA, with the European Medicines Agency. We've also continued our discussions with the Irish

rapporteur and British co-rapporteur countries who will be leading the review of our MAA, and we've received scientific advice and support from both agencies for our application.

At the same time, we have continued to meaningfully advance discussions with potential commercial and development partners for Probuphine in Europe and elsewhere.

And lastly, in October of 2017, Titan received a Notice of Allowance from the European Patent Office for a patent covering methods and use claims for treating opioid dependence with a subdermal implant containing buprenorphine. Upon issuance, this patent is expected to provide protection for Probuphine in Europe into 2023.

Now, in addition, if approved by the EMA, Probuphine will receive eight to 10 years of data exclusivity from the date of approval. This means that potential competitors would not be able to reference the Probuphine data as part of a generic development program.

Now, turning to our ropinirole implant program for Parkinson's disease. The ropinirole implant is designed for the long-term continuous delivery of ropinirole HCl for the treatment of signs and symptoms of Parkinson's disease, like stiffness, tremors, muscle spasms and poor muscle control. Ropinirole is a dopamine agonist currently available in daily or more frequently dosed oral formulations for both the treatment of Parkinson's disease symptoms and restless leg syndrome.

In October, we treated the first patient in our Phase I/II trial of the ropinirole implant, and this study is progressing. The primary objectives are to characterize the pharmacokinetic profile of the ropinirole implants, to evaluate their safety and tolerability, and also to explore potential signals of efficacy using established disease-specific assessment scales. Patients on a stable dose of L-DOPA plus oral ropinirole will have their oral ropinirole switched to ropinirole implants for three months of treatment in this study. Initial data from the first cohort of patients is expected in the first half of 2018, and the study completion is targeted for the end of next year.

This quarter, we also announced that we are collaborating with Opiant Pharmaceuticals on a feasibility assessment of a ProNeura-based subcutaneous implant to administer an opioid antagonist for the prevention of opioid relapse and overdose. Currently, the only FDA-approved opioid antagonist for relapse prevention is a monthly depot injection of naltrexone. Our goal would be to develop a product with at least a six-month duration that would allow patients to be opioid-free for a longer period, providing a greater window for long-term recovery, and most critically, relapse and overdose prevention.

Relapse and fatal overdose among those with opioid use disorder is significantly higher than any other type of drug addiction. For example, as many as 91% of those in recovery will experience a relapse. At least 59% of those who relapse do so within the first week of sobriety, while about 80% relapse within a month after discharging from a treatment or detox program. The risk of a fatal overdose is at its highest during a relapse.

Now, we are also evaluating the feasibility of several other product candidates across a variety of different chronic disease indications for potential inclusion in our portfolio. Early nonclinical testing is being conducted for the development of a Kappa-opioid-receptor implant for the

treatment of chronic pain. If successfully developed and approved, this would offer a potential non-addictive opioid analgesic for the treatment of chronic pain.

We are also activing working on formulation optimization and early in-vitro testing for liraglutide, otherwise known as Victoza, for adults with type 2 diabetes.

Titan also presented data from a nonclinical study on the use of its ProNeura subdermal implant for the long-term sustained delivery of liothyronine, or LT3, during a poster session at the annual meeting of the American Thyroid Association. The ProNeura implants continuously released LT3 dose-dependently for more than six months, providing important initial in-vivo information for the potential development as a treatment of hypothyroidism.

In addition, Titan, the Southwest Research Institute and the Walter Reed Army Institute of Research, or WRAIR, are collaborating to evaluate the ProNeura platform for the long-term prevention of malaria. In November 2017, the WRAIR presented encouraging nonclinical data from this collaboration during a poster session at the annual meeting of the American Society of Tropical Medicine and Hygiene, demonstrating sustained release of antimalarial drug atovaquone and protection from malaria for up to 12 weeks. This program is being fully funded and conducted by WRAIR.

These early-stage product candidates will be prioritized and pursued as resources allow. Our ProNeura continuous long-term drug-delivery platform holds great promise for the treatment of select chronic diseases for which maintaining consistent levels of a medication in the blood over long periods of time may offer safety or other health benefits. We look forward to updating you on continued progress as we develop our portfolio of ProNeura-based product candidates.

Now I'll turn the call over to Brian. Brian?

Brian Crowley: Thank you, Kate. The summary of the financial results was provided in our press release this morning, and details are available in the Form 10-Q filed with the SEC. At this time, I will just highlight a few items.

In the third quarter of 2017, we reported approximately $40,000 in license revenue from royalties earned on net sales of Probuphine by Braeburn, compared with approximately $26,000 in the third quarter of 2016.

Research and development expenses for the third quarter of 2017 were approximately $2.7 million, compared with approximately $1.6 million for the third quarter of 2016, an increase of approximately $1.1 million. The increase in R&D expenses was primarily associated with increases in external expenses related to the support of our ropinirole implant program and expenses on other ProNeura product development programs.

General and administrative expenses for the third quarter of 2017 were approximately $1.4 million, compared with approximately $1.1 million in the third quarter of 2016. The increase was primarily related to increases in noncash stock compensation and employee-related expenses, fees and expenses related to the Horizon loan, and other expenses.

Net loss applicable to common shareholders in the third quarter of 2017 was approximately $4.2 million, or approximately $0.20 per share, compared with a net loss of approximately $2.6 million, or approximately $0.12 per share, in the same quarter in 2016.

At September 30, 2017, we had cash and cash equivalents of approximately $11.7 million, which we believe is sufficient to fund our planned operations through August of 2018. We are evaluating funding options, including, but not limited to, partnering opportunities for Probuphine outside of the U.S., collaborations for one or more of our ProNeura programs, and various financing strategies.

Now I will pass the call back to Sunil. Sunil?

Sunil Bhonsle: Thank you, Brian. While we are disappointed at the low numbers for Probuphine in the third quarter, we continue to believe that Probuphine has an important role in the treatment of opioid use disorder. The clinicians we have spoken with continue to indicate a desire to treat patients with Probuphine, and while the numbers are small, the patients appear to like the benefits this product can provide. However, the restrictive REMS program, together with inadequate reimbursement to patients and their doctors from insurance providers, has hampered adoption of Probuphine.

We are in dialogue with Braeburn to fully understand and address the issues limiting Probuphine sales, and as needed, establish new strategies to help advance adoption of the product. We will also be closely monitoring the treatment landscape as new extended-release and depot injections become available in order to identify the best position for Probuphine in the marketplace.

We're also pleased to announce that we filed the MAA for Probuphine with the EMA on November 6, and we also received a Notice of Allowance on a patent that will offer protection for Probuphine in Europe through 2023.

Now, simultaneously, we continue to advance our other ProNeura-based products with the belief that this long-term continuous drug-delivery platform can have significant advantages over current daily-dosed chronic disease treatments.

During the third quarter, we treated the first patient in our Phase I/II trial of ropinirole for the treatment of the signs and symptoms of Parkinson's disease, and we began a collaboration with Opiant Pharmaceuticals on a feasibility assessment of a subcutaneous implant using our ProNeura technology to administer an opioid antagonist for the prevention of opioid relapse and overdose.

Additionally, we are continuing feasibility evaluation and nonclinical studies in the areas of chronic pain with a Kappa-opioid-receptor agonist and type 2 diabetes with the currently marketed products.

Lastly, we reported encouraging nonclinical data from our programs in hypothyroidism and in the long-term prevention of malaria.

So, while we work rapidly to get Probuphine back on track, we intend to pursue these additional programs based on priorities and, of course, resources. Although we can't go into all the details right now, I want to assure you that the board and management are looking at all options for maximizing the value of Titan, both from the product portfolio and other strategic considerations. We look forward to reporting continued progress as we move forward.

This brings us to the end of our formal remarks. And now, Amy, if you are ready, we are ready to take questions from the call participants.

Questions & Answers

Operator: Thank you.

(Operator Instructions)

The first question is from John Vandermosten at Zacks.

John Vandermosten: Good afternoon, everyone.

Sunil Bhonsle: Hi, John, good afternoon.

Kate Beebe: Hi, John.

John Vandermosten: Just first wanted to get a sense of Braeburn's ability to get done what needs to get done. I'm thinking maybe a larger partner might have had the relationships or some other skills or experience that might have helped them do a little bit better, and I'm wondering if you can perhaps point to a few things that maybe you're missing that could be there, or -- for getting Probuphine -- deeper penetration of the product.

Sunil Bhonsle: Thanks, John. Certainly, our focus right now is to understand the nitty-gritty details of why Probuphine lost momentum. Clearly, there was momentum building in the second quarter, and when we saw the results for the third quarter, it was very disappointing to see that that momentum was not carried forward.

Now, it's been only a few days since we have learned of this progress, and so we've started digging. We've started talking with clinicians out in the field to understand what are the issues. We have, of course, spoken with Braeburn to understand how they see it. And this is going to continue for a few days. So I cannot give you specific answers now, except assuring you that we really are getting involved in the details to understand this and come up with strategies that will provide the correct -- getting Probuphine on the correct track. That is really our commitment and goal, and that's what we are attempting to do. I'm sure that benefits everyone, including Braeburn, but we will look forward to seeing how best to progress this from here on.

John Vandermosten: Okay. And Mike took over as CEO back in June, and I was wondering if maybe he changed the strategy up, and every time there's a change in strategy maybe there's a

little slowdown or something until the new approach kicks over, and I was wondering if that might be part of it.

Sunil Bhonsle: John, I mean, it's certainly -- Mike, and our conversations with Mike when he came in, clearly had intended to support Probuphine just as it had been previously, and their commitment to that product, we felt, was strong. Of course, it's the only product they are currently marketing. Our dialogue with Braeburn, which is periodic, they always indicated that they continue to support Probuphine. So in that sense, that's all I can point out, that that's what they have indicated. Clearly, at the same time, the momentum was lost. So how and why, that's the key part we want to find out, and we will.

John Vandermosten: Okay. And then, the licensing agreement with Braeburn, are there certain minimums that have to be met to maintain the license, or once they have it, they have it, and they can do whatever they want with it?

Sunil Bhonsle: The licensing agreement does not have minimums in it. It does require them to actively market and support the product, similar to other products that they would. So it has some things, but not specific to minimums, so these are typical of the licensing agreements for new products, and that's how it's set.

John Vandermosten: Okay. And then, Canada: I know that they sublicensed that to Knight, I believe.

Sunil Bhonsle: Yes.

John Vandermosten: Has there been any sales in Canada yet?

Sunil Bhonsle: It has not been approved in Canada yet. I believe it's sometime next year, in mid-next year or so, is what the dates seem to -- that I recall for approval in Canada.

John Vandermosten: Okay, okay. And then, just the last question is on R&D expense and, as we've continued with the development programs, it's come up a little bit, and I guess we should expect a similar level to continue through the fourth quarter and into next year.

Sunil Bhonsle: To some extent, the third quarter included the startup of parts of the ropinirole study, but also some of the expenses associated with filing the MAA that we just did in the beginning of November. So preparation of these things took some extra expenses.

We, of course, are very conscious of, now, the cash position we are in as well, and what potentially we may see as revenues from Probuphine, so we will look to contain our expenses within manageable levels. Key part, of course, is the ongoing clinical study for ropinirole, which we intend to pursue, and we will keep things in mind with other programs to make sure we stay within our budget. So I would expect the fourth quarter research and development expense to be probably a little less than the third quarter, but not by a lot.

John Vandermosten: Okay, thank you, Sunil.

Sunil Bhonsle: Sure, John. Thank you very much.

Operator: The next question is from Scott Henry at Roth Capital.

Scott Henry: Thank you, and good afternoon. Just a couple questions.

Sunil Bhonsle: Hey, Scott. Glad you could join in.

Scott Henry: Oh, certainly. As you kind of survey the landscape to try to get a sense of what's happening with Probuphine, what kind of feedback have you received from physicians? Is there a general -- is demand not the issue, and it's more of the execution of getting reimbursement? Or just any feedback that you're getting that you find interesting.

Sunil Bhonsle: Well, I mean, certainly, we have spoken with a handful of clinicians out in the field. We haven't -- so it's not a large group yet. We are doing this and continuing to do this. What we do see is that patients who are treated like this product. That's what they have indicated. They have indicated that patients that they believe would benefit, and when they talk to them about it, they get a favorable response. So it's good from that standpoint, at least in the small numbers, positive feedback about the patients is very good. What frustrates the physicians is the length of time it takes to get preapprovals. They give us examples where it goes from few weeks to few months, and their maintaining patients' enthusiasm to switch to this treatment is not so simple when it takes that long. And so, these are the frustrations that the physicians talk about. The -- how best to address that clearly has to also do with the insurance systems, and this should be addressed and will be addressed.

Scott Henry: Okay, great. Thank you for that color.

Sunil Bhonsle: (Inaudible) the patient.

Scott Henry: If I could just ask another question, with regards to monetization of some of the pipeline products or the ex-U.S. rights, what sort of timetable would you expect? I mean, obviously, you don't know for certain, but do you think you could monetize something in the next six months? Or just any color you could provide.

Sunil Bhonsle: Sure. Yes, I mean, the -- obviously, the farthest along we have been pursuing Probuphine in Europe and the potential for establishing a partnership for that, and we certainly hope that over -- in the next six-month period, that that is in place. Clearly, submitting the MAA is a major milestone. It starts a clock ticking in terms of acceptance, approval and all these things that come down the road. So that is certainly something we are very eager and keen and interested in pursuing as rapidly as we can.

Outside of that, you know we are collaborating in the early assessment with Opiant Pharmaceuticals with an antagonist implant for treating opioid disorder, and that, the early assessment results from both the technical side, which we are pursuing, and the commercial evaluation that Opiant is doing, will be available in the first half of next year. And I certainly

hope that that will be a successful result that can lead into a potential program as well that has value and shows substantial value added to Titan.

So those certainly are the early ones we have, and obviously, the WRAIR, the Walter Reed program, going on, and we look for funding for that from the government, and if that's available, that will be very meaningful. And we will look at other avenues, including what NIH can provide for, say, the collaboration with Opiant and others. Okay?

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

Sunil Bhonsle: Thank you very much. Take care.

Operator: The next question is from John Vandermosten at Zacks.

John Vandermosten: I just had a followup.

Sunil Bhonsle: Hey, John.

John Vandermosten: Hello again. Is there any way that the Opiant collaboration might get ahead of the ropinirole or T3 programs at all? Just because it maybe has a lot more focus or partners eager to push it along?

Sunil Bhonsle: I mean, that's certainly a very timely program. It has -- there's a lot of attention to the epidemic opioid crisis right now. And funding for something like that, if it is made available by the NIH, it can certainly speed up that program tremendously. So it's our hope that that will be the case, that it's a meaningful program and is looked at that way by the medical community, as well as NIH.

John Vandermosten: Okay, thank you.

Sunil Bhonsle: Sure.

Operator: This concludes our question-and-answer session, and I would like to turn the conference back over to Mr. Bhonsle for closing remarks.

Sunil Bhonsle: Thank you, Amy. Thank you, everyone, for participating in this call today. I know it's not an easy one at times, but trust us, we are trying to accomplish a lot during this coming quarter, and we will attempt to get Probuphine back on track. As always, we appreciate your ongoing support, and we will provide periodic updates as we move forward.

So thanks, everyone, and have a good day.

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