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**Officers and Speakers:**

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**Analysts:**

Scott Henry, Roth Capital Partners, LLC

John Vandermosten, Zacks Investment Research

**Presentation**

**Operator:** Thank you for holding, and welcome to the Titan Pharmaceuticals Second Quarter 2017 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 website 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.

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

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

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, Vice President of Finance.

But before we get started with the financial results and provide an update on the company, I would like Jennifer Kiernan to review the required cautions regarding forward-looking statements. Jennifer?

**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. Today, we will start the call with an overview from our Executive Chairman, Dr. Marc Rubin. That will be 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. Marc?

**Marc Rubin:** Thank you very much, Sunil, and hello, everybody. Thank you all for joining us. We are pleased to be here today to share with you our business highlights for the quarter and to update you on the progress we're making across the portfolio of products based on our ProNeura long-term continuous drug-delivery technology.

I would like to begin with a note about the loan agreement we secured with Horizon Technology Finance Corporation in July. This provides Titan up to \$10 million in borrowing capacity. The first tranche of \$7 million was funded upon execution of the loan agreement, and this significantly expands our cash runway with minimal dilution for stockholders. This financing will help support our growth of our product portfolio while Probuphine establishes a good hold as an important treatment option for opioid dependence.

And now, I'd like to focus on the progress that's been made during the quarter with our pipeline of product candidates based on our ProNeura platform.

During the quarter, our partner, Braeburn Pharmaceuticals, continued to execute on the full commercial launch of Probuphine, which began earlier this year. As you all know, the commercial product is based on our long-term delivery technology, ProNeura, and it's now the

only product available for the six-month, long-term treatment of opioid addiction. Braeburn continues to make progress with the launch, and I'd like to share some of the highlights now.

- The number of patients seeking treatment with Probuphine grew during the second quarter, which was reflected in the license revenue of \$77,000, which, although it was less than we would all like to see, it does represent a significant increase - in fact, a 93% increase - over the first quarter.
- Braeburn has indicated that the majority of patients completing their first six-month treatment with Probuphine during the second quarter opted for treatment continuation.
- Early in the second quarter, Braeburn expanded its distribution channels and processing capacity by adding a second specialty pharmacy company to increase third-party payor coverage across the country.
- Braeburn indicated continued progress with third-party payor document processing and reimbursement. However, this progress is not yet completely consistent across payors.
- Finally, in June, Braeburn appointed former head of CNS and Pain Therapeutics for Teva Pharmaceuticals Mike Derkacz as its president and CEO. Mr. Derkacz has deep commercial experience launching new pharmaceutical products, particularly depot and medical device products, and we're very encouraged by this appointment at Braeburn. We've met with Mr. Derkacz, and we firmly believe that he is committed to maintaining a strong focus on opioid-dependence treatments, and importantly, to advancing the commercialization of Probuphine.

Commercial uptake of Probuphine thus far has been slow, and we absolutely share stockholders' frustration with this. Given the severity of the opioid epidemic and the limited medically-assisted treatment options available, we would have certainly hoped for fewer hurdles to patient access. However, we are encouraged by the actions Braeburn has been, and is, taking to address the challenges it's facing. We continue to expect Probuphine sales to gradually increase over the next several quarters, as third-party payor coverage improves and access to Probuphine expands.

At the same time, it's important to put Probuphine's launch into the context of the evolving market dynamics for opioid dependence treatments. Along with a continued emphasis from the medical community and the government on expanding access to treatment, particularly medication-assisted treatment, there is a growing understanding that opioid addiction is a severe, chronic, neurobiological disease that requires long-term treatment. Today, more than 2.4 million Americans are battling opioid addiction. Long-term treatments that focus on enhanced compliance and quality of life are the goal of opioid addiction treatments and are receiving strong recognition in the medical community.

More specifically, we believe Titan will benefit from the trend of opioid addiction treatment's move towards extended-release formulations, which will include one-week and one-month depot injections, and two companies have recently submitted new drug applications to the FDA for these types of products. These products, if approved, will focus on patients during the initial stage of the treatment, which can then enable clinicians and patients to become accustomed to procedure-oriented treatment, which we believe will have the potential to significantly enhance the use of Probuphine during the maintenance-treatment stage.

In a moment, Dr. Beebe will 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, our T3 implant for hypothyroidism, and our early nonclinical research in other chronic disease settings.

So the board is very supportive of Titan's product development activities, and we look forward to further advancing our ProNeura-based product portfolio in the coming months, especially with potential products that can garner early support from other companies and research institutions, and help build further value in the company.

And with that, I will now turn the call over to Kate, who will provide an update on the product pipeline. Kate?

**Kate Beebe:** Thank you, Marc, and hello, everyone. I'm very pleased to provide you with additional details of our product development pipeline.

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. Our first commercialized product based on ProNeura, Probuphine, provides an important validation of our technology, and we are moving forward with advancing product candidates across a diverse range of indications.

First, I'll start with an update on Probuphine outside of the United States. While Braeburn holds commercialization rights to Probuphine in the U.S. and Canada, 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 more than \$2 billion U.S. market.

During the quarter, we continued to make progress in our efforts to advance the regulatory review process of Probuphine in Europe. As you may know, the European Medicines Agency, or EMA, in the first quarter, informed us that Probuphine is eligible to follow the centralized review and approval process for its Marketing Authorization Application, or MAA. In the second quarter, the EMA appointed two member countries, Ireland and the U.K., as rapporteur and co-rapporteur for Probuphine, respectively. Last month, we met with these regulatory authorities in person. We familiarized them with the overall Probuphine development program, and received

their advice on the MAA preparation and presentation. Overall, we received strong support for our application, and we are on track to submit it to the EMA later this year.

During the second quarter, the EMA also granted a pediatric indication waiver for Probuphine, which simplifies preparation of the MAA by eliminating the need for submitting detailed clinical evaluation plans for a pediatric indication, and importantly, means that we will not be required to conduct a clinical study in children and adolescents.

Additionally, this regulatory clarity has allowed us to advance our discussions with potential commercial partners for Probuphine in Europe and elsewhere. Our goal is to have a partnership in place around the time we file the MAA later this year.

Next, I'd like to discuss our ropinirole implant for Parkinson's disease program. 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, including stiffness, slowness of movement, tremors, muscle spasms, and poor muscle control, among others. 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.

As you may know, we are pursuing a 505(b)(2) registration pathway for this product candidate.

As we've announced previously, we submitted an investigational new drug application with the FDA in January following completion of required non-clinical studies. We received verbal communication in February, followed by written confirmation from the FDA in late March, requesting additional information on the final release test data on the implant and on the applicator before the clinical trial proceeds. The work required to collect the FDA-requested information was completed as planned, and the information was submitted to the FDA in mid-July. The review date communicated by the FDA is August 13, and as previously indicated, we hope to receive FDA authorization to start the clinical study in the third quarter. We have selected clinical sites for the Phase I/II pharmacokinetic study and qualified the first site so that we can begin screening study subjects immediately following FDA clearance of the IND.

This study will enroll Parkinson's disease patients who are receiving adjunctive therapy with oral ropinirole. Their oral ropinirole therapy will be replaced with the ropinirole implant, to first characterize the pharmacokinetic profile of the implant, to assess its safety and tolerability, and to explore efficacy over a three-month treatment period.

We were also excited in the quarter to embark on a new program to evaluate the development of ProNeura-based implants for the prevention of malaria. This work is being done through a Cooperative Research and Development Agreement, otherwise known as a CRADA, with the Walter Reed Army Institute of Research and the Southwest Research Institute, which we announced in July. Results from the initial nonclinical studies were presented by the

Experimental Therapeutics branch of the Walter Reed Army Institute of Research at the 2017 Asia Pacific Military Health Exchange in Singapore. This program is being funded and conducted by the Walter Reed Army Institute of Research.

And finally, I'd like to say a few words about our existing pipeline of product candidates. We are completing the nonclinical evaluation of a reformulated T3 implant for hypothyroidism. Our in-vivo nonclinical studies, which evaluated implant formulations for drug-release characteristics, demonstrated non-fluctuating levels of T3 over several months in small and large animal models. We believe that this delivery system more closely approximates the normal endocrine physiology and may confer additional benefits to patients. We will evaluate further development of this product, dependent on available resources.

We are also assessing the feasibility of several other product candidates across a variety of different chronic disease indications for potential inclusion in our portfolio, with a focus on products with potential for early support from commercial partners and/or research institutions, and these include liraglutide, otherwise known as Victoza, for adults with type 2 diabetes, and other opportunities that we look forward to sharing with you in the future.

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, and we look forward to expanding our portfolio and advancing our existing product candidates.

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

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

For the second quarter of 2017, we reported approximately \$77,000 in license revenue from royalties earned on net sales of Probuphine by Braeburn, a 93% increase over the prior quarter. The \$15 million in revenue in the same period a year ago reflected the one-time milestone payment that was earned from Braeburn upon approval of Probuphine by the FDA.

Research and development expenses, or R&D expenses, for the second quarter 2017 were approximately \$2.5 million, compared with approximately \$1.7 million for the same quarter in 2016, an increase of approximately \$0.8 million. The increase in R&D expenses was primarily associated with increases in external expenses related to our Probuphine and ProNeura product development programs and other research and development activities.

G&A expenses for the second quarter of 2017 and 2016 were approximately \$1.2 million.

Net loss applicable to common shareholders in the second quarter of 2017 was approximately \$3.5 million, or approximately \$0.16 per share, compared with net income of approximately \$11.9 million, or \$0.58 per share, in the same quarter of 2016.

We had cash and cash equivalents of approximately \$8.4 million as of June 30, 2017. In July 2017, we completed a debt transaction providing us with up to \$10 million in borrowing capacity. A first tranche of \$7 million was funded upon execution of the loan agreement. We believe that the funds available at June 30, 2017, together with the net proceeds from the first tranche of the Horizon loan, are sufficient to fund our operations into the first quarter of 2019.

Now I'll pass the call back to Sunil, and I'd be happy to address any questions you may have during the Q&A at the end of the presentation. Sunil?

**Sunil Bhonsle:** Thank you, Brian. As you have heard from Marc, Kate and Brian, it's been a productive quarter, and we're looking forward to continued progress in the second half of 2017. As Marc mentioned, while the slowness of the commercial uptake of Probuphine to date is frustrating, we are very encouraged by the progress Braeburn is making, and we expect the positive trends in patient treatment, third-party payor coverage, and revenue from Probuphine will continue at a steady pace throughout the year. The medical community continues to view Probuphine as an important treatment option, and Braeburn is committed to the successful launch of the product.

We have also made further progress in Europe. We have met with the rapporteur and co-rapporteur countries, the teams that are evaluating Probuphine for the EMA, and provided the full background on the development of the product. In turn, we have received advice on the MAA preparation and presentation, which we expect to file in the fourth quarter. The regulatory clarity resulting from this dialog has also helped advance our discussions with potential partners for Probuphine in Europe, and as you know, our goal is to have a partnership in place around the time we file the MAA.

Building value through a product pipeline is important, and we are looking forward to potentially advancing our ropinirole program into the clinic this quarter. We have identified clinical sites for the Phase I/II pharmacokinetic study and have made preparations to initiate the first site pending FDA clearance of the IND.

In the second quarter, we also began a new program to evaluate the development of ProNeura-based implants for a long-term regimen in the prevention of malaria, and this is in conjunction with Walter Reed Army Institute of Research and the Southwest Research Institute. The non-clinical evaluation of reformulated T3 implant for hypothyroidism is nearing completion, and we are progressing with our early-stage non-clinical research with a focus on programs with early partnership potential and our external support for the development program from other research institutions.

So I'll summarize with saying, while Probuphine provides a significant validation of our ProNeura technology and remains an important part of our portfolio, we are very committed to building our product pipeline and adding value for our stockholders based on achievements with our other ProNeura-based products.

This brings us to the end of our formal remarks. And now, Allison, we're ready to take questions from the call participants.

## **Questions & Answers**

**Operator:** Thank you. We will now begin the question-and-answer session.

(Operator Instructions)

Our first question will come from Scott Henry with Roth Capital.

**Scott Henry:** Thank you, and good afternoon, guys.

**Sunil Bhonsle:** Hi, Scott.

**Scott Henry:** Hello. Just a couple questions: I guess, first, when we think about the ramp for Probuphine and when we may see an inflection point, how do you see the distribution and reimbursement channel looking in third quarter versus second quarter? Are there any fundamental changes in the next quarter such as new payors, or anything that we should expect differently, or is it more, just, continue to execute within the constraints that you have?

**Sunil Bhonsle:** Very good question, Scott. I mean, clearly, the major challenge to rapid uptake of Probuphine has been in getting timely processing of the pre-approvals that are necessary before a Probuphine treatment can start. So the process takes, essentially, patients are identified by the clinician, they go ahead and submit all of the paperwork, and then, if it is not approved in a timely manner, you go into a whole process where you're not sure the patient will still continue to get treated with Probuphine, and so on. So you create an environment that is somewhat not conducive to this process.

What Braeburn has done is two things: One is, added a second specialty pharmacy. As you know, specialty pharmacies have, also, relationships with the third-party payors, and typically work well with certain third-party payors. So having more distributions through specialty pharmacies provides a broader access, makes it easier in dealing with the third-party payors. The second part is, the J code that was approved at the beginning of this year, it takes some time for the third-party payors to assimilate that information into their computerized systems. As you know, when a paperwork comes in, the person reviewing it is going straight to the computer system, and if they don't see the right codes in there, it becomes a tedious process. So these two things certainly are helping towards getting a better process in place, and what is being seen in



the latter part of last quarter is that it's been still somewhat -- the consistency isn't fully there. But that's what Braeburn is trying to accomplish. So I certainly hope and expect that the process will improve. The encouraging part is that the medical community does accept Probuphine as a product that is an important part of the treatment milieu. They are looking to treat patients with Probuphine and prescribing it, and that's a very strong position to have, so that once the processes fall in place, it will help improve the uptake.

**Scott Henry:** Okay, great. Thank you for that color. And, I guess, just one other question: Given that there are really no similar treatments available, and compliance is such an issue with these products, or with the oral products, are you noticing any patient awareness out there in the market, or are patients starting to be aware of this, and at some point would you expect that patients would request Probuphine?

**Sunil Bhonsle:** I mean, certainly, awareness of Probuphine and long-term treatments is a very important part of spreading the use of this. And Kate can probably add to that in more details with what's happening in the whole industry.

**Kate Beebe:** Yeah, Scott, I would just say that I think we've always had really good awareness on the patient level, and very good demand. You'll recall that all of our Phase III trials enrolled months ahead of schedule, meaning there's a lot of pent-up demand out there. And I think it's really just a matter of Braeburn continuing to do the work that Sunil described in getting the third-party payor system more efficient and user-friendly, not just for the patients but for the doctors who are treating them.

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

**Sunil Bhonsle:** Thank you, Scott. Appreciate it.

**Operator:** Our next question will come from John Vandermosten with Zacks Investment Research.

**John Vandermosten:** Good afternoon, Sunil, Kate, Marc, and Brian. How are you?

**Kate Beebe:** Hi, John.

**Sunil Bhonsle:** Hey, John.

**John Vandermosten:** Just a few questions: One thing I've heard anecdotally is that a lot of payors, when a new product comes out, for the first six months or so, they don't put it on the formulary, just trying to see if there's interest, and also probably trying to control costs a bit too. And I'm wondering if that's something that is applicable to Probuphine as well.

**Sunil Bhonsle:** It's a very good question. From what we were informed by Braeburn, when they met with the third-party payors over the latter half of last year and early this year, that the general acceptance of Probuphine was good. They received positive comments, and that more than 70 third-party payors were -- acknowledged that they will be putting this on their medical benefits programs.

Now, the reality -- and that's very encouraging, on the one side, but when the actual process to get approvals and so on, you see some of the challenges and hurdles over there. So now whether that is because the full implementation at the third-party payor end has not been completed that causes some of these delays, certainly I'm sure that is part of the problem. But whether that's sort of a way for the third parties to monitor what's happening in the first six months, I really don't have a way of judging that, so. But, so, on the one side, I can say the acceptance was good when Braeburn was trying to get it into the third-party payors, but on the other side, the hurdles are still there, so. I can read between the lines, I guess, at what -- it takes time.

**John Vandermosten:** Exactly. And since Mike took over, and I guess it's been a month or so, maybe a little bit longer, has he put in any new initiatives, I think, different from what was in place before? In terms of trying to change things around, given his experience in the space?

**Sunil Bhonsle:** In terms of our -- and we've had a chance to meet with Mike, and then also talk to him after a period of time to see how things are progressing, his -- first of all, both Marc and I, when we met with him, he's very straightforward and focused, marketing-oriented and commercialization-oriented approach to the business, which is very good for what Probuphine needs. Clearly, he has focused on what is the important pieces for success, and in that setting, looking at which are the regions, which are the centers, that truly are actually using Probuphine, and wants to make sure that they get the focus and resources necessary to continue to build on that. So, it's -- in one way, it's to look at it saying, okay, there are clearly areas where Probuphine has been successful. There are regions where it is still not a major treatment. So they are continuing to do that.

At the same time, over the next few months, there are some clinical studies that were commitments as part of the approval of the product that are expected to start, and this has to do with, for instance, retreatment in a previously-used site, and things like that, that will commence. And I think that will also start building awareness of Probuphine and the support that Braeburn is putting behind the longer-term success of Probuphine and building on its capabilities as well.

So in all of this, I think both Mike's attention to how best to succeed in this setting, and one of the comments that he made to us was also that, look, the ability of having their one-week and one-month depot injections once those are approved really enhances the capability of Probuphine to come in as the long-term treatment. He sees it as a sort of -- from the beginning to the end capability that Braeburn will have to treat patients, and the earlier they get patients onto a

procedure-oriented treatment, the easier it becomes to get them into long-term maintenance treatment with Probuphine.

So he sees this as a synergistic program, and truly looks at it as a long-term treatment paradigm, which the whole industry, he expects, is shifting towards. And he feels they're at the right place at the right time.

**John Vandermosten:** Okay.

**Sunil Bhonsle:** Yeah. Marc, anything you want to add to that?

**Marc Rubin:** I'm sorry, Sunil, were you talking to me? I -- that got muffled.

**Sunil Bhonsle:** Right, no, I was just saying, if there's anything you wanted to add about our meeting with Mike Derkacz.

**Marc Rubin:** No, nothing to add. I think you covered it. We were very encouraged by the meeting, as you said. I think he's -- has tremendous experience, is clearly committed to this space overall and to Probuphine, and so it was a very good meeting. We're very encouraged by the hiring of Mike.

**Sunil Bhonsle:** Right.

**John Vandermosten:** And just a further question on efforts on the government level to perhaps support Probuphine and addiction management: It seems like probably a year ago, the federal government would take a lead here, but it seems like nothing much is happening on that side, so I was wondering if you have seen any efforts on the state level that might be supportive of Probuphine, or any addiction-management-type products?

**Sunil Bhonsle:** I mean, clearly, there's a lot of rhetoric that you see about wanting to support addiction. The funding has always been the issue. The federal funding hasn't fallen in place yet, just from what I have been able to see, but some states are, indeed, building on that. And sort of the two, three more recent examples that I read, one was where the states are actually now thinking of providing treatment in their prison systems rather than only looking to provide something at the end, when they're leaving. So that whole process of, hey, there's a lot of recognition that a lot of the population in the prisons are addicted to opiates, and providing treatment, that is -- it requires funding. And so they're willing to do that now. The direct increase through Medicare-type programs and so on, I haven't read much about that. I don't know if Kate, Marc, or Brian have seen something on that.

**Kate Beebe:** Nothing -- I haven't seen anything recently, but I know that states are continuing to work towards healthcare parity for substance-use-disorder treatment. That's on a state-by-state basis, but just to add, Sunil, to what you've said, I think, clearly, the epidemic of opioid use

disorder is gaining a lot more attention. There was a high-level Senate meeting that was held by President Trump this week. There have been calls for naming the opioid crisis as a major health crisis, a medical emergency, so to speak, and you're probably aware that the son of the mayor of Nashville, Tennessee, died last -- two weeks ago of an opioid overdose, and she's been doing a lot of interviews recently. So, raising public awareness, this is at the highest level of government, and I myself have been participating in an opioid summit with leadership from NIDA, from Health and Human Services, from FDA and NIH, that were continued. So I really think that we're moving towards a time when access to care will be addressed in a more strategic way.

**John Vandermosten:** Okay, thank you for (*technical difficulty*) - appreciate it.

**Operator:** And, ladies and gentleman, that is all the time that we have for our questions today. I would like to turn the conference back over to Mr. Sunil Bhonsle for any closing comments.

**Sunil Bhonsle:** Thank you, Allison. And thank you, everyone, for participating today. We look forward to a busy and successful second half of 2017, and we remain enthusiastic about the progress that is being made, both by Braeburn and by us with our product portfolio.

I know this is a period where everyone would like to see rapid progress, but sometimes patience is also -- has its rewards. I believe Probuphine will become successful, but it does require some time. And we look forward to the next few quarters to see the trends that can be assessed and provide more information to all of you during these conference calls.

So thank you, once again, for your support, and we look forward to speaking to you the next time.

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