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Presentation

Operator: Good afternoon. Thank you for holding, and welcome to the Titan Pharmaceuticals full year and fourth quarter 2016 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'd like to turn the conference call over to Sunil Bhonsle, President and CEO of Titan Pharmaceuticals. Please go ahead.

Sunil Bhonsle: Thank you, Jamie, and thank you all for joining us. Welcome to the Titan Pharmaceuticals call to review financial and operational results for the full year and fourth quarter of 2016 and recent business updates.

Before we begin, I wanted to inform you that on March 16, today, we filed our 2016 Annual Report on Form 10-K with the SEC, and the press release issued this morning provides a summary of the results and can 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, 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, Jennifer Kiernan will 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 conditions 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.

As always, we will start 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 by reviewing our goals for this year before opening the call for your questions. Let's get started. Marc?

Marc Rubin: Thank you very much, Sunil, and hello to all, and, as always, thank you for joining us this afternoon. We are very pleased to be here today, as we always are, to be able to share with you an overview of our accomplishments in 2016 as well as an update on Probuphine and an update on our pipeline of products based on our ProNeura long-term, continuous delivery platform.

As you know, following FDA approval in May of 2016, Probuphine is now the first and only product available for the six-month, long-term maintenance treatment of opioid addiction in adults stabilized on 8 mg or less a day of buprenorphine. We're very proud of this achievement, particularly as Probuphine is our first commercialized product employing our long-term continuous drug delivery technology. We view Probuphine's approval as a strong validation of ProNeura, which is the delivery platform used in our products in development for Parkinson's disease and hypothyroidism.

So let me start with an update and an overview of Probuphine. Following Probuphine's approval last May, our partner, Braeburn Pharmaceuticals, began a medical affairs-driven product introduction, and this has recently been augmented by a full commercial launch. We are very encouraged by their progress to date. Braeburn is fully committed to the long-term commercial success of Probuphine and has laid a strong foundation for that to happen.

So let me give you a brief recap of Probuphine in 2016. More than 2,500 healthcare providers received training in 2016 under the REMS program, and they were certified to provide Probuphine. More than 70 payers, including private insurance, Centers for Medicare and Medicaid Services, or CMS, and VA programs now cover Probuphine.

As I just mentioned, following a medical affairs-driven introduction of Probuphine in the second half of 2016, Braeburn commenced a full commercial launch of Probuphine in the first quarter of this year, with 60-plus field salesforce and medical support staff focusing on more than 80 key treatment centers that they have targeted as future centers of excellence for the treatment with Probuphine.

Probuphine also received a permanent J-code from the CMS that became effective in January of this year, facilitating the third-party payer reimbursement process. Braeburn continues to work to obtain additional codes to further facilitate reimbursement of the Probuphine insertion and removal procedures. Additionally, scientific data confirming Probuphine's effectiveness continues to be presented at key conferences, including the International Society of Addiction Medicine, the American Society of Addiction Medicine, and the College on Problems of Drug Addiction.

As you saw from our release this morning, Braeburn has accomplished a great deal since commencing commercialization of Probuphine, and we expect a gradual ramp-up to continue over the next several quarters. I'd like to take just a few moments to provide you with a bit of context around that.

First, the commercialization of Probuphine comes as the field of addiction is certainly experiencing a significant paradigm shift that has broad ramifications for patients, for providers, and those of us who have developed new, innovative addiction treatments. The treatment market in 2016 for addiction grew in the range of 8% to 9%, and more physicians were certified to treat addiction with medication-assisted treatment than ever before.

There are currently more than 37,000 DATA 2000-certified buprenorphine prescribers, according to the Substance Abuse and Mental Health Services Administration. Today, more than 2.4 million Americans are battling this chronic relapse in disease. 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 requiring long-term treatment.

We believe, as does Braeburn, that treatments that focus on minimizing diversion, enhancing compliance and improving the quality of life of patients are the wave of the future in opioid addiction treatment, and they will be receiving gradually increasing and ultimately strong market validation.

While this shift is positive, the nature of launching a long-term treatment such as Probuphine is complex and challenging, and it requires a higher level of physician and payer education and support than do many products. There have also been challenges with expanding coverage and reimbursement, including payers' requirements to physicians to buy and bill and a process among

insurers to cover new products that is somewhat cumbersome. These market-wide trends and challenges are not unique to Probuphine, however. They're being experienced both within and outside the addiction treatment market.

But, importantly, we are encouraged by the very substantial resources Braeburn has deployed and will continue to deploy to address and overcome these challenges. And we certainly remain confident in their ability to build a strong foundation for the long-term success of Probuphine.

As we continue to follow the commercial progress of Probuphine, we are advancing our other product development programs, and in just a moment Dr. Beebe will provide additional details on our pipeline, in particular our ropinirole implant for Parkinson's disease and our T3 implant for hypothyroidism, as well as our efforts to secure approval for Probuphine in Europe.

But before I conclude I'd like to acknowledge some additional accomplishments in 2016 and in the first quarter of this year. In June, we were added to the Russell 3000 and 2000 Indices, bringing us broader exposure among new potential institutional investors, and we also welcomed two new Board members, Mr. Scott Smith, who has been a senior executive at Celgene for nine years, and who, as recently announced, will become President and COO of Celgene in April of 2017, and Dr. Raj Kumar, President and CEO of MeRad. Each brings a wealth of invaluable experience and skills to the team, and we look forward to working with them in the coming year.

And so the Board is very pleased with the progress Titan made in 2016. We remain very enthusiastic about the prospects of our ProNeura-based product portfolio and the opportunities we have to further build value in Titan.

And with that I will now pass the call back to Kate, who's going to provide an update on the product pipeline. Kate?

Kate Beebe: Thank you, Marc, and hi, everyone. I'm pleased to provide you with some additional details of our product development pipeline, including efforts to secure a regulatory pathway for Probuphine in Europe, to engage a commercial partner for ex-US territories, and our ropinirole implant for Parkinson's disease and our ProNeura T3 implant for hypothyroidism.

Now, as Marc mentioned, as Braeburn expands the commercial availability of Probuphine in the US and Canada, we are simultaneously evaluating ex-US opportunities for regulatory approval and commercialization of Probuphine. The rest-of-the-world market for buprenorphine products for opioid addiction is about 15% of the US market, with an estimated 2.5 million people afflicted with this disease in Europe alone.

As we've mentioned before, we've conducted initial discussions with opinion leaders and regional pharmaceutical companies and countries where buprenorphine products are used for the treatment of opioid addiction, and several of these companies, as we've mentioned before, have commenced due diligence. In December of 2016 we received positive scientific and regulatory guidance during meetings with the British and German health authorities regarding centralized submission plans. In January of this year we applied to the European Medicines Agency for

eligibility, and we are pleased to have received EMA confirmation of our eligibility for review and approval under the centralized procedure.

As we continue discussions that will help identify a suitable partner for commercializing Probuphine in Europe, our goal is to file the marketing authorization application with the EMA in Q4 2017. Now, additionally, last month we also received small manufacturing entity, otherwise known as SME, status in Europe, which will provide economic benefits as we move forward with this process.

And now I'd like to switch gears and talk about our ropinirole implant for Parkinson's disease program. The ropinirole implant, as you know, is designed for the long-term, continuous delivery of ropinirole HcL for the treatment of signs and symptoms of Parkinson's disease, including stiffness, tremors, muscle spasms and poor muscle control. Ropinirole is a dopamine agonist that's currently available in daily or more frequently dosed oral formulations for the treatment of Parkinson's disease and restless leg syndrome.

As you may know, Titan is pursuing something called a 505(b)(2) registration pathway for this product candidate. In January 2017 Titan submitted an investigational new drug application with the FDA following completion of the required nonclinical studies, which were then reviewed by the FDA in the pre-IND briefing materials that we provided them. The FDA then verbally requested additional information on final release test data on the implant itself and on the applicator that we use for administration of the implant, all before the clinical trial may proceed.

We fully expect their written communication later this month, and then our intention is to initiate a Phase 1 pharmacokinetic study in mid-2017. 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 both characterize the pharmacokinetic profile of the implant and to assess its safety and tolerability over a three-month treatment period.

In addition to the progress that we're making with our ropinirole implant program, we continue to advance our implantable T3 product for the treatment of hypothyroidism. Hypothyroidism is a disease affecting about 15 million Americans. Most of them are women.

Based upon symptoms and blood tests, it's estimated that as many as 15% to 20% of hypothyroid patients are not adequately treated with a standard therapy, resulting in a persistent deficiency in the primary active form of thyroid hormone, T3. And physicians typically then add an oral T3 regimen to the treatment of these patients.

We've completed initial formulation development of the implant and conducted in vitro and in vivo drug release studies to further define the implant formulation. Our in vivo nonclinical studies, which evaluate implant formulations for drug release characteristics, demonstrated non-fluctuating release of T3 over several months in both small and large animal models. We believe that this delivery system more closely approximates normal endocrine physiology and may confer additional benefits to patients.

However, we experienced a temporary delay as we awaited supply of GMP-qualified T3 material. Now after receiving the material at the end of January, we are now completing the implant formulation optimization and final testing, and establishing the nonclinical study plan that will provide safety data for the IND. We anticipate that we will hold a pre-IND meeting with the FDA in the third quarter of this year and will evaluate the program's development schedule based on available resources.

As Probuphine activities progress we are also evaluating several other product candidates across a variety of different chronic disease indications for potential inclusion in our portfolio. We believe our ProNeura continuous, long-term drug delivery platform holds great promise for the treatment of select chronic diseases for which maintaining consistent levels of the medication in the blood over long periods of time may offer safety or other health benefits, and we remain enthusiastic about advancing our development programs.

And now I'll turn the call over to Brian. Brian?

Brian Crowley: Thank you, Kate.

As you know, a summary of the financial results was provided in our press release issued this morning, and the details are available in the Annual Report filed on Form 10-K with the SEC earlier today. So at this time I'll just highlight a few key items.

We recognized total revenue of approximately $15.1 million for 2016, which consisted of approximately $15 million from a milestone payment receiving from Braeburn upon approval of Probuphine by the FDA in May 2016, and approximately $65,000 from royalties earned on net sales of Probuphine. Revenue of approximately $1.7 million in 2015 reflected the amortization of the upfront license fee received from Braeburn in December 2012.

Research and development, or R&D expenses for 2016 were approximately $6.1 million, compared with approximately $4.7 million in 2015. The increase was primarily associated with external research and development expenses related to our ProNeura product development programs, employee-related expenses and other R&D expenses, which were partially offset by the reimbursement of Probuphine-related expenses by Braeburn.

General and administrative expenses, or G&A, were approximately $4.6 million in 2016, compared with approximately $3.8 million in 2015. The increase in G&A expenses was primarily related to noncash stock-based compensation and employee-related costs, legal and professional fees and a contractual fee obligation related to Probuphine.

Net income for 2016 was approximately $5.1 million, or approximately $0.25 per share, compared with a net loss of approximately $11.3 million, or approximately $0.56 per share, for 2015. We had cash and cash equivalents of approximately $14 million at December 31, 2016, and we believe our working capital at December 31, 2016 is sufficient to fund our operations through the first quarter of 2018.

Now for the fourth quarter. During the fourth quarter of 2016 we recognized revenue of approximately $35,000 from royalties earned on net sales of Probuphine. We recognized no revenue in the comparable period of 2015.

R&D expenses were approximately $2.1 million, compared with $1.1 million in the comparable period of 2015.

G&A expenses were approximately $1.2 million, compared with approximately $1.1 million in the comparable period of 2015.

Our net loss in the fourth quarter of 2016 was approximately $2.3 million, or approximately $0.11 per share, which was approximately the same as in the fourth quarter of 2015.

Now I'll pass the call back to Sunil, but if you have any questions I'll be happy to address them during the Q&A. Sunil?

Sunil Bhonsle: Thank you, Brian, and hello, everyone, again. The financial results are as expected, and, as you can tell from all the presentations so far, 2016 was a busy year, and I expect 2017 will be even busier.

Braeburn did the groundwork last year to prepare for a full commercial launch of Probuphine. With the sales and medical support team now in place, they are focused this year on building on that foundation, with focusing on more than 80 academic and clinical centers that are capable of providing long-term maintenance treatment with Probuphine and can be the future sites of excellence.

While the commercial launch of Probuphine in the US is on its way, we have been successful in the early steps of the regulatory process for a marketing authorization application in Europe, and we will be working hard to accomplish our goal of filing the application before the end of this year. I am encouraged by the interest in Probuphine expressed by potential ex-US partners, and we will continue our efforts in this endeavor.

Validation of our ProNeura platform provides the basis to build value, and it is our goal to add to the product pipeline starting with the ropinirole implant for Parkinson's disease. We hope to commence a pharmacokinetic clinical study in Parkinson's patients around midyear, following FDA clearance of the IND, and we'll provide additional details at that time.

While we optimize the T3 implant formulation in the first half of this year, we will also continue to evaluate the feasibility of the ProNeura platform in other chronic diseases and opportunistically add to the product pipeline, resources permitting. This is an important year for Titan to transition from a single-product company to one with a product pipeline, adding value as we achieve key milestones. Our Board is fully supportive of these plans, and I look forward to the year ahead.

This brings us to the end of our formal remarks, and now, Jamie, we are ready to take questions from the call participants.

Questions & Answers

Operator: (Operator Instructions)

And our first question today comes from (inaudible), from (inaudible). Please go ahead with your question.

Unidentified Participant: Hello, and good afternoon, everyone. The first question I had was I wanted to see if you could just outline the cost and benefits of waiting to commence commercial launch a few months after approval was granted instead of doing it right up front.

Sunil Bhonsle: Sure. I think the best way to characterize it, John, is clearly the first few months for Probuphine have gone into educating and training the healthcare providers, without which Probuphine cannot be prescribed. So you have to lay that groundwork and foundation, and, as you know, Braeburn spent considerable resources going across the country and getting more than 2,400 healthcare providers trained last year.

At the same time getting reimbursement from the third-party payers is a critical part of treating addiction, and so that was one of the key goals they had, and there again established 70-plus insurance plans that now cover Probuphine. Along with that, and, now, don't get me wrong, they were also looking to sell the product, and they did start selling the product, but they were also building a sales field force as well as a medical support staff team, and along the way they saw what challenges would come along in terms of how to get the best way to get product delivered to these sites.

This included expanding from a buy-and-build mode to actually having a specialty distribution pharmacy approach. That in itself required actually clearance from the DEA. So there were many hidden things that had to be accomplished before you can really have the ability to do a full commercial launch.

And so that's what Braeburn really spent time and effort on. A lot of money behind it, a lot of establishing the key components necessary so that once you have your large, 60-person force going out and marketing and selling the product, you'll have the pieces in place to be successful. So I commend them for that.

Unidentified Participant: Okay. That makes sense. And second question is on ropinirole. And as we progress forward with that in the trials, what will some of the primary and secondary endpoints be for the registrational studies?

Kate Beebe: Hi, John. This is Kate, and thank you for your question. At this stage we've only planned to do the PK study, the initial clinical study. Of course, the primary goal of that will be to look at the pharmacokinetic characteristics of the ropinirole implant, how it reacts in humans, and then we're also, in a secondary way, we'll be looking at safety and some efficacy endpoints.

We haven't decided and we haven't discussed yet with the FDA what the primary and secondary endpoints of our full clinical program might look like, but you can expect them to be similar to other Parkinson's disease products that are on the market that have already been approved, things like controlled motor symptoms, dyskinesias, abnormal bodily movements, things like sleep, etc. And that's really all I can say about it at this point.

Unidentified Participant: Okay. That's helpful. And the last question I had was on further pipeline development. You had mentioned a few words about that on the call, and I was wondering if there's any more idea you could provide on that in terms of working with generic versus branded. Maybe there's a specific therapeutic area, perhaps working in tandem with another company. Are all those things you've considered, or is there any kind of part of that that you'd focus on specifically, or maybe just a couple of words on new additions to the pipeline after ropinirole and T3?

Sunil Bhonsle: Sure, John. I mean, clearly the immediate things besides ropinirole, we are doing some work with T3. There are both approaches that we are taking. One is clearly the easy access to compounds with a 505(b)(2) regulatory approach is with products that are already approved and are off patent.

At the same time, having established the ability to provide long-term drug delivery with this platform, we want to look at branded products, want to see if we can establish development partnerships with companies who have proprietary drugs, and we are pursuing that avenue, as well.

In terms of the areas of interest, clearly, as you know, this has to be selective. It's dependent on the types of compounds and the potency of the compound, with low doses that are deliverable very easily. And we are looking at some of the areas of interest that we've talked up in the past, and Kate has exposed some, as well.

Kate Beebe: Yes, just to add to that, what Sunil has said, John, we're looking at opportunities in chronic diseases for which a long-term, continuous, non-fluctuating delivery of good medicine would be of benefit to patients and potentially offer some kind of superiority over existing treatments.

So you can think of areas like diabetes, for example, HIV prevention, other chronic diseases like that. And we're open to -- we're really looking for those opportunities, and, as Sunil mentioned before, we're also looking for companies that have existing proprietary development opportunities that we can partner with.

Unidentified Participant: Great. Yes, that's very helpful. Thank you.

Operator: (Operator Instructions)

Our next question comes from Mitchell Kapoor, from Rodman & Renshaw. Please go ahead with your question.

Mitchell Kapoor: Hi, there. Thanks for taking my questions. My first one is how much of the $2 billion buprenorphine market do you think that Probuphine can penetrate?

Sunil Bhonsle: Hi, Mitchell. Obviously we are at the beginning of a marketing cycle and process that Braeburn controls. Braeburn has done their market research and surveys to look at what the potential for this product is. We believe it is considerable.

In terms of reports, analyst reports, I'm sure you've seen, have projected peak sales in the ranges of $250 million to $300 million plus ranges. And we will see how the next few quarters progress and provide further guidance once we've seen how the acceptance builds.

Mitchell Kapoor: Okay, great. Great. So my next question is what is the amount of the next sales milestone expected from Braeburn?

Sunil Bhonsle: Well, unfortunately, as much as I would love to tell you all of the milestones and when we could expect them, Braeburn has not allowed us to divulge this. And you can understand. This is all competitive information in terms of their expected sales and expenses. So I cannot share that.

But what I can say is of the $165 million, up to that $165 million in sales-based milestones, if we were to reach the peak sales of that $250 million to $300 million range, we would have received about 60% of those milestones already. So it is not just backend loaded. It is actually progressive through the sale cycles.

Mitchell Kapoor: Okay, great. That's very helpful. And just one more for me. At what level of Probuphine sales can Titan achieve cash flow breakeven?

Sunil Bhonsle: Let me put it in a slightly different way in terms of what our expenses typically are, and that will give you a better understanding of the way we operate. We're a small company. Our base expenses typically are around $8 million a year, and then on top of that are the expenses associated with nonclinical and clinical studies that we get involved with.

So, for instance, right now with the involvement with ropinirole product going into the clinic, our expenses start going up somewhat, and we will be typically in the range of, say, $12 million to $13 million a year in our burn. So clearly cash flow positive would imply getting revenues of that magnitude for us at this stage. But it will vary depending on really the development, number of development products in the cycle. Okay? Hopefully that's helpful.

Mitchell Kapoor: Yes, thank you so much. I really appreciate it, guys. Thanks.

Operator: And, ladies and gentlemen, showing no additional questions, this will conclude our question-and-answer session. I'd like to turn the conference call back over to Mr. Bhonsle for any closing remarks.

Sunil Bhonsle: Thank you, Jamie, and thank you all for participating in this call. We are enthusiastic about the progress we continue to make both in our Probuphine program and in

developing ProNeura for Parkinson's disease and hypothyroidism. We will keep you updated as we go forward, and we truly appreciate your ongoing support. Have a great day.

Operator: Ladies and gentlemen, that does conclude today's conference call. We do thank you for attending. You may now disconnect your lines.