Company: **Titan Pharmaceuticals**

Conference Title: **Third Quarter 2016**

Moderator: **Sunil Bhonsle**

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Operator: Good day, and welcome to the Titan Pharmaceuticals Third Quarter 2016 Financial Results call. Today's conference is being recorded. At this time, I'd like to turn the conference over to Sunil Bhonsle. Please go ahead.

Sunil Bhonsle: Thank you, Evan. And thank you all for joining us. Welcome to the Titan Pharmaceuticals call to review financial and operational results for the third quarter of 2016.

Before we begin, I want to inform you that this morning we filed our third quarter 2016 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 Executive Chairman Marc Rubin, Dr Kate Beebe, our Executive Vice President and Chief Development Officer and Brian Crowley, our Vice President of Finance.

So before we go into the details of the financial results and provide an update on the company, I want to remind everyone that certain matters we will discuss today, other than historical information, consist of forward-looking statements relating to, among other things, our expectations concerning our financial results, available cash, development programs, partnering arrangements, regulatory strategies, and business plans. The forward-looking statements are not guarantees of future performance, and are subject to a variety of risks and uncertainties that could cause actual results to differ materially from the results contemplated by the

forward-looking statements. These risks and uncertainties are described in our annual report on Form 10-K filed with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today. We undertake no obligation to update or revise the information provided in this call, whether as the result of new information, future events or circumstances or otherwise.

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

Marc Rubin: Thank you very much, Sunil, and hello and thanks to all of you for joining us today. We are pleased to be here to provide you with a review of the third quarter of 2016.

As you know, Probuphine is the first and the only product for the six-month long-term maintenance treatment of opioid addiction in adults that are stabilized on 8mg a day or less of buprenorphine. Buprenorphine is currently available in the form of daily-dosed sublingual formulations, with annual sales around $2 billion in the United States. However, unlike other buprenorphine products on the market, Probuphine is uniquely positioned as a maintenance therapy providing a powerful new option for people who are already in recovery.

Since the approval of Probuphine in May, we have seen a strong early interest from physicians, patients, and insurance companies. During this quarter, our partner Braeburn has made a conscious effort to focus primarily on two key activities necessary to set the stage for Probuphine's future growth. The first is training and certification of the healthcare providers on the insertion and removal procedures, and the second is obtaining third-party payor coverage. To date, Braeburn has trained and certified more than 2,400 healthcare providers from all 50 states and Puerto Rico, and has obtained third-party coverage for Probuphine from large and regional insurance companies, as well as coverage under

Medicare, Medicaid and the Veterans' Administration. This carefully planned and methodical initial product launch lays a strong foundation for the increasing adoption of Probuphine.

Probuphine represents a true paradigm shift in the treatment of opioid addiction, and we believe that its acceptance and its adoption will continue to grow by both the physician and the patient communities. We believe this growth will be bolstered by the continued and the growing recognition that medication-assisted therapy is a critical component in the armamentarium and treatment of opioid addiction.

While Probuphine is gaining strong early acceptance by the medical community, the paperwork required to be reviewed from initiation to final treatment is currently somewhat time-consuming, and this results in a longer than desired sales cycle. So in order to address and to fix this, Braeburn is devoting significant resources to streamline the process and to minimize any delays. Braeburn is also building upon the initial distribution model for Probuphine with a new specialty pharma distribution model, which will allow for a much smoother prescription process.

In addition, Braeburn is now building a full-scale commercial launch of Probuphine with a fully-deployed field force about of 60 addiction sales representatives, clinical educators, and national account executives.

Obviously, these ongoing and near-term activities are not reflected in our third quarter financial results, but we look forward to increasing Probuphine revenues as Braeburn's commercialization efforts progress.

We are also enthusiastic about our pipeline of products based on our ProNeura long-term continuous drug delivery platform. We're advancing development of our ropinirole implant for Parkinson's disease, and our T3 implant for hypothyroidism.

And in just a moment, Dr. Beebe will provide additional details on the product pipeline.

Our financial position remains strong, and the board is enthusiastic about Titan's prospects and the potential value that our ProNeura product development pipeline brings to the company and the shareholders.

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

Sunil Bhonsle: Thank you, Marc. And as I mentioned earlier, we filed our third quarter Form 10-Q this morning, so I will provide you with the summary of these results, and some comments regarding our progress.

Titan reported approximately $26,000 in license revenue for the third quarter of 2016, compared with no revenue for the comparable quarter in 2015. License revenue during this third quarter included recognition of royalties earned on net sales of Probuphine by Braeburn.

As Marc mentioned, during the third quarter, Braeburn focused primarily on building a foundation through the training and certifying of healthcare providers, and securing third-party coverage for treatment with Probuphine. While awareness of treatment with Probuphine continues to grow, as you may have seen in the various news media and TV programs, this growth in the medical and patient community continues. The process of converting this demand to final sales has experienced some "teething problems", as previously mentioned, and these are now being addressed thoroughly by Braeburn.

The total operating expenses, consisting primarily of research and development – or R&D – expenses, and general and administrative expenses were approximately $2.6 million in in the third quarter of 2016, compared with about

$1.8 million in the third quarter of 2015. R&D expenses for the quarter were approximately $1.6 million, compared to about $1 million for the same period in 2015. So it's an increase of about $0.6 million. The increase in R&D costs is primarily a result of increases in our external R&D expenses, related to the support of our ProNeura product development programs, and some increases in employee-related expenses and other R&D expenses. So these are primarily related to our ropinirole implant and the T3 implant programs. These expenses were partially offset by the reimbursement by Braeburn of about $0.4 million of Probuphine-related expenses.

The general and administrative expenses for the third quarter were about $1.1 million this year, compared with about $0.8 million for the same quarter last year, so an increase of about $0.3 million. This increase in expenses is primarily related to increases in non-cash stock compensation, a little bit on employee-related costs and professional fees.

Net loss for the quarter ended September 30th 2016 was approximately $2.6 million, or about $0.12 per share, compared with a net loss of about $1.8 million, or $0.09 per share, for the comparable quarter in 2015.

At the end of September, Titan had cash of approximately $16.5 million, which we believe is sufficient to fund our current operations into early 2018. Importantly, to date this does not include any shares sold pursuant to the ATM that we established with Cantor Fitzgerald. Given our current financial position and the market price of our stock, we have not used this ATM.

Just to remind you, under terms of the licensing agreement, Braeburn will pay Titan tiered royalties on net sales of Probuphine in the US and Canada at rates ranging from the mid-teens to low-twenties. We will receive sales reports quarterly, a few weeks after the end of each period, and we will report this in our 10-Q quarterly report for the same quarter. We expect that during the next

several quarters, as commercialization efforts ramp up, the royalty rate will remain in the mid-teens.

Additionally, Titan is eligible for up to $165 million in future milestone payments based on achievement of certain annual sales targets. However, we are not able at this time to estimate the extent and timing of any such additional payments, and we will let you know as we progress and we have more information in the future.

Now, to provide you an update of recent ProNeura product pipeline activities, let me turn the call over to Dr. Beebe. Kate?

Kate Beebe: Thank you, Sunil, and hi, everyone. I am pleased today to provide you with some additional details on Probuphine, as well as our ropinirole implant for Parkinson's disease and our T3 implant for hypothyroidism.

Now, as Braeburn implemented initial commercial launch activities for Probuphine in the quarter, we also continued to present and publish data that further supports its important role in the treatment of opioid addiction. Most notably, in October, there were three Probuphine presentations that were featured at the International Society of Addiction Medicine meeting in Montreal. These included a description of the Probuphine Risk Evaluation and Mitigation Strategy – or REMS – and that was implemented to train and certify healthcare providers to prescribe and implant Probuphine. As previously mentioned, a total of 2,400 healthcare providers were certified in the first eight weeks after approval. The trained Probuphine providers practice across specialties including family medicine, general practice, psychiatry, neurology, anaesthesiology, and emergency medicine, among others.

A second presentation described a data analysis that modelled the health benefits and healthcare costs of Probuphine compared to extended release

injectable naltrexone and subliminal buprenorphine. Now, in this analysis, Probuphine was found to have clinical health and economic benefits in those stabilized patients, due to little or no potential for abuse or diversion and the sustained delivery for buprenorphine for up to six months. An earlier version of these data was featured as a poster presentation at the Academy of Managed Care Pharmacy – AMCP – annual meeting in April 2016.

And lastly, an encore presentation was given on the Probuphine pivotal trial results, which were the basis for Braeburn's NDA that ultimately led to FDA approval of Probuphine. These data were presented earlier this year at the American Society of Addiction Medicine, or ASAM, meeting, in April, and also published in the *Journal of the American Medical Association* in July of 2016.

We were also very pleased that in October, *Popular Science* magazine recognized Probuphine as one of the "12 Most Important Innovations of the Year" in the health category of its annual Best of What's New issue.

We also recognize that opioid addiction is indeed a global crisis, and to that end, as Braeburn expands the commercial availability of Probuphine in the U.S. and Canada, we at Titan are evaluating opportunities for regulatory approval and commercialization of Probuphine outside of the U.S. and Canada. We've conducted initial discussions with opinion leaders and regional pharmaceutical companies in countries where buprenorphine products are used for the treatment of opioid dependence, and now several of these companies have commenced their due diligence process. And we're finalizing the required briefing materials for initial meetings with European health authorities, which is scheduled for next month. Now, these meetings will help us to further define the pathway to product approval in Europe, and they also represent an important step in the partnership discussions for the commercialization of Probuphine in this region.

And now, I'd like to shift gears and talk about our Parkinson's disease program. We now have completed the manufacturing and release of ropinirole implants for GLP toxicity studies, we've completed pharmacokinetic and dose-ranging studies in non-human primates, completed some of the required local toxicity studies, and a 13-week chronic toxicity study in non-human primates. All of these comprised the required non-clinical studies to support the submission of an IND application by the end of this year, or in early January 2017, which will then be followed by the initial pharmacokinetic and proof-of-concept clinical study. As we said before, Titan is pursuing a 505(b)(2) registration pathway for the product candidate.

The ropinirole implant, as you know, is design for the long-term continuous delivery of ropinirole for the treatment of signs and symptoms of Parkinson's disease, and these often include stiffness, tremors, muscle spasms, and poor muscle control. Ropinirole is a dopamine agonist, which is currently available in daily or more-frequently dosed oral formulations for the treatment of both Parkinson's disease symptoms and restless leg syndrome.

The ProNeura continuous drug delivery platform can potentially offer a way of providing around-the-clock stable levels of medicine, 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 this terrible disease.

In addition, we continue to advance our implantable T3 product for the treatment of hypothyroidism. We've now tested our current formulation in animal models, and are preparing to request a pre-IND meeting with the FDA. We hope to have feedback from the FDA and commence non-clinical studies early next year.

Hypothyroidism is a disease that affects about 15 million Americans, most of them women, and based upon symptoms and blood tests, it's estimated that as

many as 15 to 20% of hypothyroid patients are not adequately treated with the standard therapy, resulting in a persistent deficiency in the primary active form of thyroid hormone, otherwise known as T3, and physicians typically add an oral T3 regimen to the treatment of these patients.

A once-daily synthetic T3, otherwise known as Cytomel, is an effective medication for hypothyroidism, but is also associated with potential side effects, such as headache, nervousness, irritability, sweating and cardiac arrhythmias, and these side effects are driven by the peak and trough blood-level fluctuations that are associated with standard oral delivery. Our implantable T3 product, providing continuous delivery of T3, could more closely replicate normal thyroid physiology, and therefore avoid some of the unwanted side effects associated with the current pulsatile release oral formulation.

In addition to these programs, we are also evaluating several other product candidates across a variety of different chronic disease indications for potential inclusion in our portfolio. We continue to be very enthusiastic about the prospects of ProNeura for continuous long-term drug delivery platform and its role in the treatment of select chronic diseases for which maintaining consistent levels of medication in the blood over long periods of time may offer real benefits to patients over oral formulations.

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, we are ready to take questions from the call participants.

Operator: Thank you. If you'd like to ask a question, please signal by pressing star one on your telephone keypad. If you're using a speakerphone, please make sure your mute function is turned off to allow your mute function to reach our

equipment. Again, that is star one for questions. We'll pause just for a moment to allow everyone the opportunity to signal for questions.

We'll take our first question from Scott Henry of ROTH Capital. Please go ahead.

Scott Henry: Thank you, and good afternoon.

Sunil Bhonsle: Hi, Scott. Good afternoon.

Scott Henry: Hi. To get started, the certifications, you mentioned more than 2,400, which was pretty similar to the number given on the 2Q call. Is – have they kind of levelled that off right now? I thought there was a goal of 4,000 by year-end. I don't know if that's still the case. I was just hoping to get some clarity on that front.

Sunil Bhonsle: Sure – sure, Scott. The initial target you know, for – during June, July, August they had – as you probably noticed, they were doing training sessions almost every other week in different cities, and that was sort of the massive initial push. They have had since then some additional training sessions more recently, but in total the numbers that they reached were about 2,400, and what Braeburn has seen clearly is, you have the early adopters, who start then using what they have learned and start using Probuphine. And one of the aspects of that is they are now focusing more on training select groups rather than doing large sessions in every city. And this is mainly because you want to focus on those people who you clearly see as being able to translate into use of the product, and through this process they've identified that and now are moving on, targeting very specific large centers and groups to train, rather than a broader across-the-board strategy from city to city. But the good news, to me, is the 2,400+ healthcare providers, they're spread out throughout the country and so there's people available in every state, in every major city, who are now trained in this program and can prescribe Probuphine.

Scott Henry: Okay, thanks for that color. Now, that being said, 2,400 is a significant number, as is 60 reps, which is a substantial sales force. So, you know, given that we now know the sales cycle will take a little time, which isn't that surprising, what kind of trajectory should we look for in revenues? Will we see a bump in third quarter higher or – or may it take a little bit longer than that? Just trying to get an idea of how to chart out this revenue.

Sunil Bhonsle: Sure. No, absolutely, Scott. Clearly there is an awareness of the product that has been seen, there is a demand for the product that is there. Getting everything in place to make sure that demand is converted into sales numbers is what is still taking the time frame. And obviously with the attention Braeburn is paying to that, and trying to smoothen out the process, that should speed it up. But to what extent and how best it will translate into the curve, it's still a little too early. I mean, it's just not enough data that I can say this is something I could provide you with, but certainly we will try and provide that. By the end of next quarter, I think you should have sufficient data. I can say that the sales reflected for the third quarter are just a fraction of the demand, so certainly expect more and more the demand to be converted to sales during this quarter and so we at least are expecting suddenly to see a increase in revenue stream.

Scott Henry: Okay, great. And then, final question, with regards to Probuphine in Europe, do you expect to have to do additional clinical work there, or do you think you can present the package of data you already have?

Sunil Bhonsle: Kate, maybe you want to –

Kate Beebe: Absolutely. Great question, Scott. We don't know yet. We believe that we have a very strong package. It's already approved by the FDA, obviously. We also have data from the earlier studies, and we're going to Europe next month, as I mentioned. We have some meetings scheduled already to seek scientific

advice around whether various countries would consider the current data package to be sufficient. Personally, I do believe that it is sufficient, and I'm going to make my best argument to support that case.

Scott Henry: Okay. Great, thank you for that color, and thank you for taking the question.

Sunil Bhonsle: Thanks, Scott. Appreciate it very much.

Katherine Beebe: Thanks, Scott.

Operator: And that looks to be all the time we have for questions. I'll turn it back to Sunil for any additional remarks.

Sunil Bhonsle: Thank you very much, everybody. Thank you for participating in our call. We know this is a time of change in the country as well, and wish everyone success. We look forward to updating you on our progress again soon, and as always, we appreciate your ongoing support. Thank you.

Operator: And this does conclude today's presentation. Thank you for your participation, you may disconnect.