

Event Name: TTNP - Titan Pharmaceuticals First Quarter 2017 Financial Results
Event Date: 2017-05-10

Officers and Speakers:

- Jennifer Kiernan; Titan Pharmaceuticals, Inc.; Executive Assistant and Investor Communications Coordinator
- Sunil Bhonsle; Titan Pharmaceuticals, Inc.; President and CEO
- Marc Rubin; Titan Pharmaceuticals, Inc.; Executive Chairman of the Board
- Kate Beebe; Titan Pharmaceuticals, Inc.; Executive Vice President and Chief Development Officer
- Brian Crowley; Titan Pharmaceuticals, Inc.; Vice President, Finance

Analysts:

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

Presentation:

Operator: Thank you for holding, and welcome to the Titan Pharmaceuticals First 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 recorded 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, William, and thank you all for joining us today. Welcome to the Titan Pharmaceuticals call to review financial and operational results for the first quarter of 2017 and provide recent business updates.

Before we begin, I wanted to inform you that on May 10th, we filed our first quarter 2017 Form 10-Q with the SEC, and the press release issued this morning provides a summary of the results, and it 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, Vice President of Finance.

Before we go 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. It has just been a few weeks since the last update in mid-March, and so today we will focus on key activity since that call. We will start 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 very much, Sunil, and hello to all. We very much appreciate your joining us on the call today.

The last quarter has been a busy one, with key internal activities focused on advancing the ProNeura product pipeline. We continue to be enthusiastic about the prospects for our technology platform for the potential to treat a broad range of chronic diseases.

Let me start with an update on Probuphine, our first commercial product based on ProNeura technology. Probuphine, as you know, is approved for the maintenance treatment of opioid addiction in adults stabilized on 8 mg or less a day of buprenorphine, and it is the first and only product that provides 6 months of treatment after a single administration in this population. As we mentioned very recently in our March call, Braeburn has executed an initial strategic product launch in 2016 following the FDA's approval of Probuphine last May. This initial product launch laid the foundation for the full commercial launch, which just began in the last quarter of this year. We are encouraged by Braeburn's ongoing commitment to growing awareness and adoption of Probuphine in an environment that provides both significant opportunity, but also clear challenges.

So let me briefly review with you some of the highlights of the launch. Braeburn has assembled a 60-plus field force and a medical support staff that's focusing on more than 80 key treatment centers solely focused on Probuphine. More than 70 payers, including private insurance, CMS and Veterans Administration programs, now cover Probuphine. Probuphine was assigned a permanent J-code from the Centers for Medicare and Medicaid Services, or CMS, which was

effective in January of this year. This is expected to facilitate third-party-payer reimbursement process, as the code is integrated into the processing systems. Braeburn also continues to work to obtain additional codes to further facilitate Probuphine insertion and removal procedures.

In April of 2017, Braeburn added a second specialty pharmacy, which has expanded the distribution network and increased the capacity to handle the pre-approval process for Probuphine. Braeburn intends to monitor progress and strategically expand the network and add more specialty pharmacies as needed.

These aggressive steps reflect Braeburn's enthusiasm for Probuphine and its commitment to the commercial success of the product. Braeburn continues to see a steady growth in the numbers of healthcare providers prescribing Probuphine, and the field sales force is actively engaged in increasing the awareness, acceptance, and adoption of Probuphine.

Importantly, while Probuphine represents a true paradigm shift in treating this disease, it has been launched in what can only be described as a challenging reimbursement environment. But we and Braeburn remain very confident in its long-term success. We expect that the ramp-up will continue to be gradual over the next several quarters.

Today, more than 2.4 million Americans are battling the chronic relapsing disease of opioid addiction. Along with a continued emphasis from the medical community and 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. Indeed, the long-term treatments that focus on enhanced compliance and quality of life are the wave of the future in opioid addiction treatment. We have heard many patients describe how the stability of the 6-month implant allows them to focus on life activities without concerns for maintaining daily dosing schedules.

At the same time, launching a long-term treatment such as Probuphine inherently requires a high level of education and support across the entire continuum of care, including patients, caregivers, physicians and payers. There have also been challenges with expanding coverage and reimbursement, including payers' requirements of physicians to buy and bill, and a process among insurers to cover new products that is not always as straightforward as we would wish. While Braeburn has deployed substantial resources to address these challenges, this process takes some time. But we are confident in Braeburn's ability to execute on the Probuphine launch, as well as their clear commitment to the long-term success of the product.

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 and our T3 implant for hypothyroidism. The board fully supports the ongoing activities, and we do look forward to further advancing our ProNeura-based product portfolio in the coming months. We realize that these are challenging times, but we remain enthusiastic about Titan's prospects and the opportunities we have to further build value in the company.

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

Kate Beebe: Thank you, Marc, and hi, everyone. I'm pleased to provide you with additional details of our product development pipeline. As a reminder, our current portfolio is based on our proprietary ProNeura technology, designed to provide the long-term continuous drug delivery for up to 12 months. We believe the approval of Probuphine was an important validation of our technology, and we are now aggressively moving forward with advancing product candidates across a range of indications.

First, let me start with an update on Probuphine outside of the United States. As you may know, while Braeburn holds commercialization rights to Probuphine in the U.S. and Canada, we retain rights in Europe and other territories. As such, we've been evaluating ex-U.S. opportunities for regulatory approval and commercialization of Probuphine, beginning now in Europe. This is the second-largest market for buprenorphine-based products, representing about 10% in sales compared to the \$2 billion U.S. market. In January, we applied to the European Medicines Agency, known as the EMA, for eligibility for review of Probuphine under the centralized procedure, and in March, we were pleased to have received EMA confirmation of that eligibility. We've now also received a pediatric indication waiver, which simplifies the marketing authorization application, or MAA, process, and this summer we plan to meet with EU regulatory authorities to review the planned content of the MAA prior to finalization. The Titan team is working diligently on constructing the MAA for Probuphine, which we expect to file with the EMA in the fourth quarter of 2017. Concurrently, we have advanced discussions with potential Probuphine commercialization partners in Europe and other ex-U.S. territories. Our goal here is to have a partnership in place prior to filing the MAA later this year, and we look forward to providing more updates in the coming months.

Next, I'd like to discuss our ropinirole implant for Parkinson's disease program. The ropinirole implant is designed, as you know, for the long-term, continuous delivery of ropinirole HCL for the treatment of signs and symptoms of Parkinson's disease, and these include stiffness, tremors, muscle spasms and poor muscle control, among others. 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, or RLS.

As you may know, Titan is pursuing 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 our required nonclinical studies. Titan received verbal communication in February, followed by written confirmation from the FDA in late March, requesting additional information from us on the final release test data on the implant and on the applicator before the clinical trial proceeds. We expect to submit the requested information by the end of next month, and we will initiate a Phase I/II pharmacokinetic study in the third quarter pending FDA clearance of the IND. This Phase I/II dose-ranging study will enroll Parkinson's disease patients receiving adjunctive therapy with oral ropinirole. In the study, their oral ropinirole will be replaced with our ropinirole implant. In addition to characterizing the PK and safety profiles, we will also evaluate potential effectiveness.

Together with the progress that we're making with our ropinirole implant, we continue to advance our implantable T3 product for the treatment of hypothyroidism. Formulation optimization studies for Titan's T3 implant are currently in process, and our in vivo nonclinical studies, which evaluated implant formulations for drug-release characteristics, demonstrated nonfluctuating release 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 benefit to patients. Titan intends to have additional discussions this quarter with experts on the clinical development pathway for our T3 product candidate. Our timing will depend on the feedback we receive there, as well as available resources.

And now, I'm happy to share with you, for the first time, that we are also actively evaluating the feasibility of several other product candidates across a variety of different product disease indications for potential inclusion in our portfolio. And these include both tenofovir and emtricitabine for pre-exposure prophylaxis against HIV acquisition, also known as PrEP; a number of antimalarial agents for malaria chemoprophylaxis and treatment; liraglutide for adults with Type 2 diabetes; and oxytocin for autism spectrum disorder. 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 to Brian. Brian?

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

For the first quarter of 2017, Titan reported approximately \$40,000 in license revenue, compared with no revenue in the same period a year ago. License revenue for the quarter ended March 31, 2017, reflects the recognition of royalties earned on net sales of Probuphine by Braeburn.

Research and development expense, or R&D expense, for the first quarter of 2017 was approximately \$2.1 million, compared with approximately \$0.7 million for the same quarter in 2016, an increase of approximately \$1.4 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 R&D activities.

G&A expenses for the first quarter 2017 were approximately \$1.4 million, compared with approximately \$1.1 million for the same period in 2016. The increase in G&A expenses was primarily related to increases in non-cash, stock-based compensation, employee-related costs and professional fees.

Net loss applicable to common shareholders in the first quarter of 2017 was approximately \$3 million, or approximately \$0.14 per share, compared with a net loss of approximately \$1.1 million, or \$0.09 per share, in the same quarter of 2016.

We had cash and cash equivalents of approximately \$10.9 million at March 31, 2017, which we believe is sufficient to fund planned operations through the second quarter of 2018.

I will now pass the call back to Sunil, but if you have any questions, I'll be happy to address them during the Q&A at the end of the presentation. Sunil?

Sunil Bhonsle: Thank you, Brian. As you can see from the update, it has been an active quarter, and we're looking forward to a busy and successful year.

With Braeburn's strong support and commitment to Probuphine, we expect sales to steadily increase over the course of the next several quarters. We were particularly encouraged by the rapid expansion of the distribution network and capacity for processing third-party-payer pre-approvals for Probuphine. We expect these efforts, along with their work to secure additional approval codes for Probuphine, will continue to expand insurance coverage and greater commercial adoption this year.

Outside of the U.S., we further defined our development pathway for Probuphine in Europe and advanced our discussions with potential partners. As Kate mentioned, it is our goal to have a partnership in place by the time we file the MAA in the fourth quarter.

Those efforts will continue during the next few months, as will our plans for further development of our portfolio of our ProNeura-based products, including our ropinirole program for Parkinson's disease. Once again, we expect to have all the information requested by the FDA for our ropinirole program by the end of next month and commence the initial pharmacokinetic study in the third quarter following FDA clearance of the IND.

Lastly, besides the T3 program, we are also evaluating the feasibility of ProNeura in other chronic disease settings that can be meaningful additions to the pipeline, resources permitting.

This is a significant and exciting year for Titan. While Probuphine remains important, we are very much focused on growing our product pipeline, and also adding value for our shareholders based on achievements with our other ProNeura-based products.

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

Questions & Answers:

Operator: We will now begin the question-and-answer session. [Operator Instructions]

And it looks like our first questioner today is Scott Henry with Roth Capital. Please go ahead with your question.

Scott Henry: Thank you, and Sunil, good afternoon.

Sunil Bhonsle: Good afternoon, Scott.

Scott Henry: I appreciate your color as far as the Probuphine ramp-up steadily increasing. I was just wondering if you could perhaps -- not looking for too much granularity, but, when would you expect that we would start to see an inflection point? I mean, I wouldn't have expected it in Q1, but perhaps seeing \$1 million in end-user revenues in a quarter. I mean, could that occur by the end of '17? Just any color you can provide would be great.

Sunil Bhonsle: Sure. We've had, of course, conversations with Braeburn and the CEO, and also asked for the same kind of direction on what to expect during this year. And clearly, one of the things that they point out is the sales force is now getting their momentum. The second quarter will provide some good indicators of the adoption of the programs that they're putting in place for the third-party payers, as well as the physicians. And so in my mind, I look at this as, I can see the steady continuing level of growth. One of the key indicators to me is they do see, from literally week to week, additional physicians coming on board and prescribing the products. So that's a very good signal that the sales force is indeed doing their job. The latter half of this year will be one where the early trends should start showing up as to what kind of a ramp-up is being expected. In terms of numbers, Braeburn said, wait for another few months before we give any guidance on that. So it's just a little too early for them to base it on just the last 2, 3 months, where they feel they've had, really, a full force in place. So I can give you not much more than that right now, but that's essentially the direction, and certainly the second half of this year would be the ones where we should be able to start picking up trends.

Scott Henry: Okay, thank you, Sunil, for that color. It's certainly a significant commitment from marketing, and it sounds like they intend to sustain that.

Sunil Bhonsle: Absolutely.

Scott Henry: Another question: When I look at Q1 as far as the spending trends for G&A and R&D, how should I think of that through the rest of the year? Is Q1 reflective, or any trends in either of those lines that I should factor in? Thank you.

Sunil Bhonsle: Certainly, Q1, with the G&A, tends to be a little higher, just from some of the cyclical expenses like D&O and things like that. But overall, it was also driven somewhat, and the high G&A, by stock and non-cash stock compensation, so it wasn't really affecting the cash flow in itself. I expect we'll see it drop a little bit during the next couple of quarters, but that's how I would view it. We haven't done anything substantial that would change it; it's just, obviously, some of these things that we don't control, the non-cash stock compensation expenses, things like that.

Scott Henry: Okay, great.

Sunil Bhonsle: In terms of R&D, the first quarter had some specific expenses, some of which, I believe, related to Probuphine will end up being reimbursed during the second quarter by Braeburn as well. So overall, I would say our expenses are expected to ramp up as the ropinirole clinical study starts during the third quarter, and the second quarter will be somewhat flat.

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

Sunil Bhonsle: Sure. No problem at all, Scott.

Operator: And our next questioner is going to be John Vandermosten with Zacks Investment Research.

John Vandermosten: Good afternoon, everyone.

Kate Beebe: Hi, John.

John Vandermosten: First question is just on the cost of stocking inventory for Probuphine. I mean, obviously, Braeburn is working on this, and they're probably a little bit closer to it, but any thoughts or discussions with them in terms of the cost of stocking inventory, perhaps, slowing the uptake?

Sunil Bhonsle: In terms of -- you're thinking, the physicians stocking inventory and things like that, in this setting?

John Vandermosten: Correct, yeah.

Sunil Bhonsle: What I can share with you, in the discussions with Behshad, the CEO, she said there are some physicians who really prefer buy-and-bill, and they have ordered multiple kits at a time. So it's not a question of the stocking of the inventory in itself. Obviously, it also depends on payment terms, right? So Braeburn clearly is making certain that availability of the product will not in any way disincentivize the physician or getting the treatments done on time. So from that standpoint, I think those who look at buy-and-bill as their preferred method of providing the product have not really been hampered in terms of maintaining an inventory, from what I can tell from Braeburn's comments. Clearly, the ones where they're getting pre-approval through third-party process and payers and so on, that product is shipped once that pre-approval is received, and essentially assigned to that patient treatment. So the physician doesn't bear, really, any cost on the inventory of the product.

John Vandermosten: Okay. Thank you for that clarification.

Sunil Bhonsle: Sure. No problem at all.

John Vandermosten: And second question is just on the ropinirole upcoming trial. Just wanted to see if there was any detail available on trial size, cost and duration of that?

Sunil Bhonsle: Certainly, and John -- in the sense that the study itself, it's a Phase I/II study. I mean, I don't want to give out numbers right now because once we initiate the study, we will provide all of that detail. It's just, the reason I don't want to give it out is that, I don't want to do anything before the FDA has accepted the IND in this setting. It's just not prudent for me to talk in too much detail about the study. But it is a Phase I/II study. Clearly, as Kate was mentioning, the key aspects of it is we're looking at the pharmacokinetic profile, we're looking at the safety

and tolerability, and it is in patients who actually are the same patients that would be eligible for treatment with an implant like this, and so we certainly hope to get some measures of effectiveness in this patient population. It is a dose-ranging study, so we are trying to establish what would be the appropriate dosage. As you know, ropinirole doses range from 2 to 12 mg -- or 2 to 24 mg. I'm sorry, I should let Kate go through all of this. She's far more conversant with it. And so, I think it's really a meaningful study. It won't be -- it's not a very expensive study either, because it's a Phase I/II study. And once we announce the actual study in details, I'd be happy to share with you some more details on the expenses and so on; it's just I don't want to do that too early.

John Vandermosten: Okay, understood. And thank you for the additional detail.

Operator: Ladies and gentlemen, that is all the time we have. I would like to turn the conference back to Mr. Bhonsle for any closing remarks.

Sunil Bhonsle: Thank you, William. And thank you all for participating in this call. I know this is a time where there are many challenges and a lot of concern over where we are, but I truly believe Probuphine has substantial value long-term. It is important to recognize that a product with a procedure takes some time during its launch, and we should expect that. Give it some time, give it the appropriate time for allowing it to be accepted and adopted by the medical community. We will see success of this starting with the second half, based on the kind of resources Braeburn is putting behind it. And the most important part for us is to make sure that Braeburn provides it the resources that it truly needs to build the franchise for Probuphine. We see that happening and feel confident with the resources and the commitment of Braeburn. It's important for all of us to keep that in mind as we go forward.

Ourselves, we are very keen on building the ProNeura product pipeline. We have good opportunities already with the products that are in the pipeline. But as Kate mentioned, many other areas that we are looking at, and so help us build that along with this. And we certainly look forward to keeping you updated and building value in Titan. Thank you.

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