TITAN PHARMACEUTICALS INC

Moderator: Sunil Bhonsle
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3:15 pm CT

Operator: Thank you for holding and welcome to the Titan Pharmaceuticals conference call to review the FDA-approved Probuphine last Thursday. 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, (Shannon). And thank you all for joining us. Welcome to the Titan Pharmaceuticals call to review the FDA approval of Probuphine last Thursday. Before we begin, I wanted to mention that Titan, Braeburn and the FDA issued press releases last week providing a summary of the product approval and Braeburn issued a press release just a little while ago with additional information on the US launch of Probuphine and all of these are available on the respective websites.

Joining me on the call today from Titan are Dr. Marc Rubin, our Executive Chairman; Dr. Kate Beebe, Executive Vice President, Chief Development Officer; and we are very pleased also to

have Behshad Sheldon, the President and CEO of Braeburn Pharmaceuticals participating in this call.

Before we get going, 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 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 a result of new information, future events or circumstances or otherwise.

While having said all that, on today's call the plan is for me to make a few brief remarks followed by remarks from Behshad on the product launch plans and then we will open up the call for your questions.

So on the afternoon of May 26 the US FDA issued the approval letter for Probuphine, the first product for the long-term maintenance treatment of opioid dependence in clinically-stable patients on 8 milligrams or less a day of oral Buprenorphine therapy. Buprenorphine is the most commonly prescribed medication for the treatment of opioid dependence.

The dose of 4 Probuphine subdermal implants which utilize Titan's proprietary ProNeura technology deliver a therapeutic dose of Buprenorphine continuously for six months following a

simple in-office procedure. This marks a major milestone for Titan especially at a time when the government is supporting the expansion of access to opioid addiction treatments.

The launch of Probuphine will provide the medical community with the novel, long-term treatment alternative that can provide benefits to many patients suffering from this disease.

Titan will receive from Braeburn a $15 million milestone payment for the FDA approval, double-digit tiered royalties on Net sales and is eligible for sales milestones of up to $165 million.

Product label emphasizes safety considerations associated with the insertion and removal procedures for Probuphine. Details describing the risks and complications associated with the insertion and removal procedures as well as rare but serious complications that may result from improperly inserting the implants are included in the Probuphine prescribing information.

Because of these risks, only certified healthcare providers may insert or remove Probuphine implants. Probuphine distribution is controlled through a REMS program which also includes details of the required training for provider certification. The approval of Probuphine also validates the ProNeura technology and our goal is to continue adding value to the company by building a strong pipeline of ProNeura-based product candidates.

We are now well positioned to devote increasing resources for Parkinson's Disease, and hypothyroidism programs and we will continue to evaluate additional opportunities for ProNeura.

Now I would like to ask Behshad to provide additional information on the commercialization plans. Behshad.

Behshad Sheldon: Thank you. Good afternoon. It's a pleasure to be with you all and to share our excitement in bringing Probuphine to patients at long last. So as Sunil already described, we do

need to train and certify clinicians in order to be able to make Probuphine available to patients. We take protecting the procedure and therefore the optimal training of our clinicians as our top priority. And so we've already begun.

We trained this past weekend including on Memorial Day, so as of now we have over 120 doctors that have been certified and are able to bring Probuphine to their patients. And we will of course be continuing this in the next - next month but certainly in the next six weeks alone we plan to certify - train and certify over 2000 clinicians.

I've been in development and commercialization, really commercialization, for over 30 years, and have been lucky enough to have contributed to products like Glucophage, Plavix and Abilify which all attained successful clinical and commercial doctor status. But I have to say that I'm pretty overwhelmed by the response already to Probuphine. We've had more than 5000 healthcare providers have gone on the Website and registered to get information on both the training and in general.

We've had insurance companies have been calling us. We have I think six meetings scheduled in the next couple - 10 days with insurance companies that want to discuss putting Probuphine on formularies. And so those are, you know, what we're focusing on are the two priorities are training and certifying the healthcare providers and then making sure that reimbursement is established as quickly and optimally as possible. And of course putting in our own patient assistance - pro pay assistance program to help patients out as well as other strategic value-based reimbursement agreements that we can discuss with an individual insurers or payers if that is the direction they would like to go.

So just the bottom line of it is that we are moving very quickly. We are kind of a fast and furious but yet quality-oriented organization as I suppose everyone is who is small and nimble but, you know, with very ambitious goals for patients and patients have waited for Probuphine way too

long and so we are doing our best to bring it to them in June. And to start a new chapter in the treatment of the horrible disease of addiction in the United States.

Sunil Bhonsle: Great. Thank you very much, Behshad, for that summary of the commercialization plan. It's great to hear that, you know, over 5000 physicians have already contacted you through your Website and you're already planning on training more than 2000 physicians in the next six weeks. And lastly, a big response from the patient community, which is very important in getting this product out to them so truly appreciate all the work that you and your team have already done.

And getting the product out in the month of June as ambitious a goal it is, I know you are very capable of getting it there so thank you very much for all of that.

With that it brings us to the end of our formal remarks. And now, (Shannon), we are ready to take questions from the call participants.

Operator: Thank you. If you would like to ask a question please signal by pressing star 1 on your telephone keypad. If you're using a speakerphone, please make sure your mute function is turned off to allow your signal to reach our equipment. Again that is star 1 to enter the question queue at this time. And we'll take our first question from Scott Henry with Roth Capital.

Scott Henry: Thank you. And congratulations on the approval. I did have a couple questions. First, when I think about the opioid addiction market, how is it launching in the summer? Is there any, you know, seasonality, not that you would expect it, but is there a better or a worse time to be launching a product into that market?

Sunil Bhonsle: Hi, Scott. Thank you very much, for participating. And, you know, I am not aware of anything specific that's different during the summer. But, Behshad, maybe some of your research has information in that?

Behshad Sheldon: Other than some access for patients being even more difficult because of maybe physician vacations, there's certainly no particularly seasonality. We know that patients with any kind of addiction, they're kind of at more - at higher risk of relapse and higher levels of danger during holiday times so actually summer is kind of okay.

But there isn't a time of year where people use more often or become addicted at a higher rate. So it's just that right now, I mean, we are at horribly high levels of terrible disease that's killing people every day, you know, while we talk during this hour three people will overdose of opioids. So I don't think there is any good time to launch. But it is time to go at it as quickly as possible and help as many people as we can in the quickest manner.

Scott Henry: Okay. Great. And then a separate question, a physician will do the implant procedure with Probuphine, how much reimbursement would you expect there to be for the procedure? And when should we think about that, you know, when that reimbursement is available? I'm just trying to get a sense of how a physician will make money by utilizing Probuphine.

Sunil Bhonsle: Behshad, once again, you're the expert in this area so.

Behshad Sheldon: Sure. There are CPT codes that are already established for implantation of originally Norplant, now Nexplanon, which is only one implant, so a combination of the CPT code for that and a modifier is the logical choice.

We're also working on a J code and prior to the J code, you know, because that, you know, at best would be in January of '17 because of the way the process works CMS is being very responsive and really bringing a sense of urgency to this process to make sure that we get the right kind of codes for the product itself and then we're going through the process for, you know, several different medical societies are teaming up to propose what the reimbursement should be

for the insertion and removal processes so that physicians can be - or clinicians can be appropriately reimbursed.

Scott Henry: Okay, now and perhaps if you can refresh me, how much would a physician get reimbursed for doing a Norplant procedure approximately?

Behshad Sheldon: For Norplant it's somewhere between $200 and $250 for the insertion and more like $300, $400 for the removal. But it might - and we'll see where we end up. And it ultimately is really between the physician and the insurer. We can't give them too much - we can kind of provide information as to what's available out there but we can't really specify what they should bill for.

Scott Henry: Okay. And then just the final question which is a little bit, you know, I'm trying to better understand this market, often it seems that someone who starts out hooked on a legal opioid would end up eventually transferring over to heroin for one reason or another. When you think about your target market, you know, how do you think of that split between, you know, legalized pain killer opioids versus the heroin addiction market? I'm just trying to get a sense of how big of that pie, how much is heroin potentially?

Behshad Sheldon: Right now, 80% of the population of opioid-addicted patients is prescription opioid pills and 20% is heroin. As we - as a society try to make it more difficult to get access to elicit use of prescription opioids, people shift, you know, it's kind of like losing the balloon, the air goes someplace. But right now it's 80% prescription opioid. And it was - the large extent the patient population that were enrolled in Pro 8-14 were prescription opioid users.

Scott Henry: Okay great. Thank you for taking the questions and congratulations again.

Behshad Sheldon: Thank you.

Sunil Bhonsle: Thanks. Thanks a lot, Scott.

Operator: And we'll move to our next question from (John Stifel), a private investor.

(John Stifel): Good afternoon. I just had a quick comment on behalf of stockholders, and especially the patients, I would like to thank Mr. Bhonsle and his team for their dedication and persistence.

Sunil Bhonsle: (John), thank you very much for that comment and certainly included in our team is Braeburn who has done a lot of the work to get this out and will be doing a lot more to really get the patients engaged in this program. Thank you for your support, (John).

(John Stifel): Thank you.

Operator: And we'll move next to (David Toma), a private investor.

(David Toma): Hi. How are you guys doing? Just want to congratulate you guys, first of all, on, you know, getting the approval, everything. I actually work as a pharmacist full time so I was - I found it also very interesting you guys Phase 1 and Phase 2 studies. And I was just kind of curious what you guys thought of the chances of both the Ropinirole and the Levothyroxine getting approved with the same delivery method. And just furthermore if you guys are looking down the road or possibly looking at getting other drugs also using this same delivery system.

Sunil Bhonsle: Hi, (David). Thank you very much of those questions. And certainly with the approval of Probuphine, our technology platform, which we call ProNeura, as an implant-based long-term drug delivery platform, has, you know, been accepted, validated, we now understand fully how best to approach getting products like this approved through the FDA.

And the two products you mention, the one with Ropinirole for the treatment of Parkinson's Disease and the one with ((inaudible)), the Levothyroxine, for the treatment ((inaudible)) for the treatment of hypothyroidism, both those programs are right now in early stages. We expect to do Phase 1, 2 clinical studies over the next 18 months or so getting started.

You know, we certainly expect to file the IND by the end of this year for the Parkinson's program and hopefully by middle of next year for the hypothyroidism program. And get into the early stage clinical studies, establish proof of principle and concept of this treatment and then proceed from there .

We are continuing to look at other opportunities as well. Kate and her team dig into, you know, all kinds of potential opportunities where long-term delivery, stable continuous medication can have benefit. So we look forward to working with you and others out there on future products.

(David Toma): I appreciate it. Thank you very much.

Sunil Bhonsle: Thanks. Thanks very much, (David).

Operator: And we'll move next to (Raymond Patel), a private investor.

(Raymond Patel): Yes, hi. Sunil, I also would like to congratulate you for getting this social service done very well. I had one concern, and sort of inquiries, to normally when you get the FDA approval of this nature, company stock goes up and people are happy all the way around. In our case it went the other way. Is there any explanation behind this?

Sunil Bhonsle: Hi, (Raymond). You know, the stock market does what the stock market does. I obviously and our company doesn't control any of that and anything I say would be just conjecture on my part. Obviously there were large volumes of trading that did occur, you know, 9 million shares

plus that were traded last week on Friday. And when you see that large volume, to me I am very happy that there were new investors who purchased 9 million plus shares.

That to me I truly appreciate that support in that large volume that came out on the market. You know, people have invested money in Titan over a long period of time, obviously there were people who, you know, felt this was an opportunity for them to get a return on their investment, and there are others who have obviously put their faith and are willing to support Titan because we truly believe the value proposition for Titan is ahead of us. And we look forward to that support from all the new investors as well.

(Raymond Patel): Okay, thank you.

Sunil Bhonsle: Sure, (Raymond).

Operator: And we'll take our next question from Aaron Thomas with Northpoint Investments.

Aaron Thomas: Hi, everyone. Congrats on approval. Can you speak to...

Sunil Bhonsle: Thank you, Aaron.

Aaron Thomas: Can you speak more to the commercial launch? Can you - are there - let's say as you get into quarter 3 and quarter 4 and beyond, are there other goals that are in place to have a certain number of docs signed up by, again, by the end of quarter 3 and into quarter 4 and so on? What - can you talk about specific goals moving forward?

Sunil Bhonsle: Sure. I mean, I think Behshad already mentioned, you know, the immediate target. In the next six weeks there are more than 2000 physicians who are signed up for the training programs

that are being offered. And the goal for this year is to have at least 4000 physicians trained in those programs. Behshad, anything else you want to add to that?

Behshad Sheldon: Sure, so in addition we'll of course be going to more remote areas - and these are just the ones that have been sent already scheduled, predetermined, if you will, in terms of capacity but we will keep going. I would just say consider the fact that 6000 clinicians in this country drive 92% of Buprenorphine sales and prescriptions, so the fact that we would get to 4000 doctors by the end of the year, knock on wood, is actually a pretty robust goal to have.

And from there we'll be focusing on making sure the first procedure goes well in terms of insertion and then few months after that the first removals go well in addition to continuing to work on training new physicians.

Aaron Thomas: Sure. Thank you for that. And that - right so you train physicians but that obviously doesn't necessarily mean that they're going to start using the product. So is there - is there plans from a sales and marketing, from a commercial perspective, I'm sure you've thought through some of the greater risks to a successful commercial launch and what strategies might be in place to mitigate those risks?

Behshad Sheldon: Sure. We do actually think that by the time a clinician decides to commit four hours to the live training program and they come and they go through the process and they get certified, there is a fairly high likelihood that they will actually try the insertion removal and try using Probuphine. But we are also not naïve that there are always barriers to any launch.

Obviously every year reimbursement becomes a tougher issue and tougher nut to crack. That's why we're right out of the gate, you know, getting together with as many of these insurance companies, both public and private, as possible to make sure that patients have access to the

product. Also trying to take through Pro Pay assistance that will be pretty generous that the patient stick stock of things out of the way.

We're also very aggressively pursuing PR opportunities and opportunities to collaborate with other thought leaders in the area who want to promote the cause of patients with opioid addiction and make sure that access for everyone is a high priority given all the government attention and the congressional attention.

We think that there's opportunity to take advantage of all the other players in the field that are on the same page. And want to see evidence-based medicine, practice in an area that unfortunately has been stigmatized for too long and where, you know, we tend to think that - or society, you know, tends to think that people could just pull themselves up by their boot straps and say no and just get clean. That's clearly not the case.

And obviously the more evidence-based medicine is propagated by all those who are interested in the cause of people with opioid addiction the better for patients and the better for Probuphine.

Aaron Thomas: Yes. Yes, good comment. And for the manufacturing, if in the ideal scenario if the product takes off and physicians begin using it as planned can you talk about the manufacturing strategy? What's - you feel like you have enough space today to make implants for the next several years? What's that plan?

(Crosstalk)

Sunil Bhonsle: ...give a little bit on that and then certainly Behshad can add to it as well, Aaron. The manufacturing of Probuphine right now is set up at a contract manufacturing facility. It is our technology, our equipment and so on but it is being managed by a contract manufacturing DPT Laboratories in San Antonio, Texas.

The capacity over there is sufficient to make, you know, currently say over half a million implants so you're treating more than 100,000 patients treatment so to speak with that. So certainly a large capacity when you go into a launch like this. So I don't see that as an issue but also Braeburn has plans on, you know, expanding and having their own facility for this down the road as well.

Behshad Sheldon: Right, so we have signed a lease and actually are moving pretty quickly with plans to alter the space for our own manufacturing facility in Raleigh, North Carolina. You might have heard about some of the controversy actually that was connected to that. But we have decided to stay in North Carolina and continue after 30 years in this field I am a big fan of having a backup site for sure.

And I've become more and more a fan of having your own manufacturing facility and being in control of your own destiny. Too many things just happen with contract manufacturer organizations.

So ultimately our plan is to shift to have Braeburn be the main source and then continue with the current suppliers as backup, you should always have a backup. We hope that we will be able to be manufacturing within 18 months out of our own facility.

Aaron Thomas: Okay very good. Thank you.

Sunil Bhonsle: Great. Thank you very much, Aaron.

Operator: And we will take our next question from Richard Sperber with Sperber Inc.

Richard Sperber: Yes, I was wondering if you have taken a stab at projecting revenues for the first 12 months and the second part of the question is can you comment on any progress that you might be making in terms of establishing marketing relationships for international markets?

Sunil Bhonsle: Sure, Richard. Why don't I - you know, certainly in terms of revenue projections we have not provided that yet. Certainly once the product is launched and we see the progress we will start providing that information down the road. We will work with Braeburn as well and, you know, make some projections that are helpful. But certainly it's not something we will be doing immediately.

In terms of Probuphine and marketing potential opportunities outside of the US and Canada we have been exploring the opportunities in different parts of Europe and, you know, certainly have met and spoken with companies that have expressed an interest with this market.

All of them were waiting to see how the FDA review is completed and now that the product has been approved it is our intention to - Kate and her team have already been working with experts who are putting together the information package to go to regulatory agencies in different European countries. And I'll let Kate mention a little bit on that as well.

Katherine Beebe: Sure, thank you Sunil. In addition to sort of getting all of the information together in a regulatory format that would be acceptable by the EU, for example, the EMEA, the MHRA, other local regulatory agencies, we've been working with experts to understand, you know, the target patient profile, how this product might be adopted and also we've been talking with pharmaceutical companies in different countries and starting to generate interest in the product we're being approached now with this FDA approval we've been approached by a few companies who are interested in starting due diligence.

So we are beginning the process not only of understanding the regulatory requirements for approval if we were to do that ourselves and to speaking in greater detail with potential commercial partners. So look forward to being able to update you further over the coming months with the outcome of the discussion.

Richard Sperber: Thank you.

Operator: And that does conclude our Q&A session for today. I'll now turn the call back to Sunil Bhonsle for closing remarks.

Sunil Bhonsle: Thank you, (Shannon). Well thank you all for participating in this call. Wanted to make sure we could provide you with sufficient information as we started off in this process. We thank Behshad and the Braeburn team for already working through this long weekend and starting off the first training sessions. I believe we will keep you updated on this launch. I truly look forward to a very successful launch of this product.

But with the fact that there's a training component, it will be a very measured and steady launch that allows for proper assimilation of these procedures into the medical practice so we are all successfully treating the patients and that is eventually the goal. I thank you very much for your support and look forward to keeping you updated as we go along. Thank you.

Operator: And that does conclude today's conference. Thank you for your participation.

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