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Officers and Speakers

- Sunil Bhonsle, Titan Pharmaceuticals, Inc., President and Chief Executive Officer
- Jennifer Kiernan, Titan Pharmaceuticals, Inc., Administration and Communications
- Marc Rubin, Titan Pharmaceuticals, Inc., Executive Chairman
- 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 Small Cap Research

Presentation

Operator: Thank you for holding, and welcome to the Titan Pharmaceuticals Fourth Quarter and Full Year 2017 Financial Results Conference Call. At this time, all participants are in a listen only mode. There will be a question-and-answer session following today's remarks. Please be advised that this call is being taped at the company's request, and will be archived on the company's website starting later today.

At this time, I would like to turn the call over to Sunil Bhonsle, President and CEO of Titan Pharmaceuticals. Please go ahead.

Sunil Bhonsle: Thank you, Rachael, and thank you all for joining us. Welcome to the Titan Pharmaceuticals call to review financial and operational results for the fourth quarter and year ended December 31, 2017, and provide an update on our business.

Before we begin, I wanted to inform you that this morning, we filed our 2017 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, Executive Vice President and Chief Development Officer; and Brian Crowley, Vice President of Finance.

But 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 Kiernan: Thank you, Sunil. I want to remind everyone that certain matters that will be discussed today, other than historical information, may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to our product development programs and any other statements that are not historical facts. Such statements involve risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from management's current expectations include those risks and uncertainties relating to the commercialization of Probuphine; the regulatory approval process; the development, testing, production and marketing of our drug candidates; patent and intellectual property matters; and strategic agreements and relationships. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

And now, back to you, Sunil.

Sunil Bhonsle: Thank you. We will start the call with an overview from our Executive Chairman, Dr. Marc Rubin, and we'll follow that with Dr. Kate Beebe, who will provide an update on our product pipeline. Then Brian Crowley will summarize the financial results. I will close with a brief recap before opening the call for your questions. Let's get started. Marc?

Marc Rubin: Thank you very much, Sunil, and welcome, everybody. Thank you for joining us today. I'd like to begin by briefly discussing some of the issues related to the commercialization of Probuphine.

When Braeburn commenced its full commercial launch of Probuphine in the first quarter of 2017, we expected that the adoption of Probuphine would be measured, but ongoing and steady, over the course of the year. Suffice is to say, the limited uptake that actually materialized came as a significant disappointment.

As we discussed in our third quarter 2017 investor call, feedback from Braeburn then indicated that there were a number of issues that contributed to that. But we were encouraged by the steps that Braeburn was taking to overcome impediments to adoption and increase sales, and, in retrospect, they seem to have had some modest impact. The fourth quarter sales indicated a reversal of the prior quarter decline, and while obviously very modest from a monetary perspective, we did report a sequential increase in revenue from royalties earned on net sales of Probuphine in the fourth, compared to the third, quarters.

Nevertheless, our hope that Braeburn could significantly improve its sales performance was further dashed in the second half of January.

A central part of Braeburn's strategy for Probuphine had been to position it within the framework of the changing landscape of treatment options in the marketplace. The rationale was that the potential near-term FDA approvals of New Drug Applications for the depot buprenorphine injection products – and, as you know, one was submitted to the agency by Braeburn, and the other by Indivior -- that these would help continue the shift of the treatment paradigm from daily oral therapy to longer-duration, procedure-oriented treatments. As opiate use disorder is a chronic neurobiologic disease that requires ongoing treatment, often for years, that dynamic would bode well for Probuphine adoption as patients entered the maintenance treatment stage. In other words, it would be a softer, more natural hand-off from daily dosing to our six-month subdermal implant if there were extended release or depot injections provided for a period in between acute and maintenance therapy.

Unfortunately, while Indivior's depot injection product was approved by the FDA, Braeburn, as you know, received a Complete Response Letter, or CRL, from the agency in late January. Given our belief that addressing the CRL would understandably become Braeburn's primary focus, which was soon confirmed by its significant sales and marketing staff reductions, we entered into preliminary discussions with Braeburn for the return of the U.S. commercialization rights to the product. Those talks are ongoing, and we hope to come to a mutually satisfactory arrangement with Braeburn soon. We will, obviously, keep you updated as those discussions progress.

So following what I think we would all describe as a soft start, it's important to know that we continue to believe very strongly that Probuphine has an important role to play in combatting the epidemic of opioid addiction, both in the United States and internationally.

So while continuing the process to regain control of Probuphine and help drive its commercial success in the U.S., we're looking forward to building a strong and successful partnership with Molteni.

As most of you know, Molteni acquired the European intellectual property related to Probuphine, including the Market Authorization Application, or MAA, that is under review by the European Medicines Agency a few weeks ago. As a result, Molteni will have the exclusive right to commercialize Probuphine supplied by Titan in certain countries of the Commonwealth of Independent States, the Middle East, and North Africa.

Molteni operates both directly and through its network of specialized partners in more than 30 countries and has a very strong track record of success, bringing new treatments for opioid addiction to both clinicians and patients. Importantly, Molteni shares our vision for Probuphine both in Europe and the U.S. Molteni's support and investment in Titan is reflective of their belief and confidence in the future role of Probuphine, both in the U.S. and internationally, and their shared vision for Titan's current and future development programs. We are very pleased to be working closely with Molteni as we look towards the future.

With that, I'm going to turn the call now over to Dr. Beebe, who will provide additional details on our development programs, including our collaborative efforts with Molteni to secure EMA approval for Probuphine in Europe, as well as our ropinirole implant for Parkinson's disease and our early-stage programs. Kate?

Kate Beebe: Thank you, Marc, and hi, everyone. I'm very pleased to update you with additional details of our product development pipeline. As you know, our portfolio is based on our proprietary ProNeura technology, which is designed to provide long-term continuous drug delivery for up to 12 months. We are optimistic and we are committed to the prospects of ProNeura across a diverse range of chronic diseases.

Let's start with an update on Probuphine in Europe. In October 2017, Titan received a notice of allowance from the European Patent Office for a patent covering methods and use claims for treating opioid use disorder with a subdermal implant containing buprenorphine. This patent will provide protection for Probuphine in Europe until into 2023, and if approved by the EMA, Probuphine will receive 8 to 10 years of data exclusivity from the date of approval. This means that potential competitors would not be able to reference the Probuphine data as part of a generic development program until 2027 to 2029.

In November 2017, the EMA accepted our Probuphine MAA for centralized review. While I can't provide a lot of additional detail at this stage of the review process, I can confirm that we have received comments and questions from the EMA reviewers, and we are actively collaborating closely with Molteni to address these questions. We expect to continue our interaction with the reviewers, and will submit the responses within the allowed time frame sometime in the early fall of this year.

Now, this spring, we have two very good opportunities to share the Probuphine story. First, the data will be presented on May 27th at the 13th European Opiate Addiction Treatment Association conference, EUROPAD, in Krakow, Poland. And second, Probuphine data will also be presented on May 29th as part of a symposium on the U.S. opioid crisis at the American Society of Clinical Psychopharmacology at their annual meeting in Miami, Florida.

And now, switching gears to the ropinirole implant for Parkinson's disease program. This treatment is designed to deliver an approved dopamine agonist, ropinirole HCl, continuously for three months or longer, and will target the signs and symptoms of Parkinson's disease, including stiffness, tremors, muscle spasms, and poor muscle control. Ropinirole is currently available in daily or more frequently dosed oral formulations for the treatment of Parkinson's disease symptoms and restless leg syndrome.

In October 2017, we treated the first patient in our Phase I/II trial of the ropinirole implant, and the study is advancing as planned. The primary objectives are to characterize the pharmacokinetic profile of the ropinirole implants to evaluate their safety and tolerability, and to explore potential signals of efficacy using established disease-specific assessment scales. Patients on a stable dose of L-DOPA plus oral ropinirole will then have their oral ropinirole switched to ropinirole implants, and then continue for three months of treatment. Initial data from the first cohort of patients is expected in the first half of this year.

In the fourth quarter, we were also excited to announce a collaboration with Opiant Pharmaceuticals on a feasibility assessment of a ProNeura formulation of an opioid antagonist for the prevention of opioid relapse and overdose, and this is in individuals with opioid use disorder. Currently, the only FDA-approved opioid antagonist for relapse prevention is a monthly depot injection of naltrexone, otherwise known as Vivitrol, and that's marketed by

Alkermes. Our goal is to develop a product with a six-month duration that would provide a long-term treatment window for sustained recovery and for the prevention of opioid relapse and overdose death. Importantly, opioid-related relapse and fatal overdose are significantly higher than in any other type of drug addiction. In fact, as many as 91% of those in recovery following opioid detoxification will experience a relapse, during which the risk of a fatal overdose is at its highest. At least 59% of those who relapse do so within the first week of sobriety, while 80% relapse within a month after discharge from a treatment program.

Now, just a brief update on our other ProNeura programs. In November 2017, during a poster session at the annual meeting of the American Society of Tropical Medicine and Hygiene, the Walter Reed Army Institute of Research presented encouraging nonclinical data from Titan's collaboration with it and with the Southwest Research Institute to evaluate the development of ProNeura-based implants for the long-term prevention of malaria. These data demonstrated sustained release of the antimalarial drug atovaquone and protection from malaria for up to 12 weeks. Now, this program is of very high interest at Walter Reed Army Institute of Research, and they are pursuing funding opportunities to advance this treatment into the clinic.

In addition to these activities, we've conducted some pilot-scale experiments in the past to evaluate the feasibility of a few other product candidates across a variety of different chronic disease indications, and these include the LT-3 implant for hypothyroidism and liraglutide for type 2 diabetes. Currently, we are completing early nonclinical testing of a kappa opioid receptor agonist implant for the treatment of chronic pain.

Of course, we will prioritize and pursue these early-stage product candidates as resources allow, and we continue to believe that Titan's ProNeura long-term continuous 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 efficacy benefits. We look forward to updating you on continued progress as we develop our portfolio of ProNeura-based product candidates.

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

Brian Crowley: Thank you, Kate.

A summary of the financial results was provided in our press release issued this morning, and details are available in the Form 10-K filed with the SEC earlier today. At this time, I will just highlight a few key items. Please note that all the numbers I'm about to present have been rounded and are therefore approximate.

In the fourth quarter of 2017, we reported $58,000 in revenue from royalties earned on net sales of Probuphine by Braeburn. This compared with $35,000 in the same period a year ago. Total revenues for the full year ended December 31, 2017, were $215,000. This compared to $15.1 million in 2016, which included $15 million from the FDA approval milestone Titan received from Braeburn and $65,000 from royalties earned on net sales of Probuphine.

For the fourth quarter of 2017, total operating expenses consisting primarily of R&D and G&A expenses were $3.4 million, compared with $3.3 million in the same quarter in 2017 -- I mean 2016, pardon me.

Total operating expenses for the full year were $14.7 million in 2017, compared with $10.7 million in 2016.

Net loss applicable to common shareholders in the fourth quarter of 2017 was $3.7 million, or $0.17 per share, compared with a net loss of $2.3 million, or $0.11 per share, in the same quarter of 2016.

For the full year, the 2017 net loss was $14.3 million, or approximately $0.67 per share, compared with a net income of $5.1 million, or $0.25 per share, for 2016.

At December 31, 2017, we had cash and cash equivalents of $7.5 million. We believe, following the $3-million prepayment of our loan from Horizon in February 2018 and the $2.4 million received from Molteni in March 2018, is sufficient to fund our planned operations into the third quarter of 2018.

Now I'll pass the call back to Sunil. 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. Well, as you've heard from Marc, Kate and Brian, we had a very active 2017, and that has continued into 2018.

We remain confident that with the right partners and strategies in place, Probuphine can grow to its full potential, and that remains our top priority.

To that end, we are looking forward to completing our discussions with Braeburn for the return of the U.S. commercialization rights to the product. We were also very pleased to move forward in our strategic partnership with Molteni, which serves to provide important outside validation of Probuphine's commercial promise.

Molteni's strong track record of success launching and commercializing innovative new pharmaceutical products, combined with its focus on the pain and drug-addiction markets, makes it an ideal partner for Titan as we work to increase Probuphine's global uptake.

In the transaction, Titan received an initial payment of about $2.4 million, and will receive potential additional payments totaling up to $5.5 million upon the achievement of certain regulatory and product label milestones. Additionally, Titan is entitled to receive earn-out payments for up to 15 years on net sales of Probuphine in the Molteni markets, and this ranges in percentage from the low teens to the mid-twenties, so it's quite a substantial amount.

As part of the transaction, Molteni also made an indirect strategic investment in Titan by purchasing $2.4 million of the outstanding $4-million principal balance owed under Titan's July 2017 loan agreement with Horizon. In connection with this transaction, Molteni was appointed collateral agent and assumed majority and administrative control of the debt, and importantly, the interest-only payment and forbearance periods were extended to December 31, 2019. Molteni has the right, and under certain circumstances, the obligation to convert its portion of the debt into shares of Titan's common stock at a conversion price of $1.20 per share, which was a decent premium to the closing price at that time.

So as is evident from these completed transactions, this is about more than just commercializing Probuphine outside of the U.S. Molteni expects in the future to be a significant stockholder and help build value in Titan. We believe that our new strategic partnership with Molteni marks a potential important inflection point for Titan. The additional financial resources and flexibility that it provided enables us to evaluate options to further strengthen our balance sheet to better position us to execute important elements of our growth strategy, and that includes driving Probuphine's commercial success and continuing to advance our pipeline of other ProNeura-based products.

As Kate mentioned, we intend to pursue our clinical development programs based on priorities and resources, and we remain enthusiastic about the prospect of our ProNeura platform for the treatment of select chronic diseases. We remain very committed to building our product pipeline and adding value for our stockholders based on achievements with both Probuphine and the other ProNeura-based products.

This concludes our prepared remarks for today, and so, Rachael, we are ready to take questions from the call participants.

Questions & Answers

Operator: Thank you.

(Operator Instructions)

The first question comes from Scott Henry with Roth Capital. Please go ahead.

Scott Henry: Thank you, and good afternoon.

Sunil Bhonsle: Good afternoon, Scott.

Scott Henry: A couple questions. I guess, starting with Probuphine, I guess, first, what should we think about for a timeline of resolution with Braeburn? I know you're not going to have anything specific, but just any general parameters. And second, how should we think about kind of end-user sales the next couple quarters? Should they be flat, or, I know there'll be a smaller sales force; should we think of them as down? I'm just trying to get a sense of how to think about 2018.

Sunil Bhonsle: Sure. Hey, Scott. Clearly, we started some discussions with Braeburn about Probuphine and reacquiring the rights. Now, at the same time, Braeburn has been interacting with the FDA, not only on the CRL that they received, but there were also some things that they needed to complete on Probuphine. And as part of our discussions, we need to make certain that the dialog with the FDA on Probuphine is also at an appropriate stage where we can indeed be looking at continuing that from that point onward. So all of these things have played into what the timeline would be. Now, clearly, we are at the stage where we want to progress this quickly, want to be able to access the product directly and conclude the transactions. We wanted to first have our agreements with Molteni all in place, which as you know was only a few days ago that everything was finalized. And with that having been completed, we are now -- our first priority is

really to look at completing the dialog with Braeburn and a transitionary period. Now, the way we envision this is really that there will be a transition that is good for both companies. Clearly, the field sales force at Braeburn has been pretty much eliminated, and the support that is there for Probuphine today is -- there is still some support, and there is some continuing period of -- during a transition period where we expect that support to continue from Braeburn so that it can be a smooth transition. Timing-wise, I hope within this quarter, this coming quarter, we are able to progress it to a stage where we will be able to tell everyone the timelines and so on that make sense, but it's going to be a smooth transition. And in terms of product sales during these next couple of quarters, I expect those to be low, but they will continue. It is not as if the product is off the market. The product continues to be used and will be supported in terms of medical support and the product support that is needed. That will continue. Hopefully that provides you sort of a -- without a specific timeline, the broad enough perspective of all the things that are going on.

Scott Henry: That is very helpful, Sunil. Thank you. And when we think about spending for 2018, how should we think about that? I guess R&D, perhaps relative to Q4, was a downtick in R&D. Should we think about Q4 as representative of '18? And then on the G&A side, I mean, G&A, I think, bounced up in Q4. I mean, should I think about more like Q2, Q3 for '17 as representative of '18? Just trying to get an idea of where we should think about the sort of level.

Sunil Bhonsle: Sure. Yes, no, I think the best way to look at -- certainly the G&A is a more -- easier answer. If you look at the total 2017 G&A expenses, we would expect it to be about the same for 2018, there are no significant changes that are happening. Quarter to quarter, it varies some, mostly because some of the -- for instance, in the first quarter, typically we have to pay for the year's full of insurance and so on, and so suddenly it bumps up. But it otherwise stays pretty flat from -- through the year.

Now, in terms of the remainder of the expenses, really, the R&D expenses will be driven also by the available resources. Right now we are committed to the Parkinson's clinical study that is going on. We expect to have some data from that during the first half, which will really provide the level of information that will tell us how we proceed further with that as well, and how much we will commit in terms of resources. So I would look at, clearly, the R&D resources that will be behind this are basically for the ropinirole study, and in amounts, in terms of dollars, they probably will not be any more than what we have already spent in 2017.

Scott Henry: Okay, great. And then the final question: When we think about the market for Probuphine in Europe relative to the U.S., how should we think about that? As far as magnitude of demand?

Sunil Bhonsle: Sure. The approach that Molteni is taking to Europe -- first of all, and in terms of approval and so on, I would expect if everything goes, timeline-wise, as planned, could be early part of 2019. And then of course, following that, there are additional requirements such as getting pricing approval in specific countries and so on. So it takes some time. In terms of the trust for Molteni, it is to provide Probuphine as a specialty product that is meant for a very precise set of patient populations. So it's not for every patient in that setting. And based on that, they believe they can get a premium pricing in these countries. And so, it is going to be a gradual climb. In terms of what total dollars that may represent, it is really a little too early to project. I

mean, obviously, compared to the U.S. markets, the markets are only about 10-plus percent in Europe right now. But I would -- I will certainly provide better guidance as we get closer to commercializing the product in Europe and provide some idea of what patient numbers and what countries would be targeted initially and so on as well. I mean, all of this is part of Molteni's strategy and plans. They, of course, haven't made it public, and rightfully so, for competitive reasons. So as we get closer to it, we will really provide that to you.

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

Sunil Bhonsle: Sure. Thanks, Scott.

Operator: The next question comes from John Vandermosten with Zacks Small Cap Research. Please go ahead.

John Vandermosten: Hi, this is John.

Sunil Bhonsle: Hey, John.

John Vandermosten: Good afternoon.

Sunil Bhonsle: Good afternoon. How are you?

John Vandermosten: I'm doing all right. I wanted to ask about capital needs related to Probuphine and it perhaps changing hands, and I'm thinking in terms of transition costs, and then also in terms of up-fronts, if it's passed on to, potentially, another developer or distributor.

Sunil Bhonsle: Sure. I mean, obviously, these are the key questions that we are going through ourselves, right now, and working out in this transition period. Let me give you sort of a more broader perspective on it, rather than very specific costs, as these are things that, as we progress, I will provide, but it's a little too early to give very precise numbers. Our goal here is clearly to reposition Probuphine within the U.S. in a way that provides a very targeted approach to who the patients are and how this can be marketed in the right hands. Right now, the resources being put behind Probuphine are extremely limited from a commercial standpoint, and that is what really needs to change. What Braeburn has committed to in our initial dialog is that they will provide assistance during the transitionary period so that Probuphine doesn't in any way suffer during that process while a new partner or a distribution or all of the above can be taken up by new entities and built up in the right way. So the best way to put this is, clearly, during this transitionary period, it will require some resources. We expect those resources to be available from a combination of Braeburn and other entities. And we, from a technical side, obviously, have the expertise in Kate's group and in supply side, and we will devote all of that to it. So that's the stage where we're at right now.

John Vandermosten: Okay, that is helpful. And there's a lot of, I guess, equipment that's used for the implementation and withdrawing the implant, and then there's also a lot of providers. Might any of those be lost in the transition? And is there a way to maintain kind of what's been developed so far by Braeburn?

Sunil Bhonsle: Absolutely, John. I mean, the -- in terms of, for instance, the applicators and the instruments, the explant clamps, things like that, all of those will transition over from Braeburn to Titan and other entities as needed. We continue to have, because of our interest in the rest of the world, we have continued to have contracts with the suppliers and so on ourselves so that there is nothing that will be missed in this transition from that standpoint, from a supply side of things. And in terms of the manufacturing and so on that is done at our contract manufacturer DPT, Titan has continued to own the process and the equipment there, and has an ongoing relationship and supply lines with DPT, so that won't change in any way, either. So I expect this to be a smooth transition. All of the equipment, as well as, possibly, inventory of product that is there, will be available to transition over into the new entities.

John Vandermosten: Okay. And then, of course, there's Canada, and I know that progress had been slow to date. Is there any update on that? And does this new potential -- and obviously you're in process with it right now, but does this new agreement potentially maintain Knight as the partner up there?

Sunil Bhonsle: Knight has an agreement with Braeburn. Braeburn had sublicensed the product to Knight Therapeutics. Knight filed with Health Canada the application for approval. It is expected, I think, timeline-wise, that this summer would be the timeframe for response from Health Canada. And assuming everything is moving along at that stage, we have provided support when questions have come up from the regulatory authorities. Our people have been involved, especially in the CMC side and so on, since that was all developed by us originally. So we know it is progressing in that setting. How the final transition from Braeburn and the Knight license agreement, sublicense agreement, gets worked out, clearly, we will continue to support it. We haven't specifically worked out whether that comes back to Titan or to some other entities, or how that will happen, but clearly Knight is interested, and we are interested. So we will make sure that it works out for everybody.

John Vandermosten: Okay, that's helpful as well. And just to close out, we've seen a lot of news come out from the feds on fighting the opioid crisis in the last months. And is there anything in particular that sticks out that you're seeing out there that might be helpful for Probuphine in particular, or some of the other items in the pipeline? And that's it, thank you.

Kate Beebe: John -- yes, John this is Kate.

Sunil Bhonsle: Sure.

Kate Beebe: That's a really good observation and question that you have made, and in fact, the good news is that there is increasing evidence and pressure on the FDA and on the federal government to provide additional resources to pay for treatment, to pay for other services related to solving this crisis. And namely, very recently, the government has made money [available] to NIDA and to other research agencies and charged them with trying to help partner with companies to develop additional treatments for this epidemic. So that's all good news. The bad news, of course, is that it is continuing to grow at a frightening pace.

Operator: And this will conclude our question-and-answer session. I would like to turn the conference back over to Sunil Bhonsle for any closing remarks.

Sunil Bhonsle: Thank you, Rachael. Thank you, everyone, for participating in the call today. Before we close, I wanted to acknowledge all of the support that you provide to Titan. And this has been a period of ups and downs, but our people and our staff, and the board and the management at Titan, is very committed and has been working hard at making sure we can continue to progress the company, and we believe in it. And we believe we can accomplish this. So truly appreciate your support during this period, and we really look forward to providing updates to you in the year to come. So thank you.

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