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Officers and Speakers

- Sunil Bhonsle; Titan Pharmaceuticals, Inc.; President & CEO
- Jennifer Kiernan; Titan Pharmaceuticals, Inc.; Administration and Communications
- Marc Rubin; Titan Pharmaceuticals, Inc.; Executive Chairman
- Kate Beebe; Titan Pharmaceuticals, Inc.; EVP & Chief Scientific Officer
- Brian Crowley; Titan Pharmaceuticals, Inc.; VP, Finance

Analysts

- Scott Henry, ROTH Capital
- John Vandermosten, Zacks Small Capital Research

Presentation

Operator: Good afternoon. Thank you for holding, and welcome to the Titan Pharmaceuticals first quarter 2018 financial results conference call.

(Operator Instructions)

Please be advised that this call is being taped at the Company's request and will be archived on the Company's website starting later today.

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

Sunil Bhonsle: Thank you, Austin, and thank you all for joining us. Welcome to the Titan Pharmaceuticals call to review financial and operational results for the first quarter ended March 31, 2018, and we'll provide an update on our business.

Before we begin, I wanted to inform you that this morning -- actually yesterday we filed our Quarterly Report on Form 10-Q with the SEC, and the press release was also issued yesterday, providing 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 Scientific Officer; and Brian Crowley, our Vice President of Finance.

Before we get into the details of the financial results and provide an update on the Company, Jennifer Kiernan will review the required cautions regarding forward-looking statements. Jennifer?

Jennifer Kiernan: Thank you, Sunil. I want to remind everyone that certain matters that will be discussed today, other than historical information, may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to our product development programs and any other statements that are not historical facts.

Such statements involve risks and uncertainties that could negatively affect our business, operating results, financial conditions and stock price. Factors that could cause actual results to differ materially from management's current expectations include those risks and uncertainties relating to the commercialization of Probuphine; the regulatory approval process; the development, testing, production and marketing of our drug candidates; patent and intellectual property matters; and strategic agreements and relationships.

We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

And now back to you, Sunil.

Sunil Bhonsle: Thank you, Jennifer.

We will start the call, as always, with an overview from our Executive Chairman, Dr. Marc Rubin, and that will be followed by Dr. Kate Beebe, who will provide an update on our product development and regulatory activities, 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 good afternoon, and thank you all for joining us, as always. As we just held our fourth quarter 2017 call a few weeks ago during which we covered some of the first quarter activities, especially the Molteni transaction acquiring Probuphine for Europe, I'm not going to repeat those details today, except to say that that transaction was truly a transformative agreement for Titan, and I thought then the best use of time would be to give you some color on the recent appointment of Federico Seghi Recli to Titan's Board in the role of lead independent director.

So, Federico's joining the Titan team comes at a very opportune time. Federico is exceptionally well-qualified to help us consider and evaluate all options for our potential commercialization of Probuphine in the United States, while at the same time to support Molteni's planned commercial expansion of Probuphine beyond the U.S. pending EMA approval.

Federico has over 24 years of leadership experience within the pharmaceutical industry, and in his most recent role as its CEO he led Molteni's successful transformation into a specialty pharmaceutical company and one that was focused on launching and commercializing innovative pharmaceutical products for the treatment of both pain and addiction. And today, largely as a result of Federico's strong leadership, Molteni operates both directly and through its network of specialized partners in more than 30 countries and is a preferred and qualified partner of a number of international organizations and nongovernmental organizations, such as UNICEF, UNDP and the IDA Foundation and Global Fund.

Our many interactions with Federico over the last 18 months or so have made clear the strong commitment that he and Molteni have to Probuphine and to Titan. Our interactions have also convinced me personally that his knowledge and expertise in commercializing pharmaceutical products as well as many longstanding industry relationships will be of significant benefit to Titan and to its shareholders going forward. So a heartfelt welcome to Federico as he joins the Titan board.

As indicated in our financial results press release, the interactions with Braeburn to regain control of Probuphine are progressing, and our initial research on potential opioid use disorder market segments, where Probuphine would be a good treatment option, leads us to believe very strongly that Probuphine has an important role to play in combating the epidemic of opioid addiction both in the U.S. and internationally. And to that end we are and will be tapping on Federico's expertise to position the product for success both here in the United States and in select international markets.

And so with that I will turn the call over to Dr. Beebe, who is going to provide additional details on our product development and regulatory activities, including our collaborative efforts with Molteni to secure EMA approval for Probuphine in Europe. Kate?

Kate Beebe: Thank you, Marc, and hi, everyone. Since I provided a full update just a month ago, I will keep this one brief and focus on some of the more salient product development and regulatory activities here at Titan. So, let's start with an update on Probuphine. As you know, Probuphine is based on our proprietary ProNeura technology. This platform provides convenient long-term continuous drug delivery and has the potential to be used to develop products across a diverse range of product diseases.

Late last year, the EMA accepted our Probuphine MAA for centralized review, and during the first quarter we have been working closely with the Molteni team to more comprehensively familiarize them with the product and with the content of the MAA. Now while the MAA was acquired by Molteni as part of the European intellectual property purpose transaction, as we announced in March, we're committed to fully supporting them in addressing all the questions raised by the rapporteur and co-rapporteur during their review. Right now we're preparing for a dialogue with these health authorities on the key questions so that we can align the final responses accordingly and submit them within the allowed timeframe in early fall of this year.

As you know, 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. Now, while this patent will provide protection for Probuphine in Europe into 2023, upon approval of Probuphine by the EMA Probuphine will receive between 8 and 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 around 2027 to 2029.

I'm also happy to say that late last month Health Canada was the first ex-U.S. regulatory agency to approve Probuphine for the maintenance treatment of opioid use disorder in patients who are clinically stabilized on no more than 8 milligrams of subliminal buprenorphine in combination with counseling and psychosocial support. Knight Therapeutics Inc., a leading Canadian specialty pharmaceutical company, has the exclusive right to distribute Probuphine in Canada under a sub-license agreement from Braeburn, and Titan is entitled to royalties from Braeburn on Probuphine sales in Canada following the launch expected late this year.

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

Switching gears now to the ropinirole implant for Parkinson's disease program, this treatment is designed to deliver an approved dopamine agonist, ropinirole HCL, continuously for 3 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 just oral formulations for the treatment of Parkinson's disease symptoms and restless leg syndrome.

In October 2017, we initiated our Phase 1/2 trial of the ropinirole implant. The primary objectives are to characterize the pharmacokinetic profile to evaluate 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 have their oral ropinirole switched to ropinirole implants for three months of treatment. Initial data from the first cohort of patients will be reviewed by the independent data safety monitoring board in early June.

As you know, we and our collaborators have conducted some pilot scale experiments in the past to evaluate the feasibility of other product candidates using our ProNeura technology. And this is across a variety of chronic disease indications such as an opioid antagonist for the prevention of opioid relapse and overdose, a treatment for the prevention of malaria, L-T3 for hypothyroidism, liraglutide for Type 2 diabetes, as well as a Kappa opioid receptor agonist implant for the treatment of chronic pain.

As we mentioned on our call a few weeks ago, we will pursue these early stage product candidates as and when resources allow. We 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 and we look forward to updating you again in the future on our progress.

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

Brian Crowley: Thank you, Kate. As mentioned earlier, a summary of the financial results was provided in our press release issued yesterday and the details are available in our Form 10-Q filed with the SEC yesterday. At this time I will just highlight a few key items. Please note that all the numbers I am about to give have been rounded and are therefore approximate.

In the first quarter of 2018, we reported $1.1 million in revenue, compared with $40,000 in the same period a year ago. Revenues for the 2018 period reflect $1 million related to the sale to Molteni of European intellectual property rights to Probuphine and $25,000 related to recognition of royalties earned on net sales of Probuphine by Braeburn.

For the first quarter, total operating expenses, consisting primarily of R&D and G&A expenses, were $3.5 million, unchanged from the same quarter in 2017. Net loss applicable to common shareholders in the first quarter of 2018 was $2.6 million or $0.12 per share, compared with net loss of $3 million, or $0.14 per share, in the same quarter in 2017.

At March 31, 2018, we had cash and cash equivalents of $3.5 million, which we believe is sufficient to fund our planned operations into the third quarter of 2018. We are currently exploring several financing alternatives to fund our operations beyond that period. However, there can be no assurance that those efforts will be successful.

Now I will pass the call back to Sunil. If you have any questions, we will be happy to address them during the Q&A at the end of the presentation. Sunil?

Sunil Bhonsle: Thank you. And as you have heard from Marc and Kate, 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 excited to move forward in a strategic partnership with Molteni, whose strong track record of success bringing new treatments for opioid addiction to clinicians and patients makes it an ideal partner for Titan as we work to increase Probuphine's global uptake. As Marc mentioned earlier, the fact that Frederico joined our Board earlier this week highlights the strong commitment that he and Molteni have for Probuphine and Titan.

We are also looking forward to completing our discussions with Braeburn for the return of U.S. commercialization rights to Probuphine. It is too early to provide any specific details, but I can tell you that in preparation for Titan's potential direct participation in commercial activities we have been conducting preliminary research in select market segments where Probuphine may be used for the treatment of opioid use disorder. Our review reinforces our belief that Probuphine has the potential to benefit patients and generate meaningful revenues as a specialty product in both the United States and internationally.

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 adding value for our stockholders based on achievements with both Probuphine and the other ProNeura-based products.

This concludes our prepared remarks for today. Before I open the call to questions, I'd like to thank Titan's Board, executive management and staff for their continued hard work and dedication.

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

Questions & Answers

Operator: Thank you, sir.

(Operator Instructions)

And our first question will come from Scott Henry, with ROTH Capital. Please go ahead.

Scott Henry: Thank you and good afternoon. Just a couple of questions. First, could you talk about the size of the Canadian market for Probuphine and is that the same royalty structure as the U.S. or how should we think about the royalty rate there?

Sunil Bhonsle: Sure. Hi, Scott. In terms of the size of the market, it certainly is a small market, and obviously the population of Canada being only about less than 10% of the U.S. it tends to be much smaller. Now in total from what I had seen, written, and this was over a year ago, so I don't know how the market may be progressing in Canada, but overall, buprenorphine sales were under $10 million at that point, but recognize that buprenorphine was approved in Canada much later than the U.S., so it hasn't had a chance to mature, necessarily, as a treatment, either.

So, and in terms of our royalties from sales in Canada, essentially our agreement with Braeburn is based upon sales in both U.S. and Canada, so the royalty structure would be essentially what is currently applied to the U.S. sales.

Scott Henry: Okay, great. And then on the pipeline, the ropinirole proof-of-concept trial, when should we expect data for investors? When will you press release that or when should we get some color on that?

Kate Beebe: Hey, Scott. This is Kate. We will be having, as I mentioned, an independent data safety monitoring board in early June, and we'll able to talk about the data in mid to late June following that meeting.

Scott Henry: Okay, great. And then, finally, with regard -- well, I guess a couple of questions still, first, could you talk about how spending, how we should think about the spending rate throughout the year? And then with regards to getting rights back to Probuphine, what's the next

event there to focus on as -- are we just waiting to hear from Braeburn, or what should we be looking for?

Sunil Bhonsle: Sure. Scott, in terms of the spending, we have been very careful in as you can see using our resources, limiting things mostly to use of things associated with Probuphine approvals in Europe. And so currently we are focused very much on continuing that pattern. And so, as in the past, you've seen our typical burn rates without any major clinical expenses being in the range of $7 million to $8 million a year, and that's the kind of burn rates I would expect to continue with at this stage.

We are very careful in making sure that we can devote the funds to the key programs that can provide the most value right now. And in terms of the key events with Braeburn, look, obviously there's a lot of information that we have to absorb that we have been going through. Like any agreements or when you are trying to rearrange things, there are issues that we are dealing with and addressing as we go forward. So we certainly want to get this done as soon as we can and we are really pushing towards that. So we'll keep you updated, all right?

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

Sunil Bhonsle: Sure. Thanks, Scott.

Operator: Your next question comes from John Vandermosten, with Zacks Small Capital Research. Please go ahead.

Sunil Bhonsle: Hi, John.

John Vandermosten: Hi, good afternoon. I wanted to ask about the situation has been in flux and moving forward, I suppose, with Braeburn, and what does the likelihood of an upfront payment look like at this point after you obtain rights back and then you look for another partner? Is that -- do you expect that to be part of a deal going forward?

Sunil Bhonsle: John, I mean, certainly good questions, but there's not a lot of detail I can really share right now in this overall one. We want to make certain that we can provide kind of the best opportunity for commercializing Probuphine, first step being getting rights to the product back, and we are focusing very much on that and trying to do that quickly.

We have also explored what would be the best way to re-launch, so to speak, the product, getting attention in the right segments of the markets and so on, and that's what we have focused on. How best we can accomplish that is what we are looking at, and we will let you know as we keep progressing. Okay?

John Vandermosten: Okay. I mean, is there any reason to think it wouldn't be what we normally see out there for any new type of deal where there is an upfront, there's royalty payments and then there are milestones? Could we expect something -- I mean, is there any reason to expect that that wouldn't be what we'd see?

Sunil Bhonsle: I think certainly in a partnering opportunity that would be the right way to look at it, but, as we have indicated, there may be potential for us to participate directly, as well, and we are looking at that possibility as well. So, both of these are very strong potential approaches that can be meaningful. And so we are looking at both.

John Vandermosten: Okay. And for Knight up in Canada, is there any confusion from their point of view on what might happen going forward? And I'm asking that thinking about how much investment they'll make if it's uncertain what they'll end up doing with the product after it's all resolved with Braeburn.

Sunil Bhonsle: John, I mean, what I can tell you clearly in our discussions with Knight during the regulatory review process, our people have been involved in addressing certain questions and have interacted with Knight people, and they seem to be very enthusiastic about the product. As we work out the details with Braeburn, we will have further dialogue with Knight, but there is no reason to believe that they are any less enthusiastic about the product, and essentially the product will be supplied from the U.S. and they will have complete rights to commercialize it in Canada.

John Vandermosten: Okay. And last thing was just if there were any observations that Federico had made that you could share with us in terms of how things could be better or changes or things like that along those lines?

Sunil Bhonsle: I mean, certainly the European markets where Molteni has a lot of experience are very specialized and different from country to country, which gives them a lot of experience in looking at other approaches. They are mostly driven by methadone centers and so on.

But some of the uniqueness of how to capture market shares by providing additional services besides just the product, something that they have worked with and have had success with it. Perhaps Marc -- Marc, anything else that you can add to that?

Marc Rubin: No, Sunil, I think that captures it. I mean, Federico just has tremendous broad knowledge and specific knowledge in the area of addiction in Europe and has a tremendous grasp of things in the U.S.

And so I think when we look at potentially how we or others could focus in the U.S. marketplace he has played a tremendous role in helping us look at that. So I think I'll stop there without going into details, but he's been a tremendous asset.

Sunil Bhonsle: Great. Thanks, Marc.

John Vandermosten: Thank you.

Sunil Bhonsle: Thanks, John.

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, Austin, and thank you, everyone, for participating in this call. As always, we truly appreciate your ongoing support, and we will continue to keep you updated as we move forward. Have a great day.

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