Titan Pharmaceuticals Third Quarter 2020 Financial Results

Monday, November 16, 2020, 9:00 a.m. Pacific Time

Officers and Speakers

- Marc Rubin; Titan Pharmaceuticals, Inc.; Executive Chairman
- Jennifer Kiernan; Titan Pharmaceuticals, Inc.; Administration and Communications
- Kate DeVarney; Titan Pharmaceuticals, Inc.; President and Chief Operating Officer

Presentation

Operator: Thank you for holding and welcome to the Titan Pharmaceuticals Third Quarter 2020 Financial Results Conference Call.

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 Dr. Marc Rubin, Executive Chairman of Titan Pharmaceuticals. Please go ahead.

Marc Rubin: Thank you, Sarah, and as always, thank you to all of you for joining us today. Welcome to the Titan Pharmaceuticals Third Quarter 2020 Conference Call.

Before we begin, I want to inform you that we have filed our quarterly report on Form 10-Q with the SEC, and the press release issued earlier today provides a summary of the financial and operational results for the third quarter ending September 30, 2020, and can also be found on our website at www.titanpharm.com.

Joining me on the call today from Titan is Dr. Kate DeVarney, our President and Chief Operating Officer. As you all know, Sunil Bhonsle has recently made the decision to retire from the company, and we would like take this opportunity to thank him for his unwavering dedication and many, many, many contributions to Titan over the years. We all wish him the best for his very, very well-earned retirement. Moving forward, Kate and I will oversee the company's product development activities.

The relevance of our prior operating results is diminished in that Titan has transitioned back from a commercial- to a development-stage company. So rather than discussing these today, I'd like to draw your attention to the aforementioned filings, and I'll now turn the call to Jennifer Kiernan, who will review the required cautions regarding forward-looking statements. Jennifer?

Jennifer Kiernan: Thank you, Marc. 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 commercialization and 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 our ability to raise capital; the winding down of U.S. commercial activities related to 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.

I'll now turn the call back over to you, Marc.

Marc Rubin: Thanks, Jennifer, and we'd like to focus today's call on a brief overview and update of our two key assets, JT-09 and nalmefene. We completed a public offering two weeks ago and have a meeting of stockholders scheduled for November 30, so the details of all recent developments at Titan are available via a number of recently filed disclosures with the SEC.

Our recent restructuring aims to position the company for future growth and is expected to result in substantial reductions in our fixed operating costs. It also means that Titan is back to being a development-stage company, which really represents our core expertise, and we have two key assets, one of which is JT-09, a kappa opioid receptor agonist peptide that we recently acquired from JT Pharma. I will briefly begin by describing this program before turning the call over to Kate, who will go on to give a brief overview of nalmefene.

The acquisition of JT-09 was based on work that we actually began several years ago to assess the feasibility of delivering JT-09 through peptide-infused ProNeura implants in animal models, and we had initially focused this work on looking at providing a nonaddictive treatment for chronic pain. But recently, we have pivoted to focus and explore the feasibility of using JT-09 implants for the treatment of chronic pruritus, initially looking at the potential for treating chronic pruritus in patients with end-stage kidney disease.

Chronic pruritus in general is a very debilitating condition defined as itching of the skin that lasts for longer than six weeks, and an estimated 23 million to 44 million Americans suffer from chronic pruritus, caused by a number of cutaneous, as well as systemic, conditions. And current treatments for chronic pruritus include antihistamines, corticosteroids, a number of over-the-counter lotions, all of which are relatively ineffective and many have undesirable side effect profiles, varying, of course, based on the etiology of the pruritus itself.

The antipruritic effect of kappa opioid agonists is thought to be related to their binding to kappa opioid receptors on keratinocytes, immune cells and peripheral itch neurons. The efficacy of a

kappa opioid agonist for chronic pruritus was first demonstrated definitely in humans by Toray Industries using a highly potent small-molecule kappa agonist called nalfurafine. Toray's application for nalfurafine was approved in Japan for the treatment of pruritus in end-stage kidney disease and in chronic liver disease. Pruritus does affect about 40% of patients who have end-stage kidney disease, so it is very prevalent and is associated with very poor quality of life, poor sleep, depression and actually overall increased mortality. Because Toray's nalfurafine is a small molecule that penetrates into the central nervous system, there have been some CNS-related adverse events observed. Nalfurafine for the treatment of chronic pruritus is approved only in Japan.

More recently, Cara Therapeutics demonstrated, in both Phase 2 and Phase 3 clinical trials, the efficacy of a selective kappa opioid receptor agonist peptide -- they call it CR845 -- in the treatment of pruritus associated with end-stage kidney disease in patients undergoing dialysis, and Cara has announced plans to submit a new drug application in the U.S. in the second half of 2020.

We believe that, based on our early animal data, subcutaneous implantation of JT ProNeura rods could potentially deliver therapeutic concentrations of JT-09 for six months or longer following a single in-office procedure. This could potentially eliminate the need for multiple weekly injections by delivering relatively nonfluctuating therapeutic levels of medication over a long period of time. We are now working toward establishing proof of concept of the JT-09 peptide and we expect to get this proof-of-concept data in the second quarter of 2021. If successful, we then plan on conducting investigational new-drug-enabling safety and pharmacology studies.

Of course, we will keep you updated on our progress and share key data as we generate it.

I now would like to pass the call to Kate, who is going to discuss our nalmefene development program. Kate?

Kate DeVarney: Thank you, Marc. As you know, we are developing a nalmefene implant for the prevention of opioid relapse following detoxification. This program is based in part on FDA's 1995 approval of an injectable formulation of nalmefene for the management and reversal of opioid overdose, including respiratory depression. In addition, oral nalmefene was approved by the European Medicines Agency in 2013 for treating alcohol dependence.

In September of 2019, the National Institute on Drug Abuse, or NIDA, awarded us an approximately $8.7-million grant over two years for this program. The NIDA grant provides funds for the completion of implant formulation development, GMP manufacturing and the nonclinical studies required for filing an IND. We are in regular communication with NIDA regarding the progress of this program, and we remain on track to meet our next milestone, which is filing the IND, in the first half of 2021. Now, acceptance of the IND by the FDA will allow us to apply to NIDA for the remaining portion of the grant, which is approximately $6.3 million.

We've received clear guidance from the FDA that this product should follow the 505(b)(1) regulatory approval pathway, and that's due to the lack of safety data on nalmefene for a long-

acting formulation. The FDA also advised on the nonclinical studies that will be required to file the IND. So based on this input, we plan to conduct an additional study as well as to increase the duration of an ongoing study and collect all the nonclinical chronic toxicology data that's required. NIDA has accepted our plan to reallocate previously approved funds to conduct these studies.

So in summary, we believe that our new corporate strategy, refocused on the potential of our ProNeura platform, has both near- and long-term value-generating opportunities. We're working toward achieving development milestones in both of our ProNeura-based programs by the middle of next year and look forward to updating you on our progress.

Thank you all for participating on this call. As always, we really appreciate your ongoing support and we look forward to reporting continued progress in our ProNeura portfolio as we move forward. Thank you.

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