Titan Pharmaceuticals Second Quarter 2020 Financial Results

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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 DeVarney; Titan Pharmaceuticals, Inc.; EVP and Chief Scientific Officer
- Joe Schrei; Titan Pharmaceuticals, Inc.; Executive Director, Commercial Operations
- Mike Fritz; Titan Pharmaceuticals, Inc.; National Sales Director

Analysts

- John Vandermosten, Zacks Small-Cap Research

Presentation

Operator: Thank you for holding and welcome to the Titan Pharmaceuticals Second Quarter 2020 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, Sarah, and thank you all for joining us. Welcome to the Titan Pharmaceuticals call to review financial and operational results for the second quarter ended June 30, 2020, and we'll provide an update on our business.

Before we begin, I wanted 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 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 DeVarney, our Executive Vice President and Chief Scientific Officer; Brian Crowley, Vice President of Finance; and we have Joe Schrei, our Executive Director of Commercial Operations; and Mike Fritz, our National Sales Director, who are joining us to provide a more detailed update on our Probuphine sales and marketing programs.

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 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 the commercialization of Probuphine; the regulatory approval process; Titan's ability to access capital; 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 over to you, Marc.

Marc Rubin: Thank you, Jennifer, and everybody, thank you for joining us, as always, and I hope you're all staying safe and healthy during these very challenging times.

We'd like to focus today's call on commercialization of Probuphine and the progress we've made in implementing our sales and marketing program and, importantly, the substantial progress made in our recently established co-promotion [work] with Indegene.

Let me start by saying that the revenue growth we originally expected continues to be impacted by COVID-19. Although we have expanded our commercial operations with additions to our sales and medical liaison teams, which now provide coverage for all 50 states and Puerto Rico, COVID-19-related travel and social distancing restrictions have substantially impacted in-person interactions between patients and their healthcare providers and have impeded the ability of our commercial team to operate with maximal effectiveness.

In response, we have undertaken a number of key activities to attempt to mitigate the impact of COVID-19 on our commercial business, including establishing relationships digitally with new healthcare providers and their staff, providing virtual communication tools for healthcare providers to use with their patients in order to highlight the potential benefits of Probuphine, establishing a social media presence to increase awareness of Probuphine, and, importantly, providing fully virtual REMS training and certification to both new and existing healthcare providers in order to continue to grow the business.

Our new co-promotion partnership with Indegene will help us achieve our current goal of rapidly

expanding our outreach capabilities to the medical community and to patients by fully embracing a digital communications approach. Using Indegene's digital communication platform, last week, we launched the first campaign to educated healthcare providers about Probuphine's value as a maintenance treatment option for select patients. In addition, we are implementing a program that focuses on OUD patients and their caregivers in order to assist in digitally connecting potential patients with REMS-certified healthcare providers and with trained staff for follow-ups.

There are early indications that the efforts of our commercial team connecting with the healthcare providers over the past few months are working. While patient enrollments for Probuphine treatment began dropping off fairly rapidly in March and continuing into May, clinics in certain regions began to see an increase in enrollments in June, which have continued, and I will let Joe and Mike elaborate on all the commercial activities in just a minute.

But before I do, I want to emphasize that any progress we make can be sustained only if our stockholders approve the proposal to increase the authorized shares at a special stockholder meeting scheduled for August 31, 2020. Currently, we need only 3.6% of the shares eligible to vote at the meeting to vote in favor in order to approve the increase. More than one third of eligible shares have not yet been voted, so I encourage all of our stockholders to vote in favor of this proposal -- we are very close -- and to support Titan through its next phase of development.

And lastly, and importantly, I want to let you know that Sunil has expressed his desire to retire by the end of the year, if possible. To prepare for this transition, and of course, contingent on our ability to raise additional capital, we plan to look for a successor with broad commercial experience as we continue our transition to a commercial-stage company.

Thank you all for your ongoing support during these challenging times, and most importantly, please be safe and stay healthy. And I will now pass the call to Joe, who will discuss our partnership with Indegene and our co-promotion strategy. Joe?

Joe Schrei: Thank you, Marc, and hello, everybody. Over the past several months, recognizing the limitations caused by the COVID-19 pandemic, we have been adjusting our plans and activities to increase Probuphine uptake and have realized the value of having a comprehensive program for digitally driven product promotion activities.

As you know, we recently entered into a co-promotion agreement with Indegene. Indegene's strength is partnering with companies throughout their brand lifecycle, providing additional commercial support by leveraging its unique digital platform. We are confident this partnership will help raise awareness of Probuphine among healthcare professionals and patients dealing with opioid use disorder.

Soon after entering into the agreement in late June, we established a core team of Titan and Indegene staff to exchange information on Probuphine and determine the quickest path forward to commence utilizing Indegene's digital capabilities to educate HCPs on the merits of the product for maintenance treatment of select OUD patients and encourage them to evaluate the use of Probuphine in their clinics. I can confidently say that we have built a strong collaboration and have made significant strides in laying out targeted plans for the next several months.

We have established four strategic imperatives to guide us through this important co-promotion process. They are: one, drive Probuphine discussion at the point of care with the right HCP and the right patient; two, accelerate and drive REMS certification with HCPs who desire training and express a strong desire to use Probuphine with a rapid conversion to prescription; three, focus and capitalize on established hotspots where we have existing business as well as on newly identified areas, increasing the reach and frequency; and finally, identify and partner with state initiatives so Probuphine becomes part of the discussion and, more importantly, part of the solution. With the growing opioid crisis and the challenges of COVID-19, more states are allocating resources to this unmet need.

We've identified a target pool of 51,000 HCPs who have written prescriptions for buprenorphine products in the last 12 months. About 20% of these account for 80% of the prescriptions, so we will allocate the bulk of our resources to this important group. For the first 12 months of the partnership, we are targeting 3 million impressions, or every time an HCP or a patient views Probuphine content, and we anticipate 63,000 engagements with this same audience.

The first digital communication from the Indegene platform sent out last week was designed to raise the awareness of Probuphine with HCPs. We successfully reached 85% of our target audience with this kickoff tactic. Over the next several months, we will be launching additional new tactics geared towards HCPs and patients that will drive a Probuphine discussion at the point of care. Additionally, Indegene will be deploying four virtual representatives at the end of this month to optimize our reach and frequency.

I would now like to tell you about another exciting program we started two weeks ago, the patient activation initiative. This three-month program is designed to drive motivated OUD patients to REMS-trained and -certified providers of treatment with Probuphine. We have identified several key geographic areas with REMS-trained HCPs, and using social media, we can identify OUD patients interested in learning about Probuphine as a new treatment option.

Engagement involves a nurse coordinator speaking with an interested patient to assess whether the individual qualifies for Probuphine treatment. If the patient does qualify and is being treated by an HCP who is not REMS-trained, their nurse coordinator can provide Probuphine education to the HCP. Of the HCP -- if the patient prefers, an appointment can be scheduled with a provider who is already REMS-trained. This program is designed to match the right patient with the right HCP for the desired treatment.

Lastly, to strengthen our commercial operations, we have been evaluating our hub processes to ensure that we have optimal patient throughput, taking into consideration ample reimbursement support and efficiencies with our specialty pharmacy providers. This is crucial as we work toward greater fulfillment in overcoming reimbursement challenges we have experienced.

I'd like to now turn the call over to Mike, who will provide an update on the sales team's activities. Mike?

Mike Fritz: Thanks, Joe. Much of the success that comes from implementing new programs

and initiatives, like our partnership with Indegene and our patient activation initiative, depends on effective execution by the sales team. I'm proud that the account team is currently driving Probuphine patient enrollments to pre-COVID-19 levels, demonstrating that we've deployed the right people in a highly effective manner and have ability to maximize the potential of these two critical new partnership efforts.

COVID-19 has presented many major challenges for OUD patients and providers. Let me first speak to the peril of the OUD patient population, which has seen as much as a 20% increase in overdoses since the onset of the pandemic, presenting a significant under-reported and growing healthcare crisis. It's a problem rooted in financial strain, anxiety, fear of healthcare facilities and exposure to the virus, and overall increase in mental health issues. These factors are keeping many OUD patients who are most in need of treatment from seeking it.

The growing need for treatment that allows for social distancing presents an opportunity for providers to an option like Probuphine, whose six-month treatment efficacy mitigates frequent access issues. To address the challenge of informing, educating and training providers on the value of Probuphine during the pandemic, the account team has had to change its tactics to grow its provider base and increase usage of Probuphine.

On March 16, when the nation was broadly shut down, we immediately designed and then implemented a virtual platform that was built to allow the account team to remain productive and continue to be a resource to their customers. The platform has evolved from phone calls to a suite of provider and patient tools, including video calls and educational meetings. The virtual platform has allowed us to provide a level of stability to the HCPs and the clinics that we work with and has started to result in increased patient enrollments for the past few months.

In fact, in July, we reached pre-COVID-19-level enrollments. It's important to note this achievement was made with only eight account managers and four medical liaisons covering all 50 states and Puerto Rico, without the might of marketing programs we are now implementing with Indegene and the patient activation initiative we recently put in place.

As we moved through July and into August, we experienced an increase in requests for healthcare provider in-person visits. These requests have largely mirrored the ebb and flow of virus surges and declines across the nation, as have the efforts of the account managers, who aim to be in great -- areas of great access. The impact of in-person visits has been immediate and measurable.

The focus of the sales team going forward is on a continuous target refinement and leveraging the medical liaison team to highlight the value of Probuphine six-month therapy, particularly for the most at-risk OUD patients. We expect the co-promotion programs initiative with Indegene will identify additional HCPs who will need to be trained and certified under the REMS program, and our account manager will be coordinating and managing these new accounts as well. Based on the upward trajectory of enrollments, we believe that our expansive marketing efforts combined with improving patient and provider access will increase Probuphine utilization volumes.

Let me now turn the call over to Chief Scientific Officer Dr. Kate DeVarney, who will discuss Titan's progress on medical affairs, drug safety and compliance functions, as well as our product development and regulatory activities. Kate?

Kate DeVarney: Thank you, Mike. A key achievement for Titan during the second quarter was the FDA approval of our fully virtual REMS training and certification program, and this is now available to qualified healthcare providers at treatment centers across the U.S., and these include qualified physicians, nurse practitioners and physicians assistants. Our program enables us to continue to safely train and certify healthcare providers to both prescribe and administer Probuphine during the pandemic, facilitating access for eligible patients with OUD.

Just as -- since June, 14 healthcare providers have been trained via our FDA-approved fully virtual format, 13 of which have written prescriptions for Probuphine. And on average, 80% of prescriptions written result in patient treatment. In addition, since Indegene's initial push, we have experienced an increased demand and interest for training from healthcare providers.

Now I'd like to turn to our Nalmefene implant development program for the prevention of opioid relapse following detoxification. As you know, NIDA, the National Institute on Drug Addiction, approved approximately $8.7 million in funding over two years for this program, providing the funds for the completion of the implant formulation development, as well as the GMP manufacturing and nonclinical studies, which are all required to file the IND. At our meeting with the FDA during the first quarter, the agency specified a 505(b)(1) regulatory pathway and additional nonclinical studies required to file an IND, which will delay filing to mid-2021. We are making good progress with the IND-enabling nonclinical studies, and NIDA continues to support our efforts, and I'm happy to report that they have accepted our plan to reallocate previously approved funds to conduct these studies.

Finally, I'd like to provide a brief update on our planned Phase 4 studies for Probuphine. In the third quarter of last year, we decided to postpone these studies in an effort to preserve our resources. We have been in contact with the FDA, who has confirmed that we may continue to delay our Phase 4 study commitments pending sufficient resources.

That concludes my remarks for today, and I look forward to keeping you updated on our progress over the next several months. Now I'll turn the call to Sunil. Sunil?

Sunil Bhonsle: Thank you, Kate. As you know, we filed our Form 10-Q with the second quarter financial results with the SEC today, and the press release issued this morning provides a summary of those results. Brian Crowley, our VP of Finance, is with us on the call today, and during the Q&A period, will be available to address any questions you may have. I hope the information provided today gives you a better understanding of the actions taken over the last few months to overcome some of the effects on our business of the COVID-19 pandemic, and we look forward to keeping you updated on the progress of Titan's commercial initiatives.

I also want to provide you an update on our partnership with Molteni. Various pandemic-related restrictions have also impacted Molteni in launching Sixmo in the EU and have delayed the completion of work here in the U.S. to modify the manufacturing facilities and set up testing

protocols to meet EU regulations. We have completed all of this work now and manufactured product for Europe and expect this will be shipped to Molteni during the third quarter. Molteni is progressing with their plans for product launch in major EU countries and expects, toward the end of this year or early next year, to be able to start the marketing and sales process.

I am extremely proud of our team for quickly adapting to this new environment. Today you heard from Joe, who discussed the four strategic imperatives of our co-promotion process with Indegene, as well as our new patient activation initiative. Mike gave you some information on the challenges posed by COVID-19 in the field and how a small but very dedicated team, along with critical support from the medical affairs [Technical Difficulty] has been able to bring patient enrollments back to prepandemic levels. This is a very important milestone for us. And we believe we have the right tools now and are on the right track to keep progressing.

Finally, Kate highlighted the FDA approval of a fully virtual REMS program, without which there was no way of continuing to increase the number of certified and trained healthcare providers, so this was very important for us, and this was launched last quarter nationwide. We believe, with these new programs in place and with the support of our co-promotion partner Indegene, we are well positioned to continue to increase Probuphine utilization.

I also want to remind you of our stockholders' meeting, which is very important for us, that's scheduled for August 31. Approval of the increase in authorized shares requires only another 3.6% of the eligible shares to vote in favor of the proposal, so we are almost there, but truly need the support of the remaining shares and the stockholders to vote. With more than one third of eligible shares not yet voted, we truly would like to encourage all our shareholders to vote in favor and support us through our next phase of development.

This concludes our prepared remarks for today. And 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. Please stay safe and healthy.

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

Questions & Answers

Operator: *(Operator Instructions)*

Our first question comes from John Vandermosten with Zacks.

John Vandermosten: I wanted to start out with a question on the timeline for the new relationship with Indegene and see when first revenues are expected from that. I mean, how many things do you have to get all lined up before those first come in the door?

Sunil Bhonsle: Hi, John. Hope all is well with you, too. And the partnership with Indegene, as you know, we signed the agreement in late June. It's a four-year agreement. And during the month of July, the primary focus was on getting the teams working together, educated on each other's capabilities, especially educating Indegene on the details around Probuphine. As you

know, with all of the REMS controls and restrictions, we have to make sure everything we use is also -- goes through a process with the PRC and so on within the company. And I am very pleased that within the month they were able to take the material and start the first campaign, which started in the beginning part of August.

This campaign is the first, as Joe mentioned -- and he can provide some more details a little later if you need -- there are several additional campaigns that will go on through the next few weeks. As Kate mentioned, we're already starting to see some interest pop up from that, from healthcare providers. My goal, or at least what we would like to see, clearly, this current quarter, the third quarter, we have started to maintain and get back to a stable level that was sort of pre-COVID enrollment levels. That is very important, and we'll start seeing some growth from that to come the following quarter, certainly. And Joe and Mike, maybe you can provide a little more detail on what we expect with the following quarters.

Joe Schrei: Sure. And Sunil, this is Joe, and what I'd like to add to what you've already said is, with Indegene, over the next three months, or at least playing out to November, we will lay out nine different types of tactics. We're moving at that aggressive of a pace. And these are tactics that are going to be geared towards HCPs, through e-mail campaigns, the virtual sales reps that we already discussed, social media campaigns, in the same waves going out towards the patients. Because one of the things that we came up with for our strategic imperative is, we need to get the right patient with the right HCP, and we know when we get them together, we know that the patient will be -- will receive the value of Probuphine. So this is all going to be accelerated, and we would anticipate that we would see significant improvement by fourth quarter as far as enrollments, which of course tie into revenue. So we're looking at approximately 50%, in the fourth quarter, increase over where we are right now.

John Vandermosten: Okay. And are there any similar products that Indegene has advanced, similar to Probuphine?

Joe Schrei: This is a really good question. I will say -- I mean, this is what they do. This is their wheel -- this is in their wheelhouse. They take these brands regardless of where they are in their lifecycle and they provide the commercial muscle. They can step in any way, and they've done extraordinarily well. I can't talk about specifics; I mean, you can go to their website and you can see all sorts of things that are populated, but they do it and they do it well.

Sunil Bhonsle: John, I just wanted to mention that in terms of products in the addiction space, this is the first product that they are working with. They're very excited because they see this as an area that requires a lot more attention and there is a required -- a big epidemic that they feel they can provide a lot of support for, providing treatment. So it's the first one. They're very eager and interested in putting all their best resources behind it because they see this as a major milestone for them as well. They have worked with both small companies with specialty products and they continue to do so at this stage. And as Joe mentioned, they have some listed on their website as well.

John Vandermosten: Okay, yes, I'll take a look at that. And do they have any geographical or provider type of focus?

Sunil Bhonsle: I didn't get that word you used in between --

John Vandermosten: Sorry, yes, I'll repeat myself. Do they have any type of -- any geographical focus or any provider type that they've developed relationships with?

Sunil Bhonsle: Indegene is actually a global company. They started off in Asia, in India. They have presence in Europe, China and the U.S. and provide support for both big pharma and small pharma in all of these regions. And as Joe mentioned, I mean, there are products in different stages of lifecycle from early stage to supporting products that may be going off patent and so on, but they are indeed a global company, more than 2,000 people strong.

Marc Rubin: And Sunil, this is Marc Rubin. Can I just interject something briefly? Joe made a comment that we expect, I think, 50% increase in the fourth quarter. I want to make it clear that we're not -- we don't make specific projections. That is absolutely a laudable goal. I think the most important thing that we can say is that we expect to see increases and meaningful increases in the fourth quarter. So I just wanted to clarify that that is not a specific projection that we're making.

John Vandermosten: Okay, thanks, Marc. And I noticed that there were some coronavirus-related delays in terms of shipping product to Italy; is that -- might that also be an issue for the Canadian partner as well, or is that something that's just overseas?

Sunil Bhonsle: The requirement for Europe and meeting the specific EU regulations required some modification in the facilities in Texas at DPT. That's what got affected because of availability of people to get there and get the work completed. It was already on -- being done when COVID restrictions came about. That has been completed now. It didn't directly affect product specifications for the U.S. and Canada, but obviously restricted use of the facility till it was completed. We don't anticipate any issues with supplying product for U.S. or Canada; in fact, we are actually planning a batch to be made shortly, and so on. So it's back on stream and continuing to make the product. It was strictly a requirement for the EU regulatory side.

Operator: This concludes 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 all for participating in this call. As always, we appreciate your ongoing support and we look forward to reporting continued progress with our Probuphine program, as well as other products from ProNeura. So stay safe, stay healthy, and we look forward to talking to you again soon. Goodbye.

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