Titan Pharmaceuticals First 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.; Executive Assistant
- Marc Rubin; Titan Pharmaceuticals, Inc.; Executive Chairman
- Kate DeVarney; Titan Pharmaceuticals, Inc.; EVP and Chief Scientific Officer
- Brian Crowley; Titan Pharmaceuticals, Inc.; VP, Finance and Administration

Analysts

- John Vandermosten, Zacks Small-Cap Research

Presentation

Operator: Good day, everybody, and thank you for holding. Welcome to the Titan Pharmaceuticals First Quarter 2020 Financial Results Conference Call.

(Operator Instructions)

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

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

Sunil Bhonsle: Thank you, Eric, 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, 2020, and provide an update on our business. It's been only six weeks since the last call at the end of March, but with the changing environment we have encountered, these have been very busy indeed.

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, Executive Vice President and Chief Scientific Officer; and Brian Crowley, 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 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.

And now back to you, Sunil.

Sunil Bhonsle: Thank you, Jennifer. We will start the call with an overview from our Executive Chairman, Dr. Marc Rubin. And, as you know, Dane Hallberg is no longer at Titan, so I will provide an update of the commercial activities, followed by medical affairs, regulatory and product development updates from Dr. DeVarney. And then Brian Crowley will summarize the financial results, ending with a closing from me, a brief recap, before opening the call for your questions. So let's get started, Marc.

Marc Rubin: Thank you, Sunil, and hello, everybody, and thank you, as always, for joining us today.

First, I want to reassure you that since the departure of Dane Hallberg from the company that the commercial organization is in excellent hands, with the sales team being led by the National Sales Director Mike Fritz, the marketing and market access and many support functions related to those being led by the Executive Director of Commercial Operations Joe Schrei. Both Mike and Joe report directly to Sunil and are supported by Titan's executive management team. We very much appreciate Dane's efforts since he joined the company in the fall of 2018 and we all wish him well.

During the 2020 first quarter, we continued to execute a number of important initiatives, and Sunil and Kate will provide more detail shortly, so let me just highlight some of the key activities. We've continued refining and validating our market segmentation strategy as well as rolling out new healthcare provider, caregiver and patient education programs to the increasing number of certified healthcare providers.

Since the beginning of this year we also strengthened our balance sheet via financing and the exercise of previously issued warrants, which together have provided approximately $8.6 million. In addition, thanks to the Payroll Protection Program, we obtained a loan of $654,000 from the Small Business Administration. This is particularly important at this time, as the environment in which we function has been dramatically affected by the COVID-19 pandemic.

I am sure all of you have experienced many changes in your daily routines with the advent of shelter-in-place policies and social distancing requirements, et cetera, and while as an organization we are operating in a virtual mode with all staff working mainly from home, there has been considerable disruption of commercial activities, as healthcare providers have also had to make significant changes, with some of them limiting direct interaction with patients and many employing telemedicine when possible. While Kate and Sunil will elaborate further, I wanted to emphasize the fact that some of these changes will continue for a long period of time and are adapting -- and we are adapting our business practices accordingly. I believe we have the right people in place to address these challenges, but we will require additional resources in order to thrive in this new market environment, and we will keep you updated as we progress and as we evolve.

Lastly, I wanted to mention that our 10-Q financial report indicates that we have sufficient funds to continue operations through the third quarter this year. While we continue to focus on growing our revenue stream and looking at business opportunities to add value, we currently have only about 5 million shares of authorized common stock remaining, making it virtually impossible to add capital via the equity markets later this year. We will address this by asking our shareholders to approve an increase in the number of authorized shares at a special shareholder meeting scheduled for June 30, 2020. Shareholders of record on May 22 will receive the appropriate proxy material later this month, and I, together with all the board members, urge all of you who are shareholders to support this request and approve it at this special meeting.

Thank you for your support. Please be safe and stay healthy. And I will now pass the call back to Sunil. Sunil?

Sunil Bhonsle: Thank you, Marc, and hello, everybody, once again. Over the past few weeks, I have been working directly with Mike, Joe and the commercial team to enable a smooth transition and, with the help of Marc, Kate and Federico Seghi Recli of Molteni, I believe we have established a structure that will provide strong leadership and direction for our commercial operations in these changing times.

The product sales revenue for the first quarter was nominally higher than the previous quarter despite the fact that some of our action plans were interrupted, primarily due to the disruption caused by the COVID-19 pandemic. As Marc highlighted, COVID-19 has made us think outside the box to create new ways of conducting business. Our staff has been rapidly implementing plans to continue interactions with our certified healthcare providers to learn of the changes that they are putting in place so we can assist them in this process while also creating new ways to conduct business in a virtual environment.

Early this year we announced that a Federal Supply Schedule pricing agreement went into effect

for a five-year term. We have made some initial inroads with the VA medical support organization; however, due to restricted travel, we have been unable to conduct the additional necessary follow-up. With the expected easing of travel-related restrictions in the coming days, we will once again focus on key VA clinics while also seeking alternative ways to interact with the VA to promote the use of Probuphine in their treatment of opiate use disorder patients.

Let me elaborate on some of the commercial activities during these past few months and the progress we are making. As you know, we started expanding our commercial team late last year and continued to do so this year, with the addition of experienced pharmaceutical-stage leadership and sales managers, such that we now have a sales professional in each of our 10 territories that cover the United States and Puerto Rico. These sales professionals are being supported by four equally qualified and experienced medical science liaisons within our medical affairs team. Our goal is to improve product adoption and generate sales growth.

When addressing the past few months' challenges, we have learned much about the target OUD treatment programs best suited for the use of Probuphine. The factors we believe that positively impact results include proper selection of the healthcare providers who provide long-term maintenance treatment support and those who we can assist in identifying those of their existing patients who meet the criteria for Probuphine treatment. We are now selecting clinics with staff experienced in managing third-party-payer coverage plans that require prior authorization due to the subdermal insertion procedure, and for those that don't have the experience, we are providing adequate staff educational support so they can manage this process with relative ease. We are being proactive.

We're also focusing on attracting healthcare providers, including nurse practitioners and physician assistants, who consider the current procedure reimbursement as being adequate while we pursue ways to get third-party payers to more appropriately reimburse their healthcare providers for this activity.

We have created pamphlets for healthcare providers that easily provide important information to educate caregivers and patients about the benefits of a long-acting medication like Probuphine and to promote the Step Into Stability campaign.

During this time of working from home, we have shifted our focus and our limited resources to preparatory work using digital communication techniques to establish relationships with new healthcare providers and their staff, provide virtual communication tools for these healthcare providers to use with their patients and highlight the potential benefits of Probuphine as a treatment modality in this increasing telemedicine environment. We have also established a social media presence in select geographies to increase awareness of Probuphine and enhance our share of voice in the medication-assisted-treatment space. This has been working very well and we plan to expand it.

Our goal is to establish strong relationships with the medical community and inform patients of the long-acting treatment option with Probuphine in order to increase the usage of Probuphine once the restrictions on mobility and medical businesses are relaxed. We strongly believe that with sufficient capital resources, Probuphine has the potential to be an important weapon in the

battle against opiate use disorder, providing healthcare providers, patients and their caregivers with an important maintenance treatment option. We are continuing to implement our patient support model, which aims to increase the number of active prescribers by supporting those clinicians who prefer to only prescribe Probuphine. These physicians have the option to have a REMS-certified clinician insert and remove Probuphine on their behalf, which could remove a potential barrier for both patients and clinicians. With initial indications of this model's success, we hope to expand this model wherever appropriate.

With that said, let me now turn the call over to our Chief Scientific Officer, Dr. Kate DeVarney, who will discuss Titan's progress on our medical affairs, drug safety and compliance functions, as well as our product development and regulatory activities, a lot of things to handle. Kate?

Kate DeVarney: Thank you, Sunil. And as you know, NIDA approved approximately $8.7 million in funding over two years for our Nalmefene development program for the prevention of opioid relapse following detoxification, and this provides funds for the completion of implant formulation development, CGMP manufacturing and nonclinical studies required for the IND filing.

During the first quarter, we met with the FDA to review our nonclinical development plans and to obtain guidance regarding filing the IND application. The FDA provided clear guidance to us on the type of development plan that we should follow, specifying a 505(b)(1) regulatory pathway, and this is due to the lack of safety data on Nalmefene for a long-acting formulation, as well as indicating the nonclinical studies that will be required to file the IND. Now, based on this input, collecting all the nonclinical chronic toxicology data will require an additional study, as well as an increased duration of a currently ongoing study, which delays the filing of the IND to Q2 2021. Now, we've discussed this with NIDA and we are collectively formulating our plans together, which we believe can be accomplished with some reallocation of funds that have already been approved.

As discussed recently on the last financial results conference call, we continue to collaborate with the Walter Reed Army Institute of Research, or WRAIR, as well as Southwest Research Institute, or SwRI, on the early nonclinical evaluation of the ProNeura platform in malaria prophylaxis.

On the Probuphine front, we continue to focus our resources on providing medical and REMS training support to the commercial team. The Drug Enforcement Agency, or DEA, has granted an exemption for telemedicine to be used in place of initial in-person visits, and many of our Probuphine healthcare providers are now using this treatment paradigm very effectively. To ensure that the insertion and removal procedures are not barriers for both healthcare providers and their patients due to the pandemic, we have recently developed a completely virtual REMS training program so healthcare providers can continue to be trained to prescribe and administer Probuphine during this period of shelter in place. This program has now been submitted to the FDA for review and approval, and we hope that this can be completed quickly so that we can start training the healthcare providers who are awaiting training that's been delayed due to the COVID-19-related restriction.

And lastly, I want to reiterate that people with opioid use disorder comprise one of the most vulnerable populations at risk for morbidity and mortality during the pandemic, not only from COVID-19 but from their underlying addiction and potential comorbidities as well. So it's critical that people who need medication-assisted therapy and other addiction treatment have access and are able to receive treatment safely and consistently in the context of this ongoing emergency. We believe that treatment with Probuphine provides the opportunity for minimizing direct ongoing physical interactions between the patient, the healthcare provider and other services, and this presents a real opportunity to more fully integrate telemedicine into the treatment process. We will continue to generate training programs and support information that makes it easier for healthcare providers to provide long-term maintenance treatment to patients while minimizing the in-person exposure and risk.

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 over to Brian to discuss Titan's financial results. Brian?

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

In the first quarter of 2020, we reported $1.3 million in revenue. This included $0.2 million from product sales, $1.1 million related to our NIDA grant. This compares with $0.9 million in revenue during the same period a year ago, which was comprised of $0.3 million in product sales, $0.3 million related to the amortization of deferred revenue related to the sale to Molteni of the European intellectual property rights to Probuphine, and $0.3 million related to the NIDA grant.

Total operating expenses for the first quarter of 2020, consisting primarily of R&D, SG&A expenses and cost of goods sold, inclusive of distribution expenses, were $5.6 million, compared with $5.2 million in the same quarter in 2019. R&D expenses for the quarter ended March 31, 2020, were $2.3 million, compared to $1.8 million in the same quarter in 2019. The increase in R&D cost was primarily associated with increased activities related to our NIDA grant and clinical activity. SG&A expenses for the first quarter of 2020 were $3.1 million, essentially unchanged from the first quarter of 2019.

Net other expense, consisting primarily of interest expense, noncash losses on changes in the fair value of warrants and costs attributable to the issuance of warrants, was $1.4 million in the first quarter of 2020. This compared to $0.2 million in the first quarter of 2019, which consisted primarily of interest expense.

Our net loss applicable to common shareholders in the first quarter of 2020 was $5.6 million, or $0.07 per share, compared with a net loss of $4.5 million, or $0.34 per share, in the same quarter 2019.

As Marc mentioned, subsequent to the quarter end, we received a $654,000 loan pursuant to the Paycheck Protection Program of the CARES Act. At March 31, 2020, we had cash and cash equivalents of $8 million, which we believe, together with the proceeds from the Paycheck Protection Program loan and cash proceeds from the subsequent exercise of warrants during May 2020, are sufficient to fund our planned operations through the third quarter of 2020.

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

Sunil Bhonsle: Thank you, Brian. I hope the information provided today gives you a good overview of the ongoing activities at Titan, especially regarding the changes we have made to rapidly adjust to the new restrictive environment without losing sight of our goal to increase utilization of Probuphine for the maintenance treatment of opiate use disorder.

Let me summarize by mentioning some of the key actions to date. We have completed the first phase of expanding our commercial organization. This includes the sales and marketing teams, as well as the medical affairs team, and I believe we have the right people in place to grow the business.

While the COVID-19 pandemic has disrupted our prior routine, we have adjusted quickly to the new environment and have implemented several plans, such as training the sales force in telemarketing techniques; creating e-documents that can provide information on Probuphine so it is easier for us and healthcare providers to communicate with patients and caregivers; we have also created virtual programs that are awaiting FDA review and approval. We've implemented social media programs to increase the awareness of Probuphine and a few more.

We are taking this opportunity to build relationships with healthcare providers and their staff, helping them with the changes they need to implement, providing training as required, and also providing them with the tools they need to manage their business successfully in this so-called new normal environment. We are identifying new healthcare providers who understand the value of long-acting medication in the maintenance treatment of their patients, and we are getting them ready to participate in the Probuphine REMS training and certification program as some of these restrictions are relaxed. We continue to emphasize the value proposition of Probuphine, especially during the COVID-19 pandemic, and we're working with the clinics that have remained open to put patients on Probuphine treatment. We have identified Probuphine-experienced healthcare providers who are willing to become the hub for insertion and removal procedures. We intend to expand the usage of Probuphine by those healthcare providers who understand the value of Probuphine and are willing to prescribe the product while using implant procedural services from others, a hub-and-spoke model.

We have also been preparing the Probuphine manufacturing site to meet all the EU regulations and we are now in the final stages of preparation to make the first batch of Probuphine next month for Molteni Farmaceutici, our partner in the EU. The remote management of the multiple activities involved has also been a challenging task in this manufacturing upgrade program, but seeing them come to completion will be a major milestone, as it is key to the launch of Sixmo, the brand name of Probuphine in the EU.

So despite working mostly from home, this has been a very busy time for all of us, and I believe our organization has rallied and come together to overcome the challenges ahead. I would like to close by repeating what Marc said about the upcoming special shareholder meeting: Without shareholder approval to increase the authorized shares for Titan, we will not have the resources needed to be successful, and implementing the plans we have presented today will be hampered. Please support us in helping to grow the company and add value for all stakeholders.

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 in these challenging times.

Eric, we are ready for -- to take questions from the call participants.

Questions & Answers

Operator: *(Operator Instructions)*

Our first question will come from John Vandermosten with Zacks.

John Vandermosten: I wanted to start with a question on online prescribing and how that is trending. Obviously this is a good time for it. Will you be looking for a partner to implement that, or is that something that you can do internally?

Sunil Bhonsle: Hi, John. The online prescribing has -- for Probuphine, of course -- has multiple steps, as you can imagine. The actual prescription is going through our hub, which today is available to be done online. It has been, through the portal that was created where a clinic, a physician, a healthcare provider that's certified can actually go ahead and process a prescription. That is then vetted by the hub. They have to check to make sure this is a certified healthcare provider prescribing, look at the third-party-payer coverage that is available for the patient, verify all of the requirements for that, before that prescription is then processed further, and by -- when I say processed further, in terms of sending it to the third-party payers and so on.

So that online prescription processing is there, where, of course, challenges that the clinicians during this time have been -- is a lot of the facilities have been closed for patient access. So they are doing their work through telemedicine, which doesn't always allow a new patient to be put on Probuphine, so those numbers have been limited just because of some of the restrictions that have come up at this stage. But the online ordering process and so on has been in place for us. It's making sure the communication between the clinic and the patient, providing all of the information now electronically, these are the things that we have been producing and providing to the clinics so they can manage the patient in a more effective way.

And Kate, if there's anything else? Or John, is that what you -- I mean, is that your -- yes.

John Vandermosten: Yes, that's helpful. Yes, I guess I want to understand, I guess, the whole

ecosystem.

Sunil Bhonsle: Right.

John Vandermosten: With the -- I guess that part of this is outside what you're doing, where a doctor or a physician or provider would be on some kind of telemedicine platform, and then when they have the patient and they prescribe it, then it goes on to the online prescribing part, which is, I guess, more where you're involved. Yes, that's helpful.

Sunil Bhonsle: Right. Oh, absolutely. And Kate, if you have something, please jump in to add.

Kate DeVarney: Sure. No, I think you've answered that very completely, Sunil. And I would just reiterate that we are -- we have developed a fully virtual REMS training that we will be rolling out as soon as we hear back from the FDA. And there are some areas now where they are lifting some restrictions, and we did a partially virtual REMS training last weekend, for example. We have another one coming up in the middle of June. So we're taking advantage of every opportunity that we can to interact either virtually or semi-virtually with healthcare providers, and we do still have quite a demand for training amongst healthcare providers who have -- currently have patients that they would like to treat.

John Vandermosten: Okay. And have you guys updated the number of providers that have been trained to date?

Sunil Bhonsle: The total number of -- and we've not updated it through the current period. I think we provided some information during our last call six weeks ago where it was close to 300 physicians who are actively prescribing right now. As you know, the number of people that have been trained and so on is much larger than that. Especially, I mean, the update in the sense that in the last four weeks, six weeks, there has been a lot of restrictions that have limited us training new people, and as Kate mentioned, they truly -- there is a backlog that we're hoping to be able to take care of very quickly once some of these restrictions are relaxed, and Kate's team has already started in certain locations where they have been relaxed already.

John Vandermosten: Okay, yes, I guess that's going to be a --

Kate DeVarney: And just to --

John Vandermosten: A rolling thing based on state. Oh, yes, go ahead, Kate. Sorry.

Kate DeVarney: Yes, sorry, John. Just to reiterate something that Sunil said earlier in the call, we are seeing a lot more interest and have been for several months now from nurse practitioners and physicians assistants who are qualified not only to prescribe Probuphine and other buprenorphine-containing products, but they also -- a subset of them have surgical training and skill, and for them, this is a great procedure to be able to do. They are satisfied with the level of reimbursement that we're able to provide right now, whereas some of the physicians are not. So to the extent that we can bring more nurse practitioners and more physicians assistants into the system -- and that is a real target for us now -- I think we're going to be able to overcome that,

until we can change the reimbursement level for physicians.

John Vandermosten: Okay. And just looking at the current impact on distributors, has there been any impact on receiving or shipping product or any part of the distribution chain that's not been operational over the last couple of months?

Sunil Bhonsle: There's been some delays that we have noticed, and it has to do more with not the shipment of product, but when there have been questions related to the third-party-payer coverage or where some information may have been missing. The process of getting back with the healthcare provider has -- and in some cases, has not been as easy because they're not always in their clinic. They are also working from home and things like that. That has been a little challenging. But the hub and the teams have been persistent in getting through it.

John Vandermosten: Okay. And moving to Europe, it seems like the bottleneck may be, right now, the production of product to send over there, but I know that pricing negotiations were also going on. How has that progressed in the corona environment? Are they able to continue that, or has it been kind of put on hold?

Sunil Bhonsle: They have been able to continue it, but it has been delayed. The target for Europe is still very much launching the product during the second half of this year. The -- for us, getting the manufacturing site fully compliant with the EU regulations, which are more -- requires a higher level of environmental monitoring, things like that, that we have been able to do that, mostly by people from here communicating via phone and bringing in people at different steps as essential services, but each one of those things that should have taken a day takes four, five days to accomplish, just because of the environment we are in.

What I'm very happy to see is, it is now finally at the stage where we are doing the actual production simulation runs to make sure everything is working in tandem, and soon after that, we'll actually make the product and make it available in Europe so they can launch the product during the second half. So that's still the plan. The pricing is expected to be approved and available for them to do that.

John Vandermosten: Okay. And also a question on the extra study for Nalmefene. Will that ultimately lead to more funds for that project, or is it just the same funds? Because, Kate, you mentioned that things might be moved around, but does it -- does that open up opportunity for, perhaps, more funds to work on that since you have taken a different pathway than originally thought?

Kate DeVarney: Yes. So as I said, we are able to reallocate funds that we currently have in the budget, and NIDA has actually given us that guidance and suggestion to do it that way so that we don't have to come up with those funds right now. But we're going to be able to cover the work that we need to do to get the IND filed at this point. As we've said in earlier calls, the second half of this funding period happens after we file the IND. So when we meet that milestone, we are then eligible to receive the funding for the rest of the development program. We will be supporting a portion of it ourselves, of course, but that's a couple of years away at this point, when we get to the clinical trial section.

Operator: This concludes our question-and-answer session. I would now like to turn the conference back over to Sunil Bhonsle for any closing remarks.

Sunil Bhonsle: Thank you, Eric. Thank you all for participating in this call. Please stay safe and healthy during these challenging times, and as always, we appreciate your ongoing support and we look forward to reporting continued progress as we move forward. Have a great day.

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