Titan Pharmaceuticals Fourth Quarter and Full Year 2019 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
- Dane Hallberg; Titan Pharmaceuticals, Inc.; EVP and Chief Commercial Officer
- Kate DeVarney; Titan Pharmaceuticals, Inc.; EVP and Chief Scientific Officer
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Analysts

- Anita Dushyanth, Zacks Small Capital Research
- Adheip Mally, Maxim Group

Presentation

Operator: Thank you for holding, and welcome to the Titan Pharmaceuticals Fourth Quarter and Full Year 2019 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 conference over to Sunil Bhonsle, President and CEO of Titan Pharmaceuticals. Please go ahead.

Sunil Bhonsle: Thank you, Andrea, and thank you all for joining us. Welcome to the Titan Pharmaceuticals call to review financial and operational results for the fourth quarter and year ended December 31, 2019, and provide an update on our business.

Before we begin, I wanted to inform you that we have filed our 2019 annual report on Form 10-K with the SEC, and the press release issued today provides a summary of the results, and these can be found also on our website at titanpharm.com.

I also want to take this opportunity to thank the team at Titan, our audit staff at OUM and our counsel at Loeb & Loeb, who have worked tirelessly from their remote locations, including over the weekend, to issue these reports on schedule. So thanks, everyone.

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; Dane Hallberg, Executive Vice President and Chief Commercial Officer; and Brian Crowley, Vice President of Finance and Administration.

Before we go 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. As always, we will start the call with an overview from our Executive Chairman, Dr. Marc Rubin, followed by commercial updates from Dane Hallberg, and then medical affairs, regulatory and product development updates from Dr. Kate DeVarney. Brian Crowley will then summarize the financial results and 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 hello to everyone, and a special thanks to all of you who are able to join us today during these very challenging times.

Before I begin, I'd like to briefly tell you about what we are doing in response to the COVID-19 pandemic. As the situation continues to evolve, we are diligently monitoring and implementing recommendations from local, national and global health organizations. Titan's top priority is the health and safety of our employees, our customers and the communities in which we live and work.

To that end, we have put proactive, precautionary measures in place, including sheltering in place and working from home, freezing all nonessential travel and switching exclusively to

virtual sales and business meetings, with the goal of keeping everyone as protected and as safe as possible.

At the same time, we remain deeply committed to continue to execute additional components of our growth plan during 2020. Everyone at Titan is working remotely, and I am pleased to say we continue to be productive. We sincerely hope that all of our stakeholders will remain safe and healthy as well.

Turning to an overview of 2019, throughout the year, we laid the foundation and we worked to create the infrastructure required to successfully transition to a commercial-stage company, and we made meaningful progress on a number of important initiatives, and some of these include the following: We refined and validated our market segmentation strategy. We expanded our specialty pharmacy network through the addition of key pharmacies with national coverage and robust coordination of care capabilities among patients, third-party payers and risk evaluation and mitigation strategies or REMS-certified healthcare providers. We streamlined the distribution process with a new hub to coordinate the REMS requirements, and we conducted the initial evaluation of health benefits available from third-party payers and utilized a digital portal to simplify the product ordering process, all of which helped significantly shorten the time from prescription to product delivery. We expanded the number of public and private insurance plans and other third-party payers that cover Probuphine under the medical and pharmacy benefits, such that more than 90% of insurance plans now offer some degree of coverage for Probuphine. We implemented a comprehensive regulatory and compliance program. We rolled out new healthcare provider, caregiver and patient education programs and we grew the number of certified healthcare providers of Probuphine.

I'm very pleased with our team's progress during 2019, especially given the resource constraints that we as a company have faced. Subsequent to year-end, we strengthened our balance sheet via a registered direct offering and exercises of warrants that well positions us to continue to execute on our growth strategy during the year.

An important 2019 milestone was the European Commission's approval of Sixmo, which is the brand name for the product in the EU, establishing this as a global -- true global product. Sunil will provide an update on this program in his closing remarks.

On the ProNeura front, we were very pleased to announce the National Institute for Drug Abuse's, or NIDA's, approval of second-year funding for our Nalmefene program, and Kate will provide more details on that in a few minutes.

Finally, once again to all of you listening, please stay safe, stay home as much as possible and stay healthy. And with that, I will now turn the call over to Dane, who will elaborate on our commercial activities and the progress that he and his team have made. Dane?

Dane Hallberg: Thank you very much, Marc. During 2019, our focus was on establishing the relationships and programs necessary to build our infrastructure and to grow our commercial capabilities. We expanded our specialty pharmacy network, improved our patient services via our new hub partner, added marketing initiatives to include federal agencies, and increased our

sales force coverage span. As a result of these sales and marketing efforts, we have realized an increase in both coverage and the number of prescribers of Probuphine.

Our commitment to our customers, patients and their caregivers remains strong even in this current environment with COVID-19. We have implemented strategies that allow all of our field teams -- field sales, REMS, medical and hub -- to continue to provide the support and tools in treating OUD.

As I mentioned, we expanded our specialty pharmacy network through a number of national partnerships: AllianceRx Walgreens Prime; Accredo specialty pharmacy, a subsidiary of Express Scripts and one of the largest U.S. specialty pharmacies; CVS Caremark, a subsidiary of CVS Health and among the largest prescription management and pharmaceutical services businesses in the U.S.

We've also established a regional partnership with Southside Specialty Pharmacy, which has a strong presence in California and Texas. These two states are among those reporting the highest number of opioid-related deaths in the U.S.

We've improved our hub patient services with AppianRx with minimal disruption to the supply chain and implemented a more efficient process that reduced prescription to product delivery time from three months to two weeks.

2019 also saw the launch of our Step Into Stability branding campaign, which highlights the unique long-term treatment features of Probuphine, and included a healthcare provider portal and branded patient website to provide patients and their caregivers easier access and improved visibility to locating qualified healthcare providers.

We also executed a Federal Supply Schedule pricing agreement that went into effect January 15, 2020, and has a five-year term. We are currently establishing a virtual training program for VA clinicians who elect to add Probuphine to their OUD treatment protocols for VA beneficiaries and others within the federal system, offering another solutions to our veterans in need.

Recently, we expanded our sales and marketing capabilities with the addition of senior sales account managers and support personnel in key geographies, which will enhance our ability to service our customers and grow Probuphine-related revenue.

To summarize some of our key accomplishments to date, at the end of 2019, we had 282 active prescribers, and the number of active healthcare providers continues to steadily increase. We achieved broad product access through a comprehensive product distribution network and by utilizing strategic partnerships. We continued to see growth in prescriptions, with an 18.6% increase in Q4 versus Q3. We significantly reduced the time between prescribing and product availability for our providers and our patients.

We are proactively reducing barriers to therapy, specifically legacy reimbursement rates for Probuphine insertion and removal as it pertains to the Centers of Medicaid and Medicare Services, also known as CMS. The current CMS and many private payer rates do not adequately

or fairly reimbursement healthcare providers for these procedures, oftentimes costing them more out of pocket than the maximum allowed. This may unfairly prevent patients from receiving the appropriate treatment. We are actively trying to engage CMS to have a frank and honest discussion regarding fair and adequate reimbursement with key opinion leaders.

While we fell short of our goal of 500 prescribers by year-end, our main focus throughout 2020 will continue to be to increase the number of active prescribers, with the goal of achieving broad product access via our fortified patient support model. This model will support those clinicians who prefer to only prescribe Probuphine to elect the option to have REMS-certified clinicians insert and remove Probuphine on their behalf. Our patient support model is built on the foundation of our updated hub partner, along with our matrix of prescriber support teams that include medical, REMS, compliance and marketing. This model is currently under a soft launch in select geographies, with the goal of rolling out nationwide by year-end, and was created with the goal of removing another potential hurdle for patients and clinicians alike.

As Marc mentioned, our commercial activities have been impacted by COVID-19 crisis, as have the majority of commercial organizations around the world. In light of our rapidly changing environment, we moved very quickly to protect our employees and our customers, as well as support our providers, so they can continue to serve their patients. By training our field sales team to work remotely via the phone, we quickly pivoted our commercial efforts to ensure clinicians and patients have unfettered access to Probuphine. We updated our existing plans to quickly and thoughtfully bring on highly skilled talent in areas of reimbursement, operations, marketing, PR, telemedicine, and implemented several support initiatives in all of our key channels, as well as added new senior sales professionals who can now support any office, patient or caregiver in the country via virtual means.

Finally, I'd like to share my thoughts in light of the COVID-19 pandemic. Probuphine's value proposition continues to grow and improve as the call to action for stronger patient compliance, steady medication delivery and the peace of mind of patients and providers alike are greatly enhanced. Our relentless efforts to support our customers and their needs are a critical part of successfully navigating these trying times for our providers, our patients, caregivers, and of course our Titan employees.

I will 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. Kate?

Kate DeVarney: Thank you, Dane. As Marc mentioned, we were pleased to announce that NIDA approved approximately $6.1 million in second-year funding for our Nalmefene development program for the prevention of opioid relapse following detoxification. The aggregate potential expense reimbursement to Titan is approximately $8.7 million, which provides funds for the completion of implant formulation development, GMP manufacturing and the nonclinical studies required prior to commencing any clinical studies under an IND. We are currently conducting these studies and recently participated in a pre-investigational new drug meeting with the FDA to review our nonclinical development plans and obtain their guidance regarding filing an IND application by the end of this year or in early 2021.

In other ProNeura development activities, we continued to collaborate with the Walter Reed Army Institute of Research, or WRAIR, and Southwest Research Institute, or SwRI, in the early nonclinical evaluation of the ProNeura platform for malaria prophylaxis. The early data from this collaboration is encouraging, and WRAIR has received additional funding from the Department of Defense to continue the program, with additional nonclinical testing of the atovaquone and proguanil implant formulations in large-animal studies. WRAIR is also pursuing additional grant funding for testing other compounds that have shown promise as prophylactic treatments for malaria, and we look forward to collaborating with both WRAIR and SwRI for the preparation of these implant formulations, which, if successful, could be available to us for potential commercialization.

And now, shifting to our Probuphine activities. Our medical affairs and drug safety compliance team has been focused on providing Probuphine training and certification to healthcare providers across the county. During 2019, we attended multiple professional conferences to raise awareness of Probuphine, and we were very pleased with healthcare providers' interest and participation in REMS training sessions. We've also been focusing our resources on providing medical and REMS training support to the commercial team, and we will continue to do so.

Now, as I mentioned on our last call, we have postponed the Phase 4 studies in an effort to preserve our resources, and we have discussed our plans with the FDA in a conference call last quarter.

Before I turn the call over to Brian, I'd like to talk briefly about how the COVID-19 pandemic is impacting exactly how healthcare providers are monitoring and treating opioid use disorder patients. People with opioid use disorder comprise one of the most vulnerable populations at risk for morbidity and mortality during this pandemic, not only from COVID-19 but from their underlying addiction and other potential comorbid diseases, so it's critical that people who need medication-assisted therapy like Probuphine and other addiction treatments are able to receive them safely and consistently in the context of the ongoing COVID-19 emergency, and this emergency threatens to curtail patient access to evidence-based treatment.

At the request of the Substance Abuse and Mental Health Services Administration, or SAMHSA, the Drug Enforcement Agency, or DEA, announced that it would grant an exemption for telemedicine to be used in place of initial in-person visits. I have spoken with some of our Probuphine healthcare providers, who have informed me that they are now using this new treatment paradigm effectively.

While we evaluate how this may impact our business, we are working rapidly to ensure that the insertion and removal procedures are not barriers to both healthcare providers and patients during this difficult time. We're in the process of developing a virtual REMS training program so healthcare providers can continue to be trained to prescribe and administer Probuphine, and we are also creating specialty treatment clinics where patients may receive Probuphine safely during the corona pandemic. This program will be shared with the FDA once it is finalized.

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 Brian to discuss Titan's financial results. Brian?

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

In the fourth quarter of 2019, we reported $1.2 million in revenue. This included $0.2 million from product sales, $1 million related to our NIDA grant. This compares with $1.2 million in revenue during the same period a year ago, which was comprised of $0.2 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 of Probuphine, and $0.7 million related to the NIDA grant.

Total revenues for the year ended December 31, 2019, were $3.6 million, which includes $0.3 million in license revenues, $1 million from sales of Probuphine and $2.3 million related to our NIDA grant. This compares to total revenues of $6.6 million in 2018, which included $5.4 million in license revenue, $0.5 million from sales of Probuphine and $0.7 million related to our NIDA grant. The $3-million decrease resulted primarily from nonrecurring license revenues in 2018 of $3.2 million in upfront and milestone payments from Molteni and $2.1 million related to reacquiring the rights to Probuphine during -- or Probuphine from our former licensee, which was partially offset by increases in product revenue of $0.5 million and grant revenues of $1.6 million, and $0.3 million of license revenue which represented the remaining amortization of the 2018 Molteni upfront payment during 2019.

For the fourth quarter, total operating expenses, consisting primarily of R&D and SG&A expenses and cost of goods sold, inclusive of distribution expenses, were $5 million, compared to $4.5 million in the same quarter in 2018. Total operating expenses for the full year were $20.5 million in 2019, compared with $14.9 million in 2018, and consisted primarily of R&D and SG&A expenses.

R&D expenses for the year ended December 31, 2019, were $7.3 million, compared to $7.5 million in 2018. The decrease in R&D costs was primarily associated with decreases in employee-related expenses and other research and development expenses, partially offset by increased activities related to the NIDA grant and in increase in our contract manufacturing costs.

SG&A expenses for 2019 were $11.9 million, compared to $6.9 million in 2018. The increase in SG&A expenses was primarily due to higher sales and marketing expenses related to establishing the infrastructure to streamline the Probuphine ordering and distribution network and increased expenses associated with expanding Titan's Probuphine commercial activities.

The net loss applicable to common shareholders in the fourth quarter of 2019 was $4 million, or $0.08 per share, compared with a net loss of $3.5 million, or $0.29 per share, in the same quarter in 2018. The full year -- for the full year 2019, our net loss was $16.5 million, or $0.72 per share,

compared with a net loss of $9.3 million, or $1.64 per share, for 2018.

At December 31, 2019, we had cash and cash equivalents of $5.2 million, which we believe, along with the net cash proceeds of $8 million received from the January 2020 offering and the exercise of warrants during the first quarter of 2020, are sufficient to fund our planned operations into the fourth quarter of 2020.

Now I'll 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. So let me begin by providing a summary of our activities with our two partners, Knight Therapeutics in Canada and Molteni Farmaceutici in Europe.

During this past year, Knight was focused on obtaining product pricing approvals and formulary listing from the provincial health authorities, and early this year, the provinces of Quebec, New Brunswick, Newfoundland, Nova Scotia and Manitoba joined Alberta and Saskatchewan in providing access to Probuphine as a treatment for opioid use disorder in eligible patients. Knight is ramping up their product promotion activities in these provinces while they continue to pursue listings in the remaining provinces, especially Ontario and British Columbia.

As you know, Probuphine was approved by the European Medicines Agency in late June 2019, and our partner Molteni commenced the next steps towards commercialization of the product, Sixmo, which is the trade name for Probuphine in Europe, specifically applying for registration and pricing approval in the key countries, first of which are expected during the first half of this year.

Now, we have been working very closely with the team at Molteni to plan the manufacturing of the buprenorphine implants that will meet all EU regulations. This has required some modifications to the facility at our contract manufacturer, DPT, and the qualification of the modified facility is nearing completion, with production scheduled very shortly. A word of caution, however: With the coronavirus spreading across the U.S., we're all monitoring the day-to-day changes in the work environment and hoping that the production at DPT in San Antonio will remain on schedule. Also, we hope that Molteni, with their headquarters in Italy, one of the worst-affected countries at the present time, will be able to complete some of the work like packaging of the kits and testing as planned to enable the scheduled product launch activities. We will keep you posted on developments as we go along over the next few months.

Now, just a quick summary of last year. During 2019, Titan was keenly focused on executing our Probuphine relaunch strategy, and with a lot of hard work from our team and our partners, we have made good progress. While the product revenue in 2019 of about $1 million averaged the same pace as the second half of 2018, we now have the infrastructure in place.

With a strengthened balance sheet, we're well positioned to expand and support our commercial operations and continue streamlining the specialty pharmacy distribution process, expanding training to mid-level providers such as nurse practitioners and physician assistants, and through targeted marketing efforts, reach out to additional healthcare providers who have a patient

population undergoing buprenorphine maintenance treatment.

I am particularly excited about implementing the fortified patient support model that Dane described. It utilizes the strengths of the trained and qualified healthcare providers, allowing the insertion and removal procedures to be performed by those best suited for it and permitting many other healthcare providers in the community to prescribe Probuphine to their patients without having to set up the system to perform procedures. I believe this could be a win-win for all.

Also, there are a number of marketing and social-media-oriented initiatives that may help patients and healthcare providers choose the right treatment approach with long-acting products like Probuphine. The sales territory managers are well supported by the medical science liaison team, and together, they can provide the right service for the healthcare providers and their patients.

Kate and her team are developing an innovative virtual process for providing training to healthcare providers that should be very beneficial in the current environment. Also, our Nalmefene implant project is progressing, with the team working diligently to get all the nonclinical data necessary to file an IND hopefully by the end of this year, and we thank NIDA for their ongoing support. Our management and the board recognize the shareholder sentiment and are being careful to use the limited resources wisely and keep expenses within our means, including a six-month 50% reduction in Marc's and my salaries, while at the same time maintaining an environment for growth of our business.

A word of caution, however: We are somewhat in uncharted waters at the present time with the rapidly changing environment created by the coronavirus pandemic. We are trying to navigate our way through these obstacles while keeping in mind that the first priority must always be the safety of our employees and partners, the healthcare providers, and most importantly, the patients. We will try to do our best to reach our goals and, as always, we will keep you updated.

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 the continued hard work and dedication during this difficult time.

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

Questions & Answers

Operator: *(Operator Instructions)*

And our first question comes from Anita Dushyanth of Zacks Investment Research.

Anita Dushyanth: First of all, I just want to say that I'm filling in for John today from Zacks, and please pass on the congratulations to Dr. DeVarney on her appointment to the board.

Just have a couple of questions here. I know you already answered a few. Probuphine was recently added to the Federal Supply Schedule. Do you have any resources that show how many

veterans comprise of the addressable market for Probuphine?

Sunil Bhonsle: Hi, Anita. Thank you for filling in for John; appreciate -- I know this is a time where there are many companies providing their financial results calls at the same time.

In terms of specific numbers of those suffering with OUD that are part of the VA system, I know Dane has looked at that specific population. Dane, do you want to address that?

Dane Hallberg: Sure, thank you. And thanks, Anita, for the question. The -- essentially, the VA, with the veterans, they are affected at about 50% greater in terms of being affected by OUD. So we know the population as a whole is affected at a higher rate than the general population. The total number of veterans that are impacted by OUD, we -- those specific numbers, I haven't seen those published yet, but looking at what we -- from the data sources that are available, we know that it is significant. We can reach over 9 million veterans, but 9 million is not the number impacted by OUD. We have a -- we need to get a more granular look at that data.

But we do know, overall, that veterans are impacted at about a 50% greater rate than the general population, so we know that -- which is one of the reasons why we wanted to contract appropriately with the government -- was to ensure access and ensure that, with Kate's team, that we're able to train the doctors who elect to use Probuphine in their practices, to do so. But that is what we have at the moment.

Anita Dushyanth: Okay. And who, besides the VA, might pull from this schedule?

Dane Hallberg: Well, the FSS is the Federal Supply Schedule, so any -- TRICARE, any federal agency that utilizes the FSS could potentially have access to Probuphine. They would just have to put that -- obviously get trained and then put the request in the normal procedures to get the reimbursement.

Anita Dushyanth: Okay, okay. And regarding the pricing discussion of Probuphine, could you throw some light on how the pricing will be in Europe as compared to U.S.? And also, if your discussions have been favorable so far?

Sunil Bhonsle: Hi, Anita. In terms of pricing in Europe, really, Molteni handles that directly. While I'm aware of generally the level of pricing that they expect to get, which will be somewhere probably in the range of 40% or so less than the U.S. pricing, that's typical of European pricing policies in there. It is quite substantially higher than, let's say, the currently available treatments in Europe.

At this stage, Molteni has focused initially on the two, three countries where the expectation of pricing is higher because of the typical healthcare systems that they have, such as Germany, U.K. And that's where they will be able to establish an appropriate price, provide the product into those markets and show the benefits of the product, and that allows the product to be appropriately spread through the rest of Europe.

So it's a very staged approach that will be taken as they go forward, but once the first two, three

country pricing is set, it creates the environment where you can actually spread into the other regions of Europe with very specific targets in mind and use partners who already have boots on the ground and can do the work with you. So that's the kind of strategy that I expect Molteni will be following, but truly, maybe what, in one of these calls, obviously, with Italy being really direly affected by the current pandemic, but maybe in the next six months, one of the calls, we will have our partners from Molteni participate and provide some guidance as well, okay?

Anita Dushyanth: Okay, okay. My other question was kind of related to the active prescribers. You probably mentioned it in the call and maybe I missed it, but you said there were 282 active prescribers as of end of 2019. What was kind of your target number you were looking at that you're working towards this year?

Sunil Bhonsle: Yes. Our original target at the middle of the year when we started looking at this, we said, well, we really would like to have 500 active prescribers. For various reasons, the -- where we are at this stage is at the number that Dane mentioned, but we still are continuing to grow, so we will see -- we'll get to the 500 numbers. I have no doubts about it.

We are looking at establishing, as we said, certain models that will help expedite that process, especially the ability to utilize sort of the centralized process for the insertion and removal of the implant, so not every physician who can prescribe the product needs to be trained to do that. We want to use these capabilities of those who like doing the procedure to focus on getting the procedure and let those who like prescribing the product prescribe it and use the services of these, and that way we can expand the number of active healthcare providers a lot faster. I mean, these are the things that Dane and his team have learnt, and they're trying to now change the paradigm to implement ways where we can move faster. Okay?

Anita Dushyanth: Okay. And what are kind of the approval rates for the prescription requests?

Sunil Bhonsle: In terms -- when you say approval rates, in terms of the processing through third-party payers? Is that . . .

Anita Dushyanth: Yes.

Sunil Bhonsle: Dane, do you want to address that?

Dane Hallberg: Yes, yes. So we have about 94% coverage on the medical benefits side for the drug. It depends on patient benefits, but we have a very high, I guess, success rate in terms of approvals. It's upwards toward 70%, but it really is dependent upon the individual patient's benefits. Many states, they reduce the barriers, the PAs and the steps. Others haven't. But it really depends on the medical exception provided by the clinician that's acceptable to the payer, whether private or Medicaid, but we do know that we have 94% coverage and a very -- I would say a very high rate of approval, but then again, it really is dependent on every individual patient's benefits, as with any medication.

Anita Dushyanth: Right, right, okay. And just one last question from me. Do you have any metrics to share on your website portal performance?

Dane Hallberg: Could you -- the portal performance? Could you clarify?

Anita Dushyanth: Yes, the -- you were going for the online telemedicine kind of thing?

Dane Hallberg: Okay, so we have a physician portal that, instead of paper-based portal, that's available to clinicians to enroll patients to -- for the prescribing process. We don't publish those. That's a firewalled, private area. But we do have other metrics that we plan on reviewing with -- internally before providing publicly within -- with Sunil and the team, and -- but for those prescriptions and the way the physicians utilize portals, those are, for the most part, firewalled from us and from the public, if you can . . .

Operator: Our next question comes from Jason McCarthy of Maxim Group.

Adheip Mally: It's Adheip on the line for Jason. I just had a question here. You mentioned earlier on the Phase 4 post-market clinical trials have been temporarily put on hold in light of the COVID-19 pandemic. Could you shed some color on when you expect to reinitiate these trials?

Sunil Bhonsle: Sure. I mean, I think the clinical studies, there were three, and one of which we actually will participate in, and then two have been postponed, but I'll let Kate give you some color around that. Kate?

Kate DeVarney: Yes, hi, Adheip. Can you hear me okay?

Adheip Mally: Yes, I can hear you.

Kate DeVarney: So we have two -- we've got two post-marketing clinical studies that we are committed to doing that we have put on hold due to our resources currently. One is a study that will look at reimplantation into a previously used site and also implantation into the lower abdomen, a different -- giving clinicians an alternate site. And that's a pharmacokinetic study, small study. Another study is a larger study, and that's looking at implant safety in large observational cohorts.

Now, these studies are, as all clinical studies, are expensive, and we are conserving our resources right now until the time is right when we can initiate them. We have been in regular communication with the FDA regarding the study timelines and the FDA, so far, is being very supportive of this.

The third study is a cardiac safety study that we have been asked by the FDA to collaborate with some of our other companies in the buprenorphine space, so we're in the process of doing that. We have a final protocol that is currently under review at the FDA, and I anticipate that in the coming months, we will be starting that study. I don't know what kind of impact the current pandemic environment may have on those study timelines. As you can imagine, doing a clinical study in an age of extreme social isolation and perhaps even quarantine is really challenging, especially when you have to do a surgery for subjects. So we'll keep you updated as we figure all of that out. And that's really all I can say at this point about those studies.

Adheip Mally: Okay, no, for sure. It's definitely understandable. It's difficult to -- given the times that we're in right now.

Kate DeVarney: Yes.

Adheip Mally: And just another quick -- just another quick point of clarification here. Earlier on you mentioned that you guys saw an 18.6% increase in active prescribers compared to 3Q '19. Is that correct?

Sunil Bhonsle: Dane, you want to address that? The percentage of prescriptions? That's what you were referring to?

Dane Hallberg: Yes. Of the increase?

Sunil Bhonsle: Yes, the increase in . . .

Dane Hallberg: All right. Can you state the question again, please?

Adheip Mally: Oh, it's just a point of clarification. I just wanted to make sure I got the number down correctly here. You mentioned that you guys saw an 18.6% increase in active prescribers in 4Q '19 compared to 3Q '19. Is that right?

Dane Hallberg: No, those were the actual prescriptions. The prescriptions have increased 18 --

Adheip Mally: Oh, the prescriptions, okay.

Dane Hallberg: Yes, yes, correct. The enrollments to the -- yes. The enrollments, the prescriptions, increased 18.6% in Q4 versus Q3.

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, Andrea, and thank you all for participating in this call. I appreciate very much your taking the time at this somewhat difficult time that the whole world is facing. We truly appreciate your ongoing support, and I would like to express, from the Titan team, that you truly take care of your health, stay safe, and we will all work hard to advance our Probuphine program as well as develop products using our ProNeura technology during this pandemic. Thank you very much, and have an excellent day.

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