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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 Beebe DeVarney; Titan Pharmaceuticals, Inc.; EVP and Chief Scientific Officer
- Brian Crowley; Titan Pharmaceuticals, Inc.; VP, Finance

Analysts

- Ben Haynor, Alliance Global Partners
- John Vandermosten, Zacks Small Capital Research

Presentation

Operator: Thank you for holding, and welcome to the Titan Pharmaceuticals Third Quarter 2018 Financial Results Conference Call.

(Operator Instructions)

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

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

Sunil Bhonsle: Thank you, Sean, and thank you all for joining us. Welcome to the Titan Pharmaceuticals call to review financial and operational results for the third quarter ended September 30, 2018, and to provide an update on our business.

But before we begin, I wanted to inform you that we filed our quarterly report on Form 10-Q with the SEC today and the press release also issued this afternoon 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; Dane Hallberg, our recently appointed Executive Vice President and Chief Commercial Officer; and Brian Crowley, our Vice President of Finance.

But 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 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; 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.

Today we will start the call with an overview from our Executive Chairman, Dr. Rubin, who will also introduce our Chief Commercial Officer, Dane Hallberg. Dane will discuss the progress on our Probuphine commercialization plans, and then Dr. Kate DeVarney will provide an update on our Probuphine medical affairs and REMS programs, regulatory activities and other product development activities. 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 and welcome to all of you. The third quarter of 2018 was marked by a number of notable achievements related to our lead program, Probuphine, and also to our ProNeura platform technology, with opportunities there to expand its application.

So let me begin by mentioning a few of the highlights. First, early in September, we initiated a pilot program with the Nevada Center for Behavioral Health that is designed to evaluate medication-assisted treatment, or MAT, programs using Probuphine to treat opiate use disorder, or OUD, patients who are within the state of Nevada criminal justice system. Then, later in September, we were very pleased to announce that we were awarded a two-year, $6.7-million

grant from the National Institute on Drug Abuse, or NIDA. We also strengthened our balance sheet by closing an underwritten public offering, which, together with the subsequent exercises of the overallotment option and warrants sold in the offering, provided us with net proceeds of about $12 million, which extends our runway through the third quarter of 2019. Those are all notable accomplishments, and my colleagues will elaborate on each in a few minutes.

But today, I want to focus my comments on our activities supporting the commercialization of Probuphine in the U.S., because this is Titan's top priority. Our goal is to complete the transition to a commercial-stage enterprise by the end of 2018. And to that end, in the third quarter, we have started by building a very strong foundation for our commercial infrastructure. This includes establishment of sales, marketing and market access teams.

And leading this initiative is Dane Hallberg, who I'm very pleased to say was recently appointed to the position of Executive Vice President and Chief Commercial Officer. Dane has over two decades of healthcare experience, including commercial leadership roles with Able Star, Sunovion Pharmaceuticals, Global Healthcare Japan, Dendrite Japan, Tierra Inc., and also Merck, where he was a key member of the team that was responsible for launching the Implanon subdermal implant contraceptive, among other products. Most recently, Dane was retained by Bristol-Myers Squibb to provide strategic guidance and project management oversight for its global research and development, business intelligence and analytics, and also health economics and outcomes research programs.

Dane brings to Titan important experience and depth of knowledge and an impressive track record in sales and marketing in product launches and market access. He has been highly successful in building out commercial capabilities, leading marketing and sales teams and cultivating strong thought leader relationships across multiple specialties in both the global pharmaceutical and the biotech industries.

So it goes without saying, but I will say it anyway, that we are extremely fortunate to have Dane join Titan's executive team in this key role at this very important time for the company. And with that, I will turn the call over to Dane to discuss our activities supporting Probuphine commercialization. Dane?

Dane Hallberg: Thank you very much, Marc. I'm excited to join Titan in this new role. In addition to being confident in Titan's ability to successfully relaunch Probuphine, I am optimistic that Probuphine has the potential to address some of the significant unmet needs in the global opioid use disorder epidemic.

Titan's focus during the third quarter was largely on transitioning Probuphine's commercialization activities with minimal interruption, if any. The key activities included the transfer of supply chain and logistics functions and maintaining market access. I am happy to report that during the third quarter, we identified opportunities to engage and provide better service for healthcare providers and patients in the long term while continuing to supply Probuphine to prescribing healthcare providers.

As Marc mentioned, we have made rapid progress building a commercial team with expertise in sales, marketing, supply chain logistics, regulatory compliance, third-party payer and medical access. We have engaged a small yet experienced and highly accomplished sales team, and their training is expected to be completed in the next coming weeks. We have a seasoned and proven team assisting us with managing not only supply chain and market access functions, but we've also engaged consultants where appropriate, such as for the purpose of navigating the regulations of commercializing a controlled substance.

We are very pleased to have been able to maintain continuity of delivery of Probuphine to REMS-certified healthcare professionals and their patients during the third quarter, generating meaningful revenue during this transition period.

We are targeting select market segments where Probuphine can provide meaningful benefit for patients, allowing for sustained market penetration and sales growth. We are focusing on high Probuphine-prescribing physicians with long-term recovery-oriented treatment programs. We are proactively engaging third-party payers and contracting with the right specialty pharmacy partners to ensure broad patient access. In addition, our market access specialists are paving the way to facilitate the supply chain and improve the reimbursement process.

We believe that in the longer term, some of the top-tier Probuphine providers may engage in investigator-sponsored research that can potentially provide clinically meaningful data, some of which could help us assess the possibility for future label expansion. We will continue laying the groundwork in the criminal justice system, residential treatment facility and academic addiction program market segments.

The pilot program we recently initiated at the Nevada Center for Behavioral Health reflects our strategy to enable treatment of OUD in the criminal justice system with the hopes of reducing recidivism. A product like Probuphine could become part of the incarceration program treatment regimen, part of a parole program, or as part of drug courts' incarceration prevention efforts. The goal of this pilot program is to generate data that supports the use of Probuphine in this setting and help the criminal justice system deal with the growing opioid addiction epidemic.

There are a large number of residential treatment facilities within the U.S., many of which do not use medication-assisted treatment, or MAT. With high rates of post-discharge relapse, the use of MAT as part of the management of opioid use disorder has been increasing and is expected to rise substantially in the near term. As such, we plan to establish alliances with a few large programs that use MAT and can integrate Probuphine as part of opioid use disorder treatment. Finally, we plan to form alliances with institutions that already have trained personnel and equipment for conducting small procedures and support their use of Probuphine as appropriate.

In summary, we are building a strong team that will be the foundation of future growth with our near-term focus on healthcare providers currently prescribing Probuphine and supporting their increased utilization of the product in patients who are likely to benefit. That being said, we are also working on a number of initiatives to support/complement these efforts, including identifying current providers who could act as advocates for Probuphine, developing an

advocacy plan for key opinion leaders and leveraging a Probuphine educational program. In this endeavor, we work hand in hand with our drug safety and compliance team.

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 Beebe DeVarney: Thank you, Dane, and I'm so excited to have you on our team.

Let me start with an overview of recent activities related to our lead product, Probuphine. During the third quarter, we established two new departments: medical affairs and drug safety and compliance. The Probuphine risk evaluation mitigation strategy, or REMS, program activities are administered through the latter. We have also hired a few highly experienced medical science liaison professionals, each of whom have strong medical community relationships, as well as expertise with Probuphine and with the REMS program training.

Since early August, they have conducted numerous training sessions for new as well as previously certified healthcare providers on the Probuphine REMS program. This training activity has been an essential part of the transition, as it allows our medical team to engage directly with the healthcare providers. We gain firsthand knowledge of their experience and their needs, and that facilitates building their skills as Probuphine treatment providers.

Now in terms of ex-U.S. activities, we continue to support our partner Molteni as the EMA reviews the Probuphine MAA that we submitted late last year. During the third quarter, we worked closely with Molteni to address all the questions raised by the agency during their initial review of our MAA. This is a standard process, and with several rounds of interactions with the agency to respond to their review questions. We remain on track for a decision from the EMA in the first half of 2019.

Now, following Health Canada's approval of Probuphine for the maintenance treatment of stable patients with opioid use disorder in April of this year, Knight Therapeutics announced its commercial launch at the end of last month. Although in a very early commercial stage, we understand Probuphine has so far been very well received by physicians in Canada. Under the licensed agreement with Knight Therapeutics, Titan is entitled to low-double-digit-percentage royalties on Canadian Probuphine sales.

In this quarter, we also initiated preparations for conducting the first Probuphine Phase 4 post-marketing requirement by FDA. The aim of this study is to evaluate the safety and pharmacokinetics of reimplantation of Probuphine into a previously used site on a patient's inner upper arm, as well as implantation into an alternate location in the lower abdomen. We also just received feedback from the FDA on the design of another required Phase 4 trial to assess implant procedure safety in an observational cohort study design, and we hope to finalize that study design with FDA by the end of the year. Both studies are targeted for initiation in 2019 and we believe will provide valuable data for healthcare providers and their patients.

Finally, as Dane mentioned, here in the U.S., we also initiated a pilot program with the Nevada Center for Behavioral Health to evaluate a medication-assisted treatment program within the state of Nevada criminal justice system using Probuphine for patients with opioid use disorder. We plan to establish similar pilots with other select criminal justice programs with the goal of generating meaningful data that potentially supports the use of Probuphine in this important population.

Moving next to our Parkinson's disease program, we announced early in the third quarter that the independent data safety monitoring board had completed its review of the data from the first cohort of patients from our Phase 1/2 trial of our ropinirole implant. The DSMB recommended that we proceed with the enrollment of a second cohort to continue to study the implant's safety, tolerability and pharmacokinetic profile. Although a positive development, we elected to postpone enrollment of the second cohort of patients. While our long-term strategy is to pursue opportunities to apply our technology platform to additional indications, we've made the decision to focus as many of our resources as we can on a successful relaunch of Probuphine in the coming months.

Now the last thing I will highlight today is some exciting news on the potential expansion of our ProNeura-based product candidate pipeline. As Marc mentioned, we were awarded a two-year NIDA grant of approximately $6.7 million in September. The grant provides approximately $2.7 million from now through August 31 of 2019 and the remainder during the second year of the grant, subject to successful progress and the availability of funds to NIDA.

This grant will fund the IND-enabling development of a ProNeura-based six-month implantable formulation of Nalmefene, an opioid antagonist for the prevention of relapse to opioid addiction in patients who have successfully undergone a detoxification program. NIDA has previously supported Titan in 2009 by awarding a grant of approximately $7.8 million in funding for a controlled Phase 3 trial of Probuphine, and we are very grateful that NIDA is again providing its support to us. If these IND-enabling studies are successful, and depending on the availability of continued funding to NIDA, the clinical portion of our grant application will be considered for another three years of potential funding.

So as you can see, we've had a busy and productive third quarter, and I really look forward to keeping you updated on our progress over the next several months. Now I'd like to turn the call to Brian to discuss Titan's financial results. Brian?

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

In the third quarter of 2018, we reported $1.7 million in revenue, compared to $40,000 in the same period a year ago. License revenues in the 2018 period reflect $0.3 million from the amortization of deferred revenue related to the March 2018 sale of the Probuphine European intellectual property rights to Molteni and approximately $1.1 million related to the amendment to the Molteni purchase agreement in August of 2018. In addition, we had our first quarter of

product revenue since reacquiring the Probuphine commercialization rights, generating $244,000 from sales.

For the third quarter, total operating expenses, consisting primarily of R&D and G&A expenses, were $3.6 million, compared to $4.1 million from the same quarter in 2017. Our net loss attributable to common shareholders in the third quarter of 2018 was $2.3 million, or $0.11 per share, compared with a net loss of $4.2 million, or $0.20 per share, in the same quarter of 2017.

In September 2018, we closed a previously announced underwritten public offering, which provided net proceeds of $8.5 million. At the end of the third quarter, we had cash and cash equivalents of $8.4 million. We believe that this, combined with $4.6 million received from the sale of shares as a result of the underwriter's exercise of the remaining overallotment option, and the recent exercises of outstanding warrants, is sufficient to fund our planned operations through third quarter of 2019.

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

Sunil Bhonsle: Thank you, everyone. As you have heard from the team, we are dedicated to a successful relaunch of Probuphine in the U.S. and, under Dane's proven leadership, we have been working hard to advance our commercialization, sales and marketing strategies to accomplish this goal.

As Dane mentioned, our primary focus right now is to work with the certified healthcare providers already prescribing Probuphine and to make it easier for them to identify additional patients that are likely to benefit from Probuphine while improving the third-party-payer reimbursement process. This is a win-win for all.

I believe we have built a strong foundation for our commercial activities, and we have already started engaging with the other key market segments in the criminal justice system, academic addiction programs and residential treatment facilities. With successful entry in these strategic market segments, we expect to be in a strong position for long-term growth through potential partnerships with complementary companies.

Kate has taken on additional responsibilities in her role of Chief Scientific Officer and put together a very capable medical affairs, safety and compliance team that complements the commercial team, and she's available to the healthcare providers to address their ongoing training and medical queries.

We will be initiating the required Probuphine Phase 4 clinical studies next year and, while our other product development programs remain an important part of the company's growth strategy, we shall advance these as resources allow. We recognize that our ProNeura platform has the potential to benefit patients with chronic disease and we will continue to pursue the development of other ProNeura-based products once we have fully executed on the Probuphine relaunch.

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.

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

Questions & Answers

Operator: (Operator Instructions)

Our first question comes from Ben Haynor with Alliance Global Partners. Please go ahead, Ben.

Ben Haynor: Good afternoon, guys. Thanks for taking the questions.

Sunil Bhonsle: Hey. Hi, Ben. Good to hear from you.

Ben Haynor: Hey, guys. So just, I guess, starting off, obviously you guys have had a pretty eventful last several months. And I was just kind of curious on, I guess, what you've seen so far from -- in Q4 from existing prescribers. Are they continuing to prescribe? Are they increasing their prescriptions or implantations? Any color that you could provide there would be quite helpful.

Sunil Bhonsle: Sure, Ben. It's a great question. And obviously from the sales that we reported for the third quarter, we have continued providing the product, and sales are occurring, but I'll let Dane give you a flavor for how things are progressing.

Dane Hallberg: Sure. Thank you, Sunil. Yes, so what we have found from going out into the market and discussing Probuphine with the physicians is that they're extremely happy that we've continued to support the access to Probuphine for the market. Titan is traditionally a science-based company, never commercialized prior to this, so we've been able to really set a strong foundation and facilitate access to Probuphine.

In concert with that, working with Kate's team, if physicians were coming up for expiry on their REMS training, we've been able to quickly get REMS trainers or medical science liaison teams to those locations to recertify or provide the initial training to those clinicians.

So overall, the response has been very positive from the physicians we've engaged with, as well as some of the payer discussions that we've had. They're also very excited about us supporting the Probuphine market access to their members. So all in all, it's been very positive.

Ben Haynor: Okay, that's very helpful. Thanks for the color there. And just thinking about it with your competitor out there having a monthly depot injection out on the market for, I don't know, about nine months now or so, it looks to me, from the data that they've shared, that each month about 25%, 20% -- 20%, 25% of the patients drop off and don't get a subsequent injection. Has that been something that's come up in your conversations with other either physicians or payers or -- if you get down to the patient level?

Dane Hallberg: So actually, what -- I believe what has happened is that that has actually paved the way, the long-term MAT therapy. So there are monthly injections, and I think what the providers and the patients really like about Probuphine is that we're a six-month treatment. It's not a monthly injection. You're not going to see a drop-off when they insert the Probuphine rods. So I think the favorability towards our product for those that have dropped off is fairly positive in terms of the treatment.

Ben Haynor: Okay. Yes, I mean, that's kind of how I would have expected it to go, but I guess you never know.

Dane Hallberg: Right.

Ben Haynor: And then just thinking about the criminal justice opportunity, I know you're -- you have the agreement with Nevada. Have you done the first implants there, and have you had discussions with corrections department or criminal justice systems from other jurisdictions yet? And -- or -- and if so, are they waiting on anything from the Nevada program, or are people willing to progress sooner rather than later? Or any color that you could have -- that you could provide there would be great.

Kate Beebe DeVarney: That's a great question, Ben. Hi, this is Kate. Yes, we have been working very closely with the Center for Behavioral Health, which is leading this pilot program in the criminal justice system in Nevada. We've trained approximately 15 to 20 of their healthcare providers. We've got a very, very positive response from the healthcare providers throughout that training. All of them are certified, and they are ready to go. They are, at this stage, identifying patients, appropriate patients according to the product labeling, which are clinically stable patients on a dose of 8 milligrams or less a day who the healthcare provider is deeming to be appropriate for treatment.

That's the process where we are, and we expect the -- in the coming weeks and months that there will be orders coming in across the entire criminal justice system, all facets of it. As you are probably aware, it's a very complicated administrative system.

Ben Haynor: Okay. And that was kind of my next question, is obviously, you've got the incarcerated population and you've got the probation population, and you probably have another couple populations that I'm not thinking of. Has it been difficult -- yes. And has it been difficult to navigate any of those populations in particular, or has it gone relatively smoothly once you've gotten buy-in from the individuals or the managers?

Kate Beebe DeVarney: It's gone very smoothly. At our -- and at our first training -- we've actually done two trainings for the Nevada group right now. At the first training, we had representatives from all the different facets of the criminal justice system. The prisons, the jails, the drug court systems, the halfway houses, et cetera. And there was a uniform interest and acceptance because, as you can imagine, clinically, this is a product, this is a treatment that is appropriate for anybody in any stage of the incarceration process. So we're hopeful that we're

going to see some orders coming in in the coming weeks and months. But as I said, we're in the process now of identifying the right patients for treatment.

Sunil Bhonsle: And Ben, this is Sunil. Just to add one thing: Keep in mind that treatment of incarcerated patients has not been something that has been in place before. So when a state like Nevada takes on this endeavor, it is a major commitment that they're making to it, and they have to establish all of their own internal procedures and so on to -- how they will manage the patients and how they will handle the follow-ups and things like that. So more than just thinking of it as a simple, let's get a patient on it, they need to establish that system, and that's what we're helping them establish, and seeing where exactly Probuphine fits so that the long-term benefits are really what will happen here. So I expect to see this building and creating sort of a model that other states can follow. So it's an important program.

Ben Haynor: Okay. That's helpful. And then I guess a follow-up on that: If that -- if they get the protocol in place and all that occurs, for the patients that are in jail and are in prison, would that eventually potentially lead to all of the patients that are stable on the daily treatments being implanted in Nevada, or am I reading too much into that?

Kate Beebe DeVarney: Well, and I think what it will lead to is the identification of the appropriate patients. And we know that across the board, not just in Nevada but throughout the U.S., about 25% of patient who are in the criminal justice system, in all stages of it, have opioid use disorder, and it's largely untreated. So this is a lot of people. We are starting with this small pilot program so that we make sure that we understand the right way to treat these patients who desperately need the treatment, and then our highest objective here is to protect them, especially once they are released, and they have a very high potential rate of relapse and overdose. That's really what we're aiming for.

Ben Haynor: Okay, great. And then I guess two more quick ones from me, if it's all right. On the investigator-sponsored trials, it sounds like that will, at a minimum, inform the trials that you might do in the future to expand the label, or could those actually expand -- help you expand the label from the -- just from you guys not doing any trials but just taking the investigator-sponsored data to the FDA?

Kate Beebe DeVarney: That is a very good question, and typically, investigator-initiated or investigator-sponsored trials are not sufficient, don't lead to supplemental new drug applications. However, I've certainly seen it done both ways in different companies that I've worked with in the past. What they're very, very valuable for, though, is picking up signals that would lead to ideas for larger development programs that we would then conduct in-house to meet all the regulatory requirements required for submission of an sNDA.

Ben Haynor: Okay. Okay, that's very helpful. And then lastly, it looks like that you saw quite a few warrant exercises. Just in the scheme of things, does that look like kind of 30% of the warrants that are outstanding, that have been exercised, or can you kind of ballpark that for me?

Sunil Bhonsle: It's about 30%. Roughly 13 million of the 43 million or so.

Ben Haynor: Okay, great. That's all I have. Thanks for taking all the questions, guys.

Sunil Bhonsle: Sure, Ben. Thanks.

Kate Beebe DeVarney: Thanks, Ben.

Operator: Our next question comes from John Vandermosten with the Zacks SCR. Please go ahead, John.

John Vandermosten: Good afternoon. I want to just . . .

Sunil Bhonsle: Hi.

Kate Beebe DeVarney: Hi, John.

John Vandermosten: How are you doing? Good to chat again. I had a couple questions just on cash flow issues. The first was on Nalmefene -- I think that's you pronounce it -- and that $6.7 million that's supposed to come in. Is that going to come over -- what period is that supposed to come over, and when should we expect to see those flows?

Sunil Bhonsle: The grant itself is over a two-year period. Of the $6.7 million, the $2.7 million is for the first year, and that period really is from September of this year to the end of August of next year. So it's sort of that -- a little bit odd in terms of timeframes. But that's the first year for the $2.7 million. And the second year, which is literally starting in September of next year to 2020, August 2020, that will end up with $4 million during that period. So it's -- the cash flow is based upon -- the first part is mostly geared towards formulation development and initial work, and then the second year is geared towards doing the work for all of the nonclinical IND-supporting work that is necessary. So that's how it's split up.

John Vandermosten: Okay. And do those grants come at the end of that fiscal year period, or at the beginning of it? Or (inaudible) over the whole thing?

Brian Crowley: The funds are available over the period of time -- as we incur costs, we will then submit them for reimbursement during that period.

Sunil Bhonsle: So it's not actually at the end of the year. It is throughout the year based upon actual expenditures.

John Vandermosten: Okay. Okay, thanks. That is helpful. Second cash-flow-related question was just on the Phase 4, and what kind of quarterly cash burn rate might we see just allocated to that effort? And I'm getting the impression it might be second half '19 when we might see that, but any help that you can give on the modeling side would be useful.

Sunil Bhonsle: Sure. John, in this setting, there are two key studies, as Kate described. The first one is a smaller study in the sense that -- again, it's a very important study, but the number of patients will be a lot smaller compared to the second one. And this is the study where we're

looking at reimplanting in a previously used site or a new site. That study, I think, as we've indicated previously as well, is something that'll end up costing $3 million to $4 million. It will be roughly two and a half years to three-year timeframe for the full study. And it'll start in early part of next year.

John Vandermosten: Okay.

Sunil Bhonsle: Okay?

John Vandermosten: Okay.

Sunil Bhonsle: The second study is a much larger study, and once -- and I don't want to give the numbers right now, but to sort of mention it, and when we actually start the study you'll know the details. But that is an observational study, but it's a prospective observational study. We haven't yet worked out all the details of the things. Things are still being discussed with the FDA. So the exact protocol is not yet in place. And this is going to be more expensive, but I really don't have a sense of how much, and it'll start sometime -- and I shouldn't say expensive, but it's only in comparison. I mean, it's probably going to be $6-million to $8-million type of a thing over a four-year timeframe. And that'll start sometime in the latter part of next year.

John Vandermosten: Okay. That is very helpful. And just moving on to Canada again, I mean, I'm excited about that because they're -- I assume they've had first sales right now in mid-November. Will they face some of the same hurdles that Braeburn faced in the U.S. in getting started? And I'm wondering, are there any things that they're worried about? Obviously the health plans are different up there than they are in the United States, but can you point out any hurdles that they may face, that they've anticipated?

Sunil Bhonsle: In terms of the marketing strategy that -- and Knight Therapeutics has set up and so on, I mean, I don't want to get into a lot of detail. It's something that had to wait till they make their own public announcements on this. But in general, their approach obviously with the different healthcare structure there, the pricing is very different, the availability of different medications including the injectables and so on, and the use of that in different populations, is quite different than here.

So all I can say is, they really have looked at this and come up with a targeted population strategy saying, where would the implants be best suited? And I believe they really have looked at a very good approach of saying, hey, patient populations in Canada who cannot easily -- who are not in urban regions, for instance, and cannot quickly get to a doctor or a clinic and so on, would be ideally suited with an implant approach, and that's what they're targeting.

John Vandermosten: Okay.

Sunil Bhonsle: Okay.

John Vandermosten: And when I was asking that question, I was thinking of some of the hurdles that Braeburn felt -- or experienced with just reimbursement, and then the REMS and

things like that. I mean, I don't think any of those hurdles exist up there, but I'm -- I don't know too well the Canadian system, but just was wondering if it's just a little bit easier because of the way it's structured.

Sunil Bhonsle: A little bit easier is the better way to put it. I mean, they will, I'm sure, have their own hurdles, as everyone does when it comes to a new treatment, but clearly, the third-party payer is not the primary driver over there. Once they get pricing approval from their healthcare system, it is a lot easier for all of the different regions, essentially, within Canada to access the drug.

John Vandermosten: Okay. And last question is on, I think, maybe a question for Dane. And congratulations for getting added to the team, Dane.

Dane Hallberg: Thank you.

John Vandermosten: Was going to ask about -- I think there was a three-pronged strategy to pursue payers, patients and physicians, and I'm just wondering how that was progressing. And maybe just an update on how that three-pronged approach is working and -- that's it.

Dane Hallberg: Yes, absolutely. Absolutely. Yes, good question. The approach has been to really put the fundamentals in place, to put a strong foundation in place, and that means working with bringing a strong regulatory compliance group to review and ensure that all of our promotional materials are approved internally before submitting to OPDP with the government, with the FDA, to ensure that we are having those engagements with the physicians to understand their needs, their patients' needs, the caregivers.

So along with that, we really had to do our segmentation properly to understand the whys. We're asking, why Probuphine? Or why MAT therapy? To the payers, to the clinicians, to caregivers and patients. And to understand overall how we can be more effective as a company in delivering healthcare to these -- to the providers and the members. So when we get that feedback, we were able to assemble, assimilate that and distill that down into the right messaging so that we are finding the correct physicians that want to treat their patients with long-term MAT therapy, as well as the right patient populations.

Along with that, we have to have access. Whenever you launch a drug, you generally -- well, you always launch with the payers first, to have those discussions, to reduce the amount of hurdles and obstacles for access. So we very quickly talked to some of the major payers in the country to get their feedback, from medical directors, from pharmacy directors, to understand their thoughts around MAT as well as Probuphine. And the response has been overwhelmingly positive that the long-term therapies are something that they want to see utilized within certain patient populations and segments.

And so we have seen a strong uptick, really, in orders. And so I believe we can -- we'll see an even stronger uptick going into the first quarter of next year. And so as long as we're able to have the right folks in the right areas, I see a clear path for us.

John Vandermosten: All right. Thank you for taking my questions.

Dane Hallberg: Sure.

Sunil Bhonsle: Thanks, John. Take care.

Kate Beebe DeVarney: Thanks, John.

Operator: This will now conclude our question-and-answer session. I would like to turn the call over to Mr. Sunil Bhonsle for any closing remarks.

Sunil Bhonsle: Thank you, Sean. Thank you, everyone. Really appreciate your ongoing support and your participating in this conference call. It is our goal to keep you all updated over time, and we will continue to do so, and certainly look forward to talking to you guys again early next year. In the meantime, happy Thanksgiving from all of us to everybody, and have a great day.

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