Titan Pharmaceuticals Third Quarter 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.; Executive Assistant
- 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
- Brian Crowley; Titan Pharmaceuticals, Inc.; VP, Finance and Administration

Analysts

- Adheip Mally, Maxim Group LLC
- John Vandermosten, Zacks Small Capital Research
- Ben Haynor, Alliance Global Partners

Presentation

Operator: Thank you for holding, and welcome to the Titan Pharmaceuticals Third Quarter 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 call over to Sunil Bhonsle, President and CEO of Titan Pharmaceuticals. Please go ahead.

Sunil Bhonsle: Thank you, Allison, and thank you all for joining us. Welcome to the Titan Pharmaceuticals call to review the financial and operational results for the third quarter ended September 30, 2019, and also 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, and the press release issued earlier today provides a summary of the results and can be found also 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; Dane Hallberg, Executive Vice President and Chief Commercial Officer; and Brian Crowley, our Vice President of Finance and Administration.

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. Thanks, 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, Sunil, and hello, everyone, and thank you, as always, for joining us this afternoon.

As we highlighted on our last call, Titan began and, of course, has continued to work on laying the foundation required to successfully transition to a commercial-stage company via a number of important initiatives that were introduced in the first half of the year. These include refining and validating our market segmentation strategy, expanding our specialty pharmacy network by adding key players with national coverage and strong relationships with third-party payers, streamlining the distribution process with the goal of significantly shortening the time from prescription to product delivery, working to expand the number of insurance plans that cover Probuphine under the medical benefit, implementing a state-of-the-art regulatory and compliance program, rolling out new doctor and patient education programs, and growing the number of certified healthcare providers providing maintenance treatment to their patients and who are supportive of long-acting products like Probuphine.

While there is no denying that successfully implementing these initiatives has been more time-consuming than we would like for various reasons, including the resource constraints we've faced, I'm pleased to report that we have made measureable and, I think, meaningful progress, and continue to do so. And Dane will elaborate on this shortly.

We have also been working with Molteni as it prepares for Sixmo's progressive commercial launch across Europe, and we anticipate initiating product shipments to Molteni on schedule by early next year.

Also, importantly 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. In addition, with the support of government grants and select other partners, we have continued to explore additional opportunities for the use of our ProNeura technology to demonstrate delivery of a few select compounds in nonclinical models, including initial evaluation of a kappa opioid as a potentially nonaddictive treatment for chronic pain, and I'm pleased to say that this has shown encouraging early results. We have also started a study at low cost to assess the feasibility of delivering long-term CBD with the ProNeura system and should have some data on that to share with you in the first quarter of next year. Kate will also discuss these programs a bit later during the call.

With the right foundation in place, and with completion of the recent public financing providing the requisite resources to execute additional components of our growth plan, Titan is poised to start seeing meaningful commercial success over the next several quarters.

And with that, I am going to turn the call over to Dane for a commercial update. Dane?

Dane Hallberg: Thank you very much, Marc. Hello, everybody, and good to speak with you once again.

As Marc mentioned, we continued to expand access to treatment with Probuphine in the third quarter by entering into a specialty product distribution agreement with CVS Caremark, a subsidiary of CVS Health, and one of the largest prescription management and pharmaceutical services businesses in the United States. And as Marc also mentioned, last month we began training healthcare practitioners in the insertion and removal of Probuphine implants at drug and alcohol rehabilitation facilities, as well as providers at prominent medical groups. We are very excited that they will be including Probuphine as part of their comprehensive opioid use disorder treatment programs.

Last quarter, I mentioned that we commenced our Step Into Stability brand campaign, which highlights the unique long-term treatment features of Probuphine. We recently launched both a healthcare provider portal and branded patient website which enables patients to easily locate qualified healthcare providers. The provider portal, titanpronet.com, provides REMS-trained physicians and streamlined and intuitive ordering process, virtually eliminating errors and omissions in patient enrollment forms.

While the commercial activities have been ongoing to establish the distribution channels,

simplify the product ordering process and build product awareness, our small sales team has also been diligent in supporting and prescribing healthcare providers to maintain prescription flow. The units of Probuphine generating revenues in the second and third quarter of 2019 were essentially the same. Our focus remains on increasing the number of active Probuphine prescribers. Ongoing tactics include continued streamlining of the specialty pharmacy distribution process, expanding training to mid-level providers such as nurse practitioners and physician assistants, and reaching out to additional healthcare providers who have a patient population undergoing buprenorphine maintenance treatment via training and marketing.

In the third quarter, we enhanced this strategy with the addition of new initiatives, including actively pursuing and engaging key decision makers at residential treatment centers, VA clinics and the federal and state prison systems. And following the recent financing, we are now expanding our reach by adding a few experienced sales personnel and pursuing co-promotional partnerships. We also entered into a strategic relationship with a major, multistate, integrated delivery network that will [indiscernible] sufficient physician ordering. We have established an interim pricing agreement with the Veterans Administration and are working toward establishing a training program for VA clinicians over the next several months. Institutional organizations such as the VA represent an important patient population, not only because Probuphine complements their existing psychosocial support therapy and programs, but because positive patient outcomes are paramount for our veterans.

To summarize some key accomplishments to date, the number of active healthcare providers continues to steadily increase, and we are working hard toward achieving our goal of 500 active prescribers by the end of the year. We have achieved broad product access through a comprehensive product distribution network, and by utilizing strategic partnerships, we are starting to see growth in prescriptions. There was a 67% growth in number of enrolled patients in Q3 2019 versus Q2 2019. We have driven significant improvement in prescription processing times, with the average hub turnaround time reduced to less than three days.

Having recently secured needed additional financial resources, I believe we are now at an inflection point where we can start to strategically grow our team and our presence in key geographies and channels where we can expect solid utilization and uptake of Probuphine without the significant barriers and hurdles of the past. Moving forward through the remainder of 2019, we have some ambitious goals. We look forward to updating everyone as we progress.

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

Kate DeVarney: Thank you very much, Dane, and hello, everyone. I'd like to start today by providing you with an update on our Nalmefene development program for the prevention of opioid relapse following detoxification.

In September of 2018 we were awarded a two-year, $6.7-million grant by NIDA to develop a six-month subdermal implant to administer Nalmefene, which is an opioid antagonist for the prevention of opioid relapse and overdose in opioid use disorder patients who have already

undergone detoxification. The award for the first year, which ended at August 31, 2019, was approximately $2.7 million. This September, NIDA approved approximately $6.1 million in second-year funding, which, as a result of a change in the grant award terms regarding company-matching funds, the second year award covers both the federal and company match amounts of the original Year 2 award. Therefore, aggregate potential expense reimbursement to Titan is now approximately $8.7 million. This second-year grant award provides funds for the completion of implant formulation development, GMP manufacturing and nonclinical studies, which together would support an IND submission to the FDA in late Q3 of 2020.

Now, over the past quarter, we have completed initial formulation development and are now conducting the IND-enabling animal studies. We anticipate the pre-IND meeting with FDA in Q1 of 2020, and following a successful IND submission, we could potentially begin the first human trial by the end of 2020.

We believe NIDA's ongoing support is a testament to the potential of our ProNeura technology in treating opioid addiction, and we hope to secure additional NIDA grant funding for clinical development activities beyond the current grant's end date of September 2020, and this would be contingent on meeting the project milestones as well as on the availability of NIDA funding at that time.

Now, we're also evaluating ProNeura's potential to develop a kappa opioid, nonaddictive treatment for chronic pain. This feasibility program is being conducted in partnership with JT Therapeutics and is currently in the nonclinical testing stage in a rodent pain model, and we have some very encouraging initial results. We've also initiated a study at low cost to assess the feasibility of delivering long-term CBD with the ProNeura system and should have preliminary data in the first quarter of next year.

Now shifting to the Probuphine activities, in the last quarter, we have focused our resources on providing medical and REMS training support to the commercial team. Now, in an effort to preserve our resources, we've postponed the postmarketing Phase 4 studies and have advised the FDA of our plans. We will continue to look for opportunities to evaluate the use of Probuphine in settings that would allow broadening of the label claims and help more patients with opioid use disorder.

And finally, in October, we presented two posters at the 10th American Conference of Pharmacometrics in Orlando, Florida. The presentations discussed results from computer modeling studies of data from our Phase 3 clinical trials with Probuphine in subjects with opioid use disorder. These studies assessed the population pharmacokinetic parameters, the exposure response profiles, as well as drug-drug interaction potential, during treatment with Probuphine. The findings of these studies were positive and informative, suggesting that pharmacokinetic profiles for Probuphine are highly predictable and that the maximum clinical benefit of buprenorphine for the treatment of opioid use disorder can be achieved in eligible patients at relatively low blood concentration levels. In addition, the potential for drug-drug interactions is similar to that reported for other marketed buprenorphine formulations.

Now I will turn the call to Brian to discuss Titan's financial results. Brian?

Brian Crowley: A summary of the financial results was provided in our press release today and the details are available in the 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 third quarter of 2019, we reported $0.9 million in total revenues, which included $0.2 million from product sales, $0.8 million of grant revenues related to our Nalmefene product development project. This compared with total revenues of $1.7 million in the same period in 2018, which were primarily related to license revenues from the sale of our Probuphine European intellectual property rights to Molteni and product revenues.

The third quarter 2019 operating expenses, consisting primarily of R&D and SG&A expenses and cost of goods sold, were $4.8 million, compared with $3.6 million in the same quarter in 2018. The increase in third quarter 2019 operating expense is primarily due to $1.5 million in additional SG&A expenses, which were partially offset by a $0.3-million decrease in R&D expenses. The increase in SG&A expenses was primarily related to the commercialization of Probuphine, which resulted in higher expenses related to employees' travel, facilities, consulting and professional fees and other outside services.

Net loss applicable to common shareholders in the third quarter of 2019 was $2.8 million, or $0.18 per share, compared with net loss of $2.3 million, or $0.64 per share, in the same quarter in 2018. In October 2019, we received net cash proceeds of $8.1 million from a public offering. We believe that these net proceeds, combined with our cash and cash equivalents of $0.9 million at September 30, 2019, are sufficient to fund our planned operations into the third quarter of 2020.

I will now 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. Thank you, Brian. Before we discuss our key areas of focus for the remainder of 2019, I'd like to provide a short update on Molteni's progressive commercial launch of Sixmo across Europe. With its headquarters based in Florence responsible for the entire European supply chain process, Molteni plans to launch Sixmo in sequence following local pricing and reimbursement approval via a dedicated field force situated in key markets. The launch will be accompanied by a clinical and medical affairs program which includes the Phase 4 postmarketing safety study agreed with the EMA, and Molteni will focus initial training on high-volume addiction centers from which trained healthcare providers will be able to deliver treatment coverage for a wide surrounding area. So essentially, it's a hub-and-spoke model. Molteni hopes to get pricing approval in the first EU country during Q1 2020, so that's when the real launch will begin.

Now, as you can see from Dane's presentation, we have made meaningful progress toward transitioning to a commercial enterprise and we are ready to expand the outreach to the medical community. While we deploy the funds from our recent financing to execute our strategy and meet this goal, we will also work to improve our overall cost structure to further extend our cash runway. We look forward to updating shareholders on our progress on both of these fronts.

Last but not least, as Kate indicated, we will continue to look for avenues to increase the usage of Probuphine in a wider patient population and also promote use of the ProNeura technology in additional product development activity like the NIDA-supported Nalmefene implant for potentially treating opiate use disorder in a different patient population. Our goal is to continue exploring opportunities to expand the use of ProNeura with support from other institutions and partners, and we look forward to advancing early-stage programs like the one with JT Therapeutics for treatment of chronic pain, among others. And as Kate also indicated, we are initiating a feasibility study for long-term delivery of CBD using our ProNeura platform.

With this, I will conclude our prepared remarks for today. Before I call -- open the call to questions, I'd like to thank Titan's board, executive management and staff for the continued hard work and dedication. So Allison, we're ready to take questions from the call participants.

Questions & Answers

Operator: (Operator Instructions)

The first question today will come from Jason McCarthy of Maxim Group.

Adheip Mally: Hi, everyone, it's Adheip on the line for Jason. Just wanted to see if you could provide us with an update on the agreements you have in place with CVS Caremark, Southside Specialty Pharmacy, and Accredo. Are there any large specialty pharmacies that you're looking to collaborate with in the near future? And if you could perhaps shed some color on the types of synergies you look for when evaluating companies to potentially collaborate with, that'd be great. Thank you.

Sunil Bhonsle: Sure, Adheip. As we've announced previously the different agreements with the specialty pharmacies, I'll let Dane expand on how we are utilizing those, as well as talk a little bit about the potential co-promotion, partnering-type opportunities that we are seeking. Dane?

Dane Hallberg: Sure. So just to add some color around this, when we do our strategic contracting with the specialty pharmacies, what we're looking at in terms of who's going to be right for us is in relation to payer contracts. So previously, when we inherited the network that we had, the majority of prescriptions were denied, and many cases it was because the specialty pharmacy was out of network and the contract could not be fulfilled. The reimbursement wasn't there for the clinicians and the patients didn't get coverage. So now that we have, as you mentioned, CVS and Accredo and Walgreens, and we're looking -- that gives us really solid coverage nationwide, with the majority of payers.

When we identify certain patients that may be covered under smaller health plans that don't fall under the larger umbrella, we consider contracting with, maybe, a medium-sized specialty pharmacy to provide that gap coverage. But right now we have a very solid network of specialty pharmacies, and what we're seeing now is, as I discussed, a very quick turnaround during the benefits investigation to less than three days. And that's down from up to 90 days before our

physician and patient could get an answer whether the drug was covered or not. So as you can see, it was a major undertaking to get those contracts in place and to ensure that we could fulfill the prescriptions for the clinicians. Does that answer your question?

Adheip Mally: Oh, yes, that's very helpful. Thank you.

Dane Hallberg: You're welcome.

Operator: And our next question today will come from John Vandermosten of Zacks SCR.

John Vandermosten: I wanted to start out with a question on your sense of price elasticity for Probuphine. Is -- have you done any work there? I mean, obviously, historically, products like this are -- we don't think about price elasticity, but I was wondering if that's something that you've looked at, at all.

Sunil Bhonsle: Hi, John. This is Sunil.

John Vandermosten: Hi, Sunil.

Sunil Bhonsle: The pricing for Probuphine that we started off with was essentially what had been set previously, and we chose not to change that because our goal was to try and establish a presence and minimize changes, especially with doctors who had already starting utilizing Probuphine. So we have maintained that approach for now. However, at the same time, looking at where Probuphine now fits in with the different treatments that are available for treating opiate addiction, and including the one-month depot injection and, obviously, the daily dosed treatments, we fall in the middle of the range. And with some of the key benefits that our product provides, we do want to look at potential for -- what pricing is appropriate, and look at doing some studies like the pricing elasticity and so on, and Dane has brought this up and looked at it, and we talk about, well, it's something we need to do, but haven't really done an extensive study. Dane, anything else?

Dane Hallberg: No, I would just add, as you mentioned, the market landscape has changed and so have the dynamics from when the drug was initially launched. So, as Sunil mentioned, we are looking at it and we'll continue to further investigate how we could evaluate the potential impact on any such price elasticity, as you mentioned. But we are examining it.

John Vandermosten: Okay, great, great. And obviously, Probuphine is a REMS product and it requires surgery, but could it potentially, at some point, be prescribed by teledoc? The -- and then they could refer the patient to the local individual to do the surgery. Is that something that's possible?

Sunil Bhonsle: It's a great question, John. I mean, certainly, with more experience with Probuphine and once it becomes part of a more routine maintenance treatment accepted by the medical community, I don't see why some things like that couldn't be enhanced. And Kate, I'm sure, has views on that as well. Kate?

Kate DeVarney: Yes, thanks, Sunil. Hi, John. I absolutely think that that is something that's feasible, and it's something we've been interested in for several years now. It's something we'll continue to explore in the future, as there are more and more companies, as you know, who are providing the platforms for telemedicine in addiction.

John Vandermosten: Okay. Yes, it seems like an interesting new way to do it that might open up some doors. And then --

Kate DeVarney: Absolutely.

Sunil Bhonsle: And Kate has explored it with specific companies as well in the past, so at the right time, I think it'll make a lot of sense.

Kate DeVarney: Yes.

John Vandermosten: Okay. And Kate, another question for you: It seems like there might be the IND by Q3 '20 for Nalmefene. Does -- what does that suggest for the revenue, the grant revenues, over the next, I guess, four quarters for that, since we -- since if we're breaking it up into four parts and it should be done by then, how would that play out on the revenue -- the grant revenue side?

Kate DeVarney: That's a good question, John. The grant revenue is contingent in two things. One, meeting milestones, and we've met our milestones to date and we are on track to continue to meet those milestones. It's also contingent, however, on the availability of money at NIH. And so right now, that money has been earmarked, but we can't predict and NIDA can't promise that that money's going to be there in the future. But for now, we expect, given our ability to meet the timelines and give them our early initial work that we've done, both in the formulation development and with nonclinical testing, that this implant should act very much as we expect it to, and we just have to get it into the first human trial and see how it looks.

John Vandermosten: Okay.

Sunil Bhonsle: And Brian can give you sort of a quick look at how we think the revenues from the grant that's committed to the $6 million for the second year will flow.

Brian Crowley: Yes. For over the next year, as the work progresses, the grant revenue is based on the efforts that we -- or the funds that we expend. And so as activity picks up, we move to the IND, et cetera, those expenses will increase and therefore the revenue will increase. So it'll be gradually moving up over -- but there will be some peaks in activity and some troughs over the next four quarters.

Sunil Bhonsle: I expect -- I mean, it clearly -- it will start increasing with each quarter and the largest amount will be in the fourth quarter, because that's when we will be really filing the IND and getting prepared for clinical studies. So I would look at it in that manner, where the next quarter starts at a level higher than this quarter by at least 20%, 30%, and then by the end of the fourth quarter, getting to be twice as much from the next quarter.

Operator: And our next question today will come from Ben Haynor of Alliance Global Partners.

Ben Haynor: So just wondering -- I heard you mention the 500 active prescribers goal. Can you maybe remind us how you define active prescribers, and maybe how many you have at the moment or at the end of the quarter or at the beginning of the year, some frame of reference of kind of where you've been at historically or now?

Sunil Bhonsle: Sure.

Dane Hallberg: Yes, sure. Oh, go ahead.

Sunil Bhonsle: Dane, go right ahead.

Dane Hallberg: Okay. All right. Yes, Ben, we're -- we've gone over half of that goal, so we're trending nicely. And when we look at active prescribers, these are folks that we've recently trained. And they sought training because they have a patient population that would benefit from Probuphine. We have a limited budget, so we want to ensure that we give the resources and provide the right resources and tools to the folks that will actually utilize Probuphine instead of a mass training of people and not having prescriptions.

So we're over half right now in terms of active prescribers, and our goal of 500 would mean that they're going to write one or more prescriptions of Probuphine. And obviously we hope they'll write much more, or much greater than the one prescription.

But that's how we define it, and we strategically set up our trainings at various conferences and we know that there's qualified healthcare practitioners there, and a lot of it's segmentation as well. When we look at the prescribing habits of clinicians, we know that for the most part the nurse practitioners are the #1 writer of long-acting MAT. So we spend a great deal of time helping our colleagues in the field of -- nurse practitioners, in that field, and ensuring they have the resources to counsel patients. So with that, we've provided some additional patient resources for those counseling sessions, so now the clinicians can have a conversation with the patients and the caregivers and they can actually feel a placebo implant, and they can see how very small it is and feel very comfortable getting the procedure done in the office setting.

So we've really closed the gap, the knowledge gap, for the providers and the patients and the caregivers with these types of resources, and we're now seeing patients coming in with the Step Into Stability campaign to our active prescriber base requesting Probuphine. We haven't seen that in the past and we're seeing it now.

Ben Haynor: Okay, great. And then just maybe one point of clarification. One or more prescriptions of Probuphine -- is that in a certain time period? Is it in a year? Is it in a quarter? Is it in six months? How do you think about that?

Dane Hallberg: Well, we ideally, once we have the clinicians trained, they have patients in

mind to utilize Probuphine with. They obviously have to go through the benefits investigation, which we've gone from 90 days to under three days, and get that to the specialty pharmacy. So we've closed that gap. So now, clinicians have the confidence that when they write Probuphine it's very likely it's going to be approved by the insurance and delivered to the offices. We can't control how much Probuphine they use, but what we can do is ensure that we support those clinicians with the right resources to begin prescribing Probuphine, as well as with Kate's team, the MSL team, and our physician trainers, when our active prescriber base may have questions about the procedure, we can very quickly address those. Our medical team can get there and address those questions or concerns and help those clinicians and the patients get the implant.

Ben Haynor: Okay, that's helpful. And then just thinking about the progress that you've made, you've got AppianRx in place, you've got Accredo, AllianceRx, CVS, Southside pharmacy, you've got the hub turnaround less than three days. But I wonder if investors, or potential investors, look at the numbers here today and see, well, product revenue was down sequentially, it was done year-over-year; what gives me the confidence that this is going to grow, and what are the biggest needle-movers that can make that happen? I mean, is it more feet on the street? Is it having a successful prescription that someone's prescribed and then six months later, now they're ready to give it to more patients? What's -- I mean, I guess, what's your response to people who might be on the fence in -- for that reason?

Dane Hallberg: Well, this is -- I'm glad you asked this question because the prescriptions that were -- the prescriptions from Q2 to Q3, the actual prescriptions and the usage, are virtually the same. A lot of the patients this quarter -- or last quarter, Q3, were on patient assistance programs. They were PAT patients. Those are not revenue-generating kits sold. So there was the usage, there's the demand for Probuphine, but a lot of these patients didn't have the resources to pay for it, and Titan offers a patient assistance program when they're not covered in their need of Probuphine, and so we supply it. So the actual usage was virtually the same as Q2; however, we can't recognize that as revenue, obviously.

So the demand is there. We're seeing the increase in the demand. But you also have to realize, and this is something that's across the space in the OUD market, 40% of the patients fall under Medicaid, and a lot of them are indigent. So they're either covered by Medicaid or they're not covered, a lot of times, with their own health plans. So we have things in place to help those patients, and we rightfully should have those in place.

So I think that you look at the revenue numbers, and I don't believe they're indicative of the demand and the usage because of the programs we have in place. But now that we're seeing demand, and we know a great deal of patients are covered by Medicaid and other health plans, we expect these numbers to fluctuate but also to start normalizing here in the next few months. So does that answer your question?

Ben Haynor: Yes, I mean, it's helpful. I'm just trying to get a sense of, okay, let's say you're at 250 prescribers now, you get another 250 in Q4, and let's say 40% of those single prescriptions are patients that are on Medicaid, so you've got 150 prescriptions that are going to be paid at $4,500 a pop, so now you're looking at whatever that is, $670,000. I mean, should investors expect that $670,000 should be the number for Q4, just ballpark, by what we've talked about? In

terms of product revenue.

Dane Hallberg: Well, we're not -- yes, obviously we can't comment on that number specifically, but what we do know is that when the patients -- we have patients on the third and fourth implants. We know that when they go on Probuphine, they like it. And what we also know is when the healthcare practitioners use Probuphine with their patients, the feedback, the response, is very gratifying for them. It reinforces the fact that their patients are on the road to stability. They don't have the peaks and troughs because the pharmacokinetic profile of the drug in the bloodstream doesn't trough. So the desire for more opioids relieves a lot of the fear. A lot of the fear with patients is that they need that dose. They can't travel. They're afraid they have to get that second dose. So when they talk to their healthcare providers, the response has been, hey, you know what? I don't have this fear.

So what I can tell you is, as we've increased the usage, whether it's through a patient assistance program or the health plans have reimbursed for it, what we're seeing through the usage is a satisfaction rate which is very, very promising for our forecast. And so I think when we -- with the resources that we now have from the capital raise, we're increasing our field sales team right now, and we're in key geographies, and as we do that, I expect to see much greater usage in strategic areas where we have ease of payer access, meaning they haven't -- it may be covered but we've looked at or addressed the steps in prior auths the payers have put in place, so we're relatively sure that when the doctor prescribes it there's not going to be any red tape and health plans trying to block it, and the patients will start using it, and they are talking to other patients in the communities, and they're -- that's driving the demand into our active prescriber base requesting Probuphine.

So when I look at that, I know that the metrics and the milestones of user satisfaction and the shipments show great promise for the months to come. So I can say that matter-of-factly and very confidently, that I believe that through greater usage, we're going to see much -- a good return on user satisfaction and the product.

Ben Haynor: Okay, I appreciate the color there. And then just on -- I noticed Indivior, the other day, they launched a DTC ad campaign for Sublocade. Do you think that helps you guys with Probuphine in raising awareness, for the longer-term treatment options, or what's a good way to think about it? I know you guys are out there with your own campaigns as well.

Dane Hallberg: Yes. I mean, what -- Indivior has been really fantastic at changing the mindsets of clinicians from the daily dose to the long-acting. So a lot of our prescriber base, that active prescriber base, really comes from the experience they've had with the monthly. And then the user satisfaction or dissatisfaction with some of the monthly treatments. And so what we're seeing is that they've been great at changing the mindset about compliance and some of the user satisfaction, and we're picking up those patients. So it's really helped us. When you look at the numbers and you look at the numbers of certain monthly medications on the market, and you see the patient -- the base that starts and then falls off, it's really been helping our clinicians make a determination to get REMS-trained and use Probuphine. So I welcome it. It's been very positive for us.

Ben Haynor: Okay, great. And then I've got one potentially stupid question and then one housekeeping question. With regard to the CBD -- CBD, I believe, is fat-soluble. Does that make it difficult to kind of dial in the dosage, or do you have some kind of an encapsulation or delivery mechanism that helps out with that? Just kind of how that works, I was curious about.

Sunil Bhonsle: Well, that's quite an important question, and one, in terms of long-term delivery of CBD, it's not something that has been tried, and not a lot of data on it. So we believe, based on certain formulation, which I won't get into, but we can provide a longer-term delivery, and this is the first nonclinical experiments, in vivo study, that's being done. So we could be the first ones to show that yes, there is a way to deliver this long-term. So it's exciting, but the answer will be sometime in the first quarter, I can tell you what it'd look like.

Ben Haynor: Great. It's always interesting, because you always wonder -- well, you kind of wonder whether it's just kind of, let's throw out CBD, and have we really thought this through or are we just trying to -- I mean, I'm not saying that you guys are doing this, but just trying to jump on the bandwagon, so to speak.

Sunil Bhonsle: No, we would have done that a long time ago when it was flying high, right?

Ben Haynor: Yes, you're late to the party, I guess.

Sunil Bhonsle: It takes some thinking in figuring out how to do it, so.

Ben Haynor: Right. No, that's good. And then lastly from me is just the kind of housekeeping question. Just in terms of the operating expenses during Q3, can you kind of break out what in there might have been nonrecurring? I know you have some expenses that look like they may have been nonrecurring that you broke out in the press release, but I was just curious, as -- what's the X amount that's nonrecurring in that?

Brian Crowley: As far as the operating expenses?

Ben Haynor: Yes. You kind of broke out the professional and outside services, and travel and such -- I mean, not that that was a big number, but just curious if there was anything nonrecurring in there.

Brian Crowley: For the most part, those are mostly going to be recurring going ahead. We didn't have a lot of nonrecurring. You have -- you had a jump between Q3 of last year to this year which -- a lot of it was the commercialization efforts.

Sunil Bhonsle: Right. In terms of the overall spend, the best way, Ben, to look at it is, during this quarter, the only sort of nonrecurring expenses were more related to development of the websites, like the portal and so on, which is now complete, and those are going into action. But at the same time, as you well know, from a marketing standpoint, we still have to sort of focus our attention into some very specific segments that we are looking at. And that sort of strategy of going out to the VA, the residence centers and so on will require some spending there as well.

What we have looked at is our overall spend based on the financing that we just did, and we want to make sure that we can get past the end of the second quarter and into the third quarter with that money. And when you look at that total amount of money, the spend is actually going to be somewhat less than what you saw in this past quarter, but where all the savings come from is a little more -- I mean, it's beyond any one single item. There's a number of things that we are doing to hold the spending down.

Operator: Ladies and gentlemen, this will conclude our question-and-answer session, and at this time I'd like to turn the conference back over to Sunil Bhonsle for any closing remarks.

Closing Remarks

Sunil Bhonsle: Thanks, Allison, and thank you all for participating in this call. We certainly want to keep you updated. We truly appreciate your ongoing support. And we will continue reporting our progress as we see it over the next few months and into next year. Thank you.

Operator: The conference has now concluded and we thank you for attending today's presentation. You may now disconnect your lines.