SLNO Earnings Call Transcript

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Quarter: 3

Operator: Good afternoon, and thank you for standing by. Welcome to Soleno Therapeutics Third Quarter 2025 Financial and Operating Results Conference Call and webcast. [Operator Instructions]. As a reminder, today's webcast is being recorded. I would now like to introduce Brian Ritchie of LifeSci Advisors. Please go ahead.
Brian Ritchie: Thank you. Good afternoon, everyone, and thank you for joining us to discuss Soleno Therapeutics Third Quarter 2025 financial and operating results. Please note, we will be making certain forward-looking statements today. We refer you to Soleno's SEC filings for a discussion of the risks that may cause actual results to differ from the forward-looking statements. On the call with me today for Soleno are Anish Bhatnagar, Soleno's Chairman and Chief Executive Officer; Meredith Manning, Soleno's Chief Commercial Officer; and Jim MacKaness, Soleno's Chief Financial Officer. With that, I will now turn the call over to Anish.
Anish Bhatnagar: Thank you, Brian, and thank you, everyone, for joining us for our third quarter results call this afternoon. Following my brief opening remarks, Meredith will review the company's commercialization progress to date, and Jim will cover the company's financial statements for the third quarter. We will then open the call for questions. We had an outstanding third quarter, building on the strong launch momentum from our second quarter. Our total net revenue more than doubled from the second quarter to $66 million, and the company achieved profitability with a positive net income of $26 million for the third quarter. Our leading indicators, including patient start forms, unique prescribers and numbers of lives covered reflect growing awareness of VYKAT XR's potential to improve hyperphagia in those with PWS. As the first and only FDA-approved treatment for patients 4 years and older for the primary feature of PWS, which is hyperphagia, VYKAT XR is providing a meaningful solution to individuals living with PWS, their caregivers and physicians. I would like to take a moment to reiterate the complexity of Prader-Willi syndrome. In addition to the hallmark symptom of hyperphagia, people with PWS suffer from a broad range of potentially serious comorbidities as well as significant behavioral problems. And while people with PWS are living longer, some into their 50s and older, the mean age of death, unfortunately still stands at around 30 years old. Patients with PWS experience a very high burden of disease compared to the general population. In particular, comorbidities associated with fluid overload, diabetes, respiratory failure and congestive heart failure are common. In a recently published registry of patients with PWS in Sweden, [Gaiseki] and colleagues observed a greater than 20-fold increase in heart failure, a tenfold increase in venous thrombosis and a fivefold increase in atrial fibrillation and pulmonary embolism. In a 40-year survey of mortality in patients with PWS, Butler and colleagues reported that respiratory failure and cardiac disease and cardiac failure together accounted for nearly half of all fatalities. The most common causes of death are respiratory failure, uncontrolled hyperphagia and hyperphagia-related behaviors, cardiac causes, infection, obesity and pulmonary embolism with each accounting for greater than 5% of deaths. A recent study in 2020 revealed that the mortality rate in people with PWS is substantially higher than the general U.S. population at 2.7%. This translates to over 300 fatalities per year, assuming a population of approximately 12,000 people living with PWS in the U.S. The VYKAT XR clinical program established both substantial evidence of efficacy and a safety profile deemed approvable by the FDA based on a comprehensive Phase III clinical program in 127 patients with over 400 patient years of exposure, including patients with nearly 6 years

of continuous treatment. At the end of Q3, at approximately 6 months in market, we had 764 active patients. Our real-world experience, including efficacy, side effects and discontinuation rates related to therapy have been in line with our expectations. As discussed in VYKAT XR's FDA-approved label, the most common adverse events reported in our clinical trials were hypertrichosis, edema, hyperglycemia and rash. Most adverse events were self-limiting with some needing dose adjustments, interruption or other concomitant treatment. In particular, regarding fluid retention-related adverse events post launch, we see on a percent basis, the incidence being lower than what we saw in clinical trials in spite of the post-launch patients being more complex and having more comorbidities. Since approval, the discontinuation rate of VYKAT XR related to AEs was approximately 8% at the end of the third quarter, and the total discontinuation was approximately 10%. While the discontinuation rate has increased, it remains below our expected long-term rate based on our clinical trial data. It is worth noting that we did see a disruption in our launch trajectory in the wake of a short seller report that was released in mid-August, mostly in the form of a lower number of start forms and increased discontinuations for nonserious adverse events. As we have anticipated, we have started to see patients return to therapy, often as withdrawal of VYKAT XR can bring a rapid return of PWS symptoms. We continue to educate physicians and families on the compelling clinical profile of VYKAT XR, and we dedicated significant resources to these activities during the third quarter. Our team of patient and community educators, known as the PACE team, is educating families and caregivers on therapy expectations, administration and monitoring at the time of first dose and throughout the patient journey. We're also hosting live community events in collaboration with advocacy organizations, health care providers and caregivers of individuals already on VYKAT XR, so they can share their experience with other caregivers contemplating initiating treatment. We're continuing our HCP education initiatives, including facilitating physician-to-physician programs, which allows physicians to learn more about VYKAT XR from experts who have experienced treating patients with PWS-related hyperphagia. Soleno has received positive feedback on our engagement with the stakeholders in the PWS community, and we believe this will continue to fuel our growth and allow us to establish VYKAT XR, as a standard of care for hyperphagia in those living with PWS. I would now like to provide a brief update on our activities in support of potential approval of DCCR in Europe. As you know, we market DCCR in the U.S. as VYKAT XR. In parallel with our U.S. commercial launch, we have continued to progress along regulatory pathways in other geographies, the most prominent of which is the EU. In May, we announced the submission and EMA validation of our marketing authorization application. We received day 120 questions during the past quarter and are preparing our responses at this time. The nature of the questions are generally similar to what we discussed with the U.S. FDA during the approval process. Gaining approval to market DCCR in the EU would represent a meaningful expansion of our addressable market and remains a priority for us, while we continue to progress our U.S. launch. Based on widely cited prevalence data, it is estimated that there are as many as 9,500 people living with PWS in France, Germany, Italy, Spain and the U.K. combined. Diagnostic rates are high, patient care is often concentrated around centers of excellence. And as with the U.S., the PWS community has strong thought leader support. We will continue to keep you apprised of our progress there and in other territories. I will now turn the call over to Meredith to provide an update on the launch. Meredith?

Meredith Manning: Thank you, Anish, and good afternoon, everyone. As Anish mentioned, since approval, we've made remarkable progress in launching VYKAT XR. Our success driving broad awareness and adoption reflects disciplined execution grounded in effectively introducing VYKAT XR to the prescriber community, individuals with PWS, their caregivers and payers. We also attribute our launch success to Soleno's steadfast commitment to educating stakeholders, sharing individuals' experience on VYKAT XR therapy and robust payer access. Soleno field teams are dedicated to ensuring comprehensive educational support on therapeutic expectations, appropriate dosing and comprehensive monitoring, all critical factors for successfully integrating VYKAT XR into clinical practice and optimizing patient outcomes. It is worth noting that many prescribers and academic centers are still in the process of setting up their designated PWS clinics. As a reminder, VYKAT XR is indicated to treat hyperphagia in adults and children 4 years of age and older with Prader-Willi syndrome. And hyperphagia is defined as extreme hunger, constant thoughts about food and constant urge to eat that cannot be satisfied with food. Throughout the last several months, we have been

hearing from families, who are seeing meaningful benefit after completing titration and finding their optimal dose. While all experiences with VYKAT XR are unique, these experiences continue to reinforce the possibilities and real-world impact of VYKAT XR. And through our responsibility to comprehensive education, we always encourage people to review the full prescribing information and medication guide for important safety information, which can be found on vykatxr.com. Our commitment to patient services and market access underpins these efforts, ensuring timely access and reimbursement across all payer channels. I will now share the results of our key performance indicators, patient start forms, unique prescribers and number of covered lives. Cumulative patient start forms from launch through September 30th totaled 1,043, of which 397 were in the third quarter. We previously commented that obtaining 646 patient start forms in our first quarter of launch was outstanding and included a bolus. We recognize the rapid uptake was due to strong operational excellence, a large unmet need and pent-up demand that carried into the early part of Q3. By the end of Q3, 764 individuals were actively treated with VYKAT XR. We believe that as more and more success stories are shared with the community, they will help create a firm foundation for continued growth. The second performance indicator is the number of prescribers. We are continuing to make great strides with expanding our prescriber base. In Q3, we added an additional 199 new prescribers, bringing total unique prescribers as of September 30th to 494. Third quarter performance highlights significant progress within our key accounts. Over 50% of our top 300 providers have submitted start forms, signaling strong adoption. Importantly, a significant share of start forms originated from health care providers, who are associated with our KOL network. This is underscoring the effectiveness of our ability to educate physicians who play a pivotal role in influencing practice patterns. We are also seeing strong adoption among community treaters, highlighting our expanded reach and continued growth beyond our core targets. We have further strengthened our messaging this quarter by spotlighting real patient experiences, launching a new campaign, Make Space for what matters, that highlights VYKAT XR, as a treatment that has the potential to lessen the relentless burden of hyperphagia, creating mental space for individuals living with PWS to focus on what truly matters to them. Our third performance indicator is payer policies. We have been working diligently to secure broad coverage for VYKAT XR, resulting in policies that cover approximately 132 million lives at the end of the third quarter, including coverage policies with appropriate criteria from the top 3 national PBMs. We have achieved broad access coverage across all channels, commercial, Medicaid and Medicare, with a strong uptick in state Medicaid coverage, where we had received reimbursed claims from approximately 40 state Medicaid programs through Q3. As I stated during our last earnings call, these positive coverage decisions demonstrate payers recognizing the seriousness of PWS -- that payers recognize the seriousness of PWS, understand the true unmet need in treating hyperphagia and appreciate the meaningful value VYKAT XR can deliver. This is great progress this early in launch because one of the perceived barriers to adoption among prescribers is the lack of coverage or the lengthy reimbursement path. As we move forward, we continue to invest in stakeholder awareness, education and access resources to ensure every individual being treated with VYKAT XR, their family and clinician feel supported throughout the treatment journey. I will now turn the call over to Jim for a review of the company's financial statements for the third quarter.

James MacKaness: Thank you, Meredith. Total net revenue for the third quarter ended September 30, 2025, was $66.0 million, which was more than doubled from $32.7 million in the second quarter of 2025, and we achieved profitability with a positive net income of $26.0 million for the quarter. In addition, we generated $43.5 million of cash from operating activities during the 3 months ended September 30th. At the end of the third quarter, we had $556.1 million of cash, cash equivalents and marketable securities. This includes the $230 million of gross proceeds that we raised through an underwritten offering of our common stock in July. Our strong balance sheet ensures that we are sufficiently capitalized to continue to execute on an effective U.S. launch of VYKAT XR , while in parallel progressing towards regulatory approval and commercialization, either on a stand-alone basis or with partners in the EU and other geographies. As a reminder, VYKAT XR was approved in March of this year, and therefore, the company generated no revenue in the third quarter ended September 30, 2024. Cost of goods sold was $1.1 million for the third quarter. Please note that prior to the FDA approval, costs associated with manufacturing VYKAT XR were expensed as research and

development expenses. As such, a portion of the cost of goods sold during the period included inventory at 0 cost. Going forward, as we continue to sell VYKAT XR, we will deplete our 0 cost inventory and replenish it with [ad] cost inventory. And consequently, cost of goods sold as a percentage of revenue will increase. Research and development expense for the third quarter was $8.4 million, which includes $2.2 million of noncash stock-based compensation compared to $30.1 million, which includes $18.5 million of noncash stock-based compensation for the same period of 2024. The cadence of our research and development expenditures fluctuates depending upon the state of our clinical programs, timing of manufacturing and other projects as we move through submission, approval and now commercialization. Selling, general and administrative expense for the third quarter ended September 30, 2025, was $33.8 million, which includes $7.8 million of noncash stock-based compensation compared to $49.2 million, which includes $38.1 million of noncash stock-based compensation for the same period of 2024. The increase in expense after removing stock-based compensation reflects our ongoing investment in additional personnel and new programs to support VYKAT XR commercial launch and in support of our increased business activities. Total other income net was $3.9 million for the 3 months ended September 30, 2025, compared to total other income net of $3.6 million in the same period of 2024. Net income was approximately $26.0 million or $0.49 per basic and $0.47 per diluted share for the third quarter ended September 30, 2025, compared to a net loss of $76.6 million or $1.83 per basic and diluted share for the same period in 2024. This concludes the financial overview, and I'll now turn the call back over to Anish for closing remarks. Anish?

Anish Bhatnagar: Thank you, Jim. In closing, we're very pleased with the trajectory we're on, and we will continue to work tirelessly to make this safe and effective therapy available to as many people living with PWS-related hyperphagia as possible. We had an outstanding Q3 marked by noteworthy advancements in each of our key metrics from start forms to new prescribers to lives covered all resulting in the doubling of our revenues from Q2 and leading to the company being cash flow positive. We look forward to continuing to deliver on the successful launch we have seen to date. And with that, we'll now open the call for questions.

Operator: [Operator Instructions] Our first question comes from the line of Paul Choi from Goldman Sachs.

Kyuwon Choi: Congrats on the good performance in the quarter with regard to the sales. My first question for the team is, can you maybe comment on the restart rate with regard to the discontinuations you're seeing? Any color from the field in terms of how many patients are restarting and sort of the time to restart there would be helpful. And then second, in terms of the number of patients on active drug that you disclosed with the press release, can you maybe comment on just how many of those are still waiting for insurance clearance versus the patient start forms? Any color there helping us connect the dots would be great.

Anish Bhatnagar: Sure. Thanks, Paul. So on the restarts, this is early. So we're just starting to see it now. There's a handful of people who have already started, and we've anecdotally heard of others who are planning to start. So this is not a metric we can give meaningful numbers on, but it's early. Your second question around number of patients on active drug. Meredith, do you want to answer that?

Meredith Manning: Yes. So I think, Paul, what you're looking at is active versus -- or paid versus free, and that's still a number that we're not reaching steady state and evolving. So all of the 764 have claims that are being reimbursed. Is that exactly what you're asking for?

Kyuwon Choi: Maybe just some clarity, any color you can offer on the lag time between the start forms and the patients actually getting coverage, that would be helpful, too, just so we can sort of triangulate maybe how many patients might be backfilled in the quarter to come.

Meredith Manning: Understood.

Anish Bhatnagar: Yes. Jim, go ahead.

James MacKaness: Yes. So we've been working closely with the specialty pharmacy on this. So you get your start forms and then obviously, there's a discontinuation cancellation that we've spoken to. And then we're seeing the fill rate somewhere around 30 days. It's plus or minus, obviously, depending on where the patient comes from and the amount of time to get through the benefits. But probably we're carrying about 1 month in backlog, if you like, of start forms.

Operator: Our next question is from Tyler Van Buren from TD Cowen.

Tyler Van Buren: Congratulations on another strong quarter of sales and achieving profitability. Curious to hear you elaborate on the impact on discontinuations and lower patient start forms due to the short report during the quarter? And I guess how you're confident that it had an impact? And then is this impact going away as we enter Q4? What can you tell us about the early launch momentum observed into Q4 here and into year-end?
Anish Bhatnagar: Yes. Thanks, Tyler. So what we can tell you is that as we look at the quarter, we saw, I would say, a decrease in the August, September time frame. Now realize there's complexity of summer as well as the short report around the same time. So with the slower August, September, we're also seeing no meaningful changes into October. So we think that there is an effect, and we unfortunately think that this is on patients who've had the nonserious adverse events, probably the people who would have benefited tremendously had they stayed on therapy. So as Meredith has mentioned, as I also talked to, we're making a lot of efforts in reaching out to these people. We're having individuals who are on drug, talking to other patients, who are on drug. Yesterday, we had a webinar with about 80-plus families on that, listening to a patient who's been on VYKAT and their experiences. So we think that it's hard to say exactly when the effect would go away, but it's certainly something that we're making serious efforts on.
Tyler Van Buren: And when you say no meaningful impact in October, are you saying that October looks similar to August and September or that there's no meaningful impact from the report and you're seeing some whatever a rebound in October?
Anish Bhatnagar: I'm saying it's looking somewhat similar to what we saw in September.
Operator: Our next question is from Moritz Reiterer from Guggenheim.
Moritz Reiterer: This is Moritz on for Debjit. Congrats on a strong quarter. I have 2 questions. First of all, could you elaborate a little bit on the average dose across all patients that are currently on drug? And secondly, for your existing prescribers, could you estimate what percent of their PWS patients are currently on VYKAT? What I'm trying to get at, is there still room to grow within those existing prescribers? Or does future growth need to come from new prescribers?
Anish Bhatnagar: Yes. I'll take the second part of it, and Meredith can elaborate on it. There's definitely room to grow. We have about 1,000 start forms right now. That's about 10% of the TAM. So I'd say across the board, there is room to grow. And that's particularly the case with our KOL accounts, where Meredith mentioned that more than half of them have written scripts. But as we had anticipated, their practices are pretty full, and they are -- they appear to be prescribing more when they see patients in their regular cadence of 1x to 2x a year. So we expect that to remain, and we expect that over time, we'll be getting access to those patients. But Meredith, go ahead.
Meredith Manning: Yes. Adding on to what Anish said, we're very pleased with the broad prescriber base, and we continue to add new prescribers on a daily basis. So we know that there is a significant amount of room for growth, and as Anish stated on the numbers with regard to the TAM. You had asked about the average dosing. So again, that's still an evolving number. One thing that we shared last earnings call, which we'll continue to reiterate is that the majority of our patient population is coming in between 4 and 26 age. And we are continuing to make progress in the younger adults, so the 27 to 45, if you will. And we are seeing the average weight coming in a little bit heavier than what we saw in our clinical trial.
Operator: Our next question is from Kristen Kluska from Cantor.
Rick Miller: This is Rick Miller on for Kristen. So you mentioned the discontinuations being up after some of the nonserious AEs after the short report. Can you give us a sense for kind of the kind of the profile of the AEs that were kind of leading to these discontinuations? Is this strictly sort of the on-label safety profile that we're used to or anything else you could talk about there?
Anish Bhatnagar: Sure. So yes, these are on-label AEs, typically low levels of peripheral edema or you can have hyperglycemia. And when I was referring to nonserious adverse events, as you can look at fares and you can see that a vast majority of events that are reported are nonserious. So I think what's happened is a concern that's been created because of the adverse event profile of the drug, which if nonserious, most patients are able to sort of power through and will start to see the benefits. And we're seeing that in real life. We've had numerous anecdotes of people who have stayed with low levels of

edema, some levels of hyperglycemia and have done really well from an efficacy perspective. So yes, the adverse events remain sort of on-label and what we are seeing is predominantly nonserious.
Operator: Our next question is from Yasmeen Rahimi from Piper Sandler.
Yasmeen Rahimi: Congrats on a strong quarter. I guess, team, when you look at -- given that August and September was impacted by the short report, like what -- is this -- is the hesitation among patients that are under the care of general endocrinology? Is there a quantification on who are the type of patients or the type of physicians that need additional outreach and communication, like what does that profile look like where you guys are targeting to really have in-depth education for? That's sort of question one. And then question two is like how do you -- obviously, I think to Tyler's question, you noted that October is looking like more like September. How will you continue to communicate when we're going to -- when are we going to be out of this, I guess, fear or worried by this report? Like any visibility like that the rest of the quarter could be very much rebounding substantially? And what would your disclosures be around it?
Anish Bhatnagar: So we don't expect to do sort of intra-quarter disclosures. And as you can imagine, Yasmeen, you know that there's a lot of complexity in treating hyperphagia and PWS. We're the first drug, and we're learning what the market is like and the prescribers are learning how to use the drug. So we realized that last quarter was perhaps a short report, perhaps it was summer, -- perhaps it was people going to a summer camp. And now this quarter, we're going to have Thanksgiving and Christmas, which obviously have meaning for everyone, but for PWS and those with hyperphagia, it has a very different meaning. So we have to navigate this. We have to see what it looks like, and we have to see how prescribers also get accustomed to it. As we said earlier, there are some hospitals, institutions that are trying to create PWS clinics to sort of figure out how to best administer VYKAT XR and sort of make sure that they can follow these patients. Meredith, would you like to add something?
Meredith Manning: Yes. I think -- Yasmeen, we're really pleased about the program that actually we launched in August, more of your traditional speakers bureau program, and we've had really strong adoption with that. So we have recruited some of the national PWS experts to be speakers in the program, which allows for both virtual and in-person as well as an opportunity to do expert on demand, and we've seen really strong interest in that. And you asked about the profile of the prescribers who are being educated. I think what you're leaning towards and you're correct in thinking that as we're adding these new prescribers on a daily basis, who are out in the community who potentially have only 1 or 2 PWS patients, those are the ones who really need additional education on the disease state in general as well as how to integrate VYKAT XR into their practice. So we've received, as Anish said in his prepared comments, really positive feedback on these programs. And additionally, we're continuing to educate caregivers and families. So we've had live patient programs, and we'll continue to do that in Q4 as well as webinars, all received very well.
Operator: Our next question is from Leland Gershell from Oppenheimer.
Leland Gershell: We just wanted to maybe understand with respect to the treating physician population of patients who are on VYKAT XR, you're having close to 500 unique prescribers at the end of Q3. But in your investor materials, you said that about 300 providers are primarily treaters of about 2,100 PWS patients. So just going back to something we've talked about in the past, is it the case that we should think about these reports of adverse events as more likely to occur amongst patients, who are being cared for by those who are less specialized in Prader-Willi treatment and therefore, maybe less astute at managing some of the side effects. Wondering if you could share your insights there.
Anish Bhatnagar: Yes. Thanks, Leland. I think it's fair to say that just a reminder, the adverse event profile, and if you look at edema as an example of fluid retention-related events, in our clinical trials was about 20-some percent. what we are seeing now, at least the reported events are actually lower than that. So it's actually a pretty small minority that has these events. And most of the events that are happening are low-grade events. So these are most often things that may not even need treatment. So what you're really probably concerned about is significant adverse events or serious adverse events. And those we do worry that physicians who are out there who don't have experience in using VYKAT XR and have one patient on it and choose a patient who had significant comorbidities, et cetera, and how would they manage the side effects. So we do -- we are concerned about that, and that's something, as Meredith mentioned, we have a significant effort in trying to mitigate. So we have our

field teams, our MSLs, who go out, have conversations with these physicians about how to manage these things better. And we have physician-to-physician programs, where there's an expert on-demand thing where you can call a physician who has significant experience and that's actually been used very successfully recently.

Leland Gershell: Great. And I just want to ask, is the time to securing reimbursement, has that changed from the past? Has that improved, increased? Or is it about the same in terms of going from start form to pull-through?

Anish Bhatnagar: Meredith?

Meredith Manning: Yes. So Leland, I think on our last earnings call, we mentioned that we were looking at a turnaround time targeting for 30 days. That's still our target. That's still optimal. But as you know, during the first year of launch, it can vary depending on the channel, but that's exactly what we're targeting is the 30 days.

Operator: Our next question is from Brian Skorney from Baird.

Brian Skorney: I just wanted to try to get a little more clarification on your comments on the disruption that occurred over the summer and how it's specifically manifesting in the numbers. Was there both a slowdown in start forms that you're saying and an increase in discontinuations and implying that you would otherwise have more than 400 start forms and/or lower than 8% discontinuation due to AEs otherwise? Or is there another figure in terms of missed refills that isn't specifically being called out on a quantification measure?

Anish Bhatnagar: So thanks, Brian. I think where I was trying to go with this is that we saw a decrease in August, September. And a, we realized it's also summer. So we think it was some combination of summer, people in camps as well as the short report that caused the start forms to decrease. Now we obviously cannot pinpoint that such and so didn't come in because of they read something or whatever. But I do think that, that could -- that was likely a factor. We don't have any specific metrics on refills, et cetera. But what we are thinking through is if you have patients, who have nonserious adverse events, who discontinue and anecdotally call into the specialty pharmacy and say, I read something that I didn't like and I'm concerned and I'm not going to continue on drug. That's what we are basing the idea on that perhaps it's these anecdotal things that are out there and misleading that are leading to discontinuation that wouldn't have occurred.

Operator: Our next question is from James Condulis from Stifel.

James Condulis: I wanted to ask one on efficacy. Obviously, it takes some time to see it, but we're now approaching 6 months kind of plus or so. And just curious what your early kind of learnings are there, what you've heard, how you kind of think that's playing into current discontinuation rates and what that may do to discontinuation rates over time as kind of patients stay on drug for longer? Any color there would be appreciated.

Anish Bhatnagar: So James, thank you for asking about efficacy. We are starting to hear anecdotes across the board on good things that are happening to these patients. There's tons of examples. We got a call the other day about a child who went without food for 9 hours. We talked to a mom about a child, who sat in temple at the Memorial service for several hours calmly without any tantrums. We heard from an adult who lives in a group home who will, after years, be able to travel alone to see their family in Florida alone. So it is starting to happen. We are seeing things happen across the board. And we think it will make a difference to these discontinuation rates. And as I was mentioning, we have started a series of patient webinars, where those who are on drug and their families are able to share their experiences with others. And the first one of those literally had 100-plus people who signed up for it. So there is a lot of interest, and this is exactly the sort of thing that will turn things around.

Operator: Our next question is from Derek Archila from Wells Fargo.

Derek Archila: Congrats on the progress. I guess, first, I guess, obviously, you're saying what you're seeing in October is kind of resembling September trends. I guess is the bolus over? Or do we think that it resumes as people get more comfortable or the messaging gets better, education gets better? So that's question number one. And then just quickly on the EU. I know you mentioned about the 120-day questions. I don't know if you can kind of characterize some of those requests, but do they improve your confidence of an eventual approval in Europe?

Anish Bhatnagar: Sure. So in terms of the bolus, we -- this is one of those situations, where when you

have the first drug for an indication, it's hard to tell what it's supposed to look like. So we're finding out as we go. But if you remember some of the conversations we had prior to launch, we said we don't know if there will be a bolus, but what we are expecting to see is a slow, steady buildup over time with a TAM of 10,000 patients, there is a lot of them out there, and it takes time for physicians to get accustomed to using a drug for an indication that has not really had a treatment before. So it's hard for us to comment on does a bolus come back or not. I think by definition, a bolus does not come back. And we're looking for a steady state that will continue over time and we'll continue to build a solid base of revenue that we have. On the EU, I can't really give you any more details on the questions, but I will say that they feel very much similar to the discussions that we had with the FDA, mostly around efficacy, the design of the studies, the sequential nature of the studies, the fact that the same patients have been used through the multiple studies, et cetera. But I would say that as we get these responses and as we get responses to these responses from the EU, we'll have a better sense of where it's going.
Operator: Our next question is from Yale Jen from Laidlaw.
Yale Jen: Congrats on a very great quarter. And basically I have 2 here. The first one is sort of related to the efficacy that you guys have talked -- in the press release, you even indicated you have 100 patients have more than 1 year treatment and many of those have multiple years of treatment. I just wonder whether you'll be able to do some studies of them to see over such a longer period of treatment, are those patients has been improved and how much those improve? Maybe this will be used for longer-term historical analysis. Then I have a follow-up.
Anish Bhatnagar: Yes. I mean, we have, as you know, been running a long-term open-label study, then there was a randomized withdrawal, then the patients went back on drug. So we've had the ability to follow these patients very carefully for a very long period of time. And as you know, it's very unusual in a rare disease to have such long-term data. And we have seen improvements of many different kinds in these patients, and this is obviously anecdotal and doesn't apply to everyone. But only yesterday, we were looking at -- we were talking to a patient who is running a triathlon or preparing for a triathlon. This is a person who's in college. We are aware of a person who's a sous-chef. We're aware of numerous people who have graduated from high school. So the long-term effects will vary by patient, but we think that taking away the hyperphagia, which is the hallmark symptom of the disease, will, over a period of time, really alter their lives.
Yale Jen: Maybe one more question here, which is about the patient size that you already have over 1,000 starting from you suggested maybe 10,000 patients, give and take. And at this stage, do you feel that you need to have additional effort to finding more patients, new patients? Or how would you prescribe -- describe your effort on that regard?
Anish Bhatnagar: Meredith?
Meredith Manning: Yes. So I think as we've said previously in our earnings call that we have a claims database, where we're confidently able to identify approximately 12,000 claims in individuals, who have PWS. And that -- when we look at that information, that brings our TAM down to around 10,000. So we know where the patients are and where they're being treated. I think one thing that we're very excited about that we're working on is more around machine learning to identify specifically when these patients might be coming into the physician's office to really optimize our effective targeting for the sales team. But with regard to traditional rare disease patient finding, we have the claims, so we know where they're being treated.
Operator: Our next question is from Katherine Dellorusso from LifeSci.
Katherine Dellorusso: Congrats on the strong quarter. So I was just curious if you have a sense of the proportion of patients, who are able to reach or be maintained on their on-label dose versus those who undergo dose reduction? And I guess, apologies if I missed this, but for those who discontinue treatment, do you have a sense of how long they're on therapy before they're coming off and kind of expectations for that going forward?
Anish Bhatnagar: Yes, I can address the second part of it. So we see the discontinuations happening earlier in treatment. So they're either in titration or just after. So think of it as sort of the first 3 months. By the way, of the active patients, we think about 2/3 are beyond the 3-month time frame at this time. Do you want to address the first question, Meredith?
Meredith Manning: Yes. I think it's a little more complicated than that with regard to reducing dose

because if you look at our label, really the therapeutic window, if you will, is between, I think, like 3 to 5 mg per kg. So any dosing around there is considered on-label dosing.
Anish Bhatnagar: So I think if you are looking at on-target dose for a given weight band, then I think it's fair to say that there's a very small minority that undergo dose reductions. In general, you would expect people to get to their target doses.
Operator: [Operator Instructions] Our next question is from Ram Selvaraju from H.C. Wainwright.
Jade Montgomery: This is Jade on for Ram. Congrats on the profitability this quarter. That actually leads me to my first question. Do you have some sort of idea when you might be in a position to start providing annualized revenue guidance? And secondly, as I'm sure you know, Rhythm is pursuing an expansion into PWS [first] setmelanotide. Do you think of that purely as a competitor drug? Or do you think there's a possibility for synergism between the 2 drugs there?
Anish Bhatnagar: I'll answer the second part. Jim can take the first part. In terms of Rhythm's drug, we still have to see efficacy. As you know, the one study that's been conducted with the drug in PWS, which was a large, randomized Phase II study was negative for weight loss and hyperphagia. I believe they are conducting an open-label study. So we'll have to see what the data shows. In terms of whether it's competitive or potentially synergistic, it can be potentially synergistic because the 2 mechanisms are different from each other. So on the competition piece, we'll have to see the data and certainly, at least theoretically potentially synergistic.
James MacKaness: Yes. And with regards to guidance, I'd say it's a bit early at this stage. We're obviously looking for a little bit of maturation in the various components of the business, but we'll continue to investigate that.
Operator: There are no questions at this time. I would like to hand the call back to Anish. Please go ahead.
Anish Bhatnagar: Thank you all for listening in today. Have a good evening.
Operator: This concludes today's conference call. Thank you for participating. You may now disconnect.