KALV Earnings Call Transcript

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Quarter: 3

Operator: Good day, and thank you for standing by. Welcome to KalVista Pharmaceuticals' 2025 Third Quarter Financial Update and Operating Results Conference Call. [Operator Instructions] Please note that today's conference is being recorded. I will now hand the conference over to your first speaker, Ryan Baker, Head of Investor Relations. Please go ahead.

Ryan Baker: Thank you, operator. Good morning, everyone, and thank you for joining us to discuss KalVista Pharmaceuticals' 2025 Third Quarter Financial Update and Operating Results. Please note, we'll be making certain forward-looking statements today. We refer you to KalVista'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 from KalVista are Ben Palleiko, Chief Executive Officer; Nicole Sweeny, Chief Commercial Officer; Brian Piekos, Chief Financial Officer; and Dr. Paul Audhya, our Chief Medical Officer. Ben will begin with a review of the company's progress during the 3 months ended September 30, including an overview of EKTERLY's early launch, both in the U.S. and abroad as well as other regulatory updates. Paul will give an update on recently presented data from our KONFIDENT-KID trial in HAE for children ages 2 to 11, as well as new patient satisfaction data. Nicole will review the company's commercial progress to date, and Brian will cover the company's financial statements for the most recent quarter. We will then open the call for questions. With that, I will now turn the call over to Ben.

Benjamin Palleiko: Thank you, Ryan, and thank you, everyone, for joining us today. And I want to wish a Happy Veterans Day to all my fellow veterans listening in. We are highly encouraged by EKTERLY's first 3 months on the U.S. market. Adoption has been steady and linear, with real-world utilization tracking as we expected. The takeaways are clear. Demand for EKTERLY is strong. It is being used to treat a significant number of HAE attacks, and it is meeting the expectations of people living with HAE for a highly efficacious and safe therapeutic alternative. We continue to believe that EKTERLY will evolve to become the foundational treatment for HAE. In addition, we are executing on our mission to bring EKTERLY to people living with HAE globally. The German launch is now underway with initial uptake validating the ex-U.S. interest in EKTERLY. The approval footprint continues to grow, with a recent approval in Australia, adding to the existing authorizations in the U.S., U.K., EU and Switzerland. In parallel, we continue to evaluate optimal strategies to expand access in geographies where we won't launch on our own. In addition to the collaborations we've previously announced, we anticipate that we will be completing more agreements later this year and in early 2026. We also continue to generate important new data to help educate the HAE community generally, as well as to demonstrate the real-world benefit of EKTERLY to people living with HAE. Last week, during the American College of Allergy, Asthma and Immunology Meeting, we provided a report on the high satisfaction rates for patients in KONFIDENT-S who had switched to sebetralstat from injectable on-demand therapies. Additionally, interim results from our KONFIDENT-KID trial showed sebetralstat enables early, effective and safe treatment of HAE attacks in children ages 2 to 11. Paul will provide more detail on all of that in a minute. We've also continued to grow the key capabilities of the company, demonstrated by the recent hires of Bilal Arif as our Chief Operating Officer; and Linea Aspesi as Chief People Officer. Both bring decades of experience that will make them important contributors as we work to evolve KalVista into a leading rare disease company. Finally, with our recent convertible note offering, we are fully

financed through profitability, allowing us to remain sharply focused on executing the EKTERLY launch while evaluating additional growth opportunities. I will now turn the call over to Paul, who will update you on the latest data from KONFIDENT-S and KONFIDENT-KID.

Paul Audhya: Thanks, Ben. I'm pleased to highlight that we continue to generate and publish important insights from our ongoing clinical trials, further building the case for EKTERLY across various patient segments. Starting with our late-breaker ACAAI, we provided a significant update on our registrational KONFIDENT-KID trial for sebetralstat in children with HAE aged 2 to 11. With 36 children enrolled, this is the largest trial ever conducted in the pediatric HAE population, and we are incredibly proud to have fully recruited it almost a year ahead of schedule. This speaks to the high level of unmet need for these children and their caregivers. A remarkable finding from the interim analysis is the extent to which this group of children is experiencing attacks. As of June 6, 2025, 65 attacks were treated by 26 children, translating to an attack rate of 0.8 attacks per patient per month. This far exceeds the historical understanding of attack frequency in this population. We believe that the high-attack rate in KONFIDENT-KID reflects an accurate unmasking of the true disease burden that was previously hidden by the difficulties associated with administering and receiving injectable treatments. The invasive and burdensome nature of intravenous and subcutaneous on-demand treatment creates a powerful disincentive for children and their parents to seek treatment for anything but the most severe attacks. We believe that this has led to significant underreporting of attacks. The availability of an oral on-demand treatment fundamentally lowers the barrier to treatment. This allows for a high-attack rate to be documented because children and their caregivers are no longer faced with the choice of enduring the trauma of an injection versus riding out a potentially worsening attack. Returning to the results. Treatment was rapid, with caregivers or the children themselves administering sebetralstat ODT in a median of 30 minutes. This option where children can actually treat themselves is a totally unique feature of KONFIDENT-KID and increases the importance of the results as the inability to self-treat attacks by children is such a major issue with injectables. The median time to symptom relief was a rapid 1.5 hours in the dosing group who experienced the vast majority of attacks. Crucially, there were no treatment-related adverse events or reports of difficulty swallowing the orally disintegrating tablets formulated for kids. These results further highlight EKTERLY's potential to expand to people of all ages living with HAE. We expect to submit the NDA for pediatrics in Q3 of 2026. Turning now to our long-term open-label extension, KONFIDENT-S. We continue to amass a large volume of data collected under conditions that mimic real-world utilization. For October 31, the trial has accumulated over 2,700 attacks treated with EKTERLY. Notably, this includes 59 laryngeal attacks, 560 attacks in patients receiving long-term prophylaxis and 584 attacks treated by adolescents. The highest number of attacks treated by an individual participant is 118 over 23 months. As our patient experience has grown, we have observed key changes in dosing behavior. We focus on patients who reached 30 treated attacks, representing about 1/4 of confidence participants. We noted a clear trend. The proportion of patients using a second dose of EKTERLY within 12 hours fell from 22.5% during the first attack to just 13.5% by the 30th attack. In the same group, the use of conventional injectable therapy dropped from 8% at the beginning of the trial to 0% by attack 30. We believe these marked reductions in the use of a second dose or conventional therapy reflect patients' growing assurance in EKTERLY's reliability. We plan to present this important data in more detail at an upcoming scientific congress. Coming back to ACAAI, we presented new treatment satisfaction data from KONFIDENT-S in participants who had switched from injectable on-demand treatments to sebetralstat. The median satisfaction score for attacks treated with sebetralstat was 2, or very satisfied on a 7-point scale, ranging from minus 3, which was extremely dissatisfied to 3, which was extremely satisfied. Overall, 84% of attacks treated with sebetralstat were rated by participants as ranging from satisfied to extremely satisfied, with the vast majority being either very or extremely satisfied. The high-satisfaction scores reported by patients who have successfully transitioned from injectable therapies to sebetralstat speak to the impact of having a simple, effective and reliable oral on-demand treatment readily available. So what are the implications? We know that a patient's decision to switch medication is often a direct measure of their unmet need or dissatisfaction with their current regimen. Therefore, as patients achieve a high level of satisfaction with EKTERLY, the probability of them seeking to switch therapies in the future is expected to decrease. This supports EKTERLY's role as a foundational

therapy for HAE for the long term. To conclude, the breadth and depth of our clinical data, coupled with a high level of patient satisfaction is translating into early commercial momentum. We're seeing strong uptake and growing confidence among the prescribers as awareness of EKTERLY continues to build. To discuss how the launch is unfolding, I'll now pass the call to Nicole.

Nicole Sweeny: Thanks, Paul. I'm pleased to share that the U.S. launch of EKTERLY continues to accelerate with sustained demand and growing enthusiasm among prescribers and patients. In less than 4 months since launch, we have received 937 start forms, representing more than 10% of the HAE community. This level of early engagement is strong by any launch standard and reflects an extraordinary level of community adoption. Importantly, this demand is broad-based. We are seeing rapid uptake across all HAE patient segments, including prophylaxis users as well as adolescents. People are switching from all on-demand therapies, but the greatest number have been from FIRAZYR and icatibant as expected, given their market share. Also, as we expected, the earliest and greatest number of those switching to EKTERLY have been high-burden patients who experienced frequent attacks, whether or not they are on prophylactic therapy. Provider activation is also expanding rapidly. We have 423 unique prescribers and continue to add 3 to 4 new prescribers each day. Awareness levels are exceptionally high with 100% of Tier 1 HCPs and 95% of all-target HCPs reporting awareness of EKTERLY. These metrics reflects both the strength of our field execution and the enthusiasm of the medical community for EKTERLY. As prescribers gain more experience with EKTERLY and hear from their patients who have switched, their confidence continues to rise. Launch to date, repeat prescribers account for 75% of all EKTERLY start forms, a strong indicator of familiarity and trust in EKTERLY's profile. This provider enthusiasm is matched by a strong depth of utilization in patients. Though the data is early, patients that are refilling their prescriptions, including those on QuickStart and paid therapy, are doing so every 3 to 4 weeks. For context, most injectable on-demand therapies average only 3 to 4 refills per year. This level of refill frequency is a clear indicator of growing real-world reliance and confidence in EKTERLY. Note that the majority of these refills are driven by patients with a high disease burden. They report experiencing 2 to 4 attacks per month, despite generally also being on prophylaxis therapy, which indicates the lack of adequate disease control. Refill quantities are consistent with this level of burden and higher than our initial expectations. That all said, as adoption expands beyond to the highest burden patients, we expect refill patterns to normalize in line with the broader HAE community with both a lower frequency of refills and a lower volume of refill quantities. As demand continues to build, payers are actively moving towards formal coverage for EKTERLY. Since approval, patients have been able to leverage medical exception to gain access to EKTERLY. The medical exception approval rate and time to ped shipment are consistent with our expectations less than 6 months following approval. It is very encouraging that we have seen medical exceptions approved by all PBMs, and all large payers for both commercial and Medicare cases. We continue to advance formal access with multiple regional and national payers already establishing EKTERLY policies. The majority of policies are ped label, which is consistent with other branded on-demand therapies. As expected, the minority of policies require a step through icatibant, which patients are able to move through quickly as most HAE patients have experienced with generic icatibant. Our market access team is currently engaged with PBMs and remaining national payers, with an aim to formalize access in early 2026. At this point in the launch, we are encouraged to see access to EKTERLY growing as payers recognize the need for EKTERLY as part of an overall HAE treatment plan. Outside the United States, we are seeing early signs of momentum as we expand the reach of EKTERLY. Following EMA approval, we launched in Germany in mid-October and recorded first-day commercial sales, an immediate validation of both prescriber enthusiasm and the strength of EKTERLY's differentiated oral on-demand profile. In the U.K., with approval now received, we are advancing pricing and reimbursement discussions with NICE in preparation for a first half 2026 launch. And in Japan, we continue to progress towards a PMDA approval and launch in the first quarter of 2026 with our partner, Kaken Pharmaceutical. Taken together, accelerating utilization, repeat prescribing and growing favorable access provide a clear signal. EKTERLY is quickly on its way to becoming the foundational therapy for HAE treatment. What initially began with the highest burden patients is now expanding in only a few short months across the broader HAE population as physicians gain confidence and patients increasingly choose EKTERLY for their attacks. I'll now turn the call over to

Brian to review our financial performance.
Brian Piekos: Thanks, Nicole. Our full financial results were included in the 10-Q filed after the close yesterday. So, I'll provide a few highlights for the 3-month period ending September 30. We are pleased to announce sales of EKTERLY were $13.7 million for the launch period through September 30, which includes the $1.4 million recorded in July and previously reported. Subsequent to the July period, our specialty pharmacy partners stocked additional locations and built inventory in a disciplined manner, supporting the growing patient demand. In the initial 3-month launch period, we are seeing the average number of cartons per shipment on the high end of our expected range, which aligns with utilization among high-burden patients, the core of our early adopter base. When looking at gross to net, I'd note it came in towards the low end of our expected range this quarter, driven largely by lower co-pay utilization typical for this time of year. Shifting to expenses. Total operating expenses for the period were $59.7 million, consisting of approximately $12 million in R&D; expenses and approximately $46.5 million in SG&A; expenses. Looking ahead to the remainder of 2025, we expect SG&A; expenses to remain relatively consistent as we continue to invest in EKTERLY's global launch. Importantly, with our recent convertible note financing, our cash position is sufficient to fund operations through profitability. With that, I'll turn the call back to Ben for closing remarks.
Benjamin Palleiko: Thanks, Brian. The early momentum and rapid growth we described today reinforce our belief that EKTERLY is positioned for long-term success as market awareness continues to grow. Our near-term focus is on aggressive and disciplined execution, scaling in the U.S., expanding access globally and reinforcing confidence in the role of EKTERLY across the treatment landscape. We continue to believe that oral on-demand therapy should broadly displace the injectable options and that EKTERLY will be the clear market leader based upon the breadth and depth of the data we have generated that shows EKTERLY can benefit all people living with HAE regardless of their attack location, frequency or severity. We are and will remain the only company that has demonstrated in a clinical trial setting, the effectiveness of our therapy for treatment of HAE attacks in accordance with modern treatment guidelines that call for patients to consider treating all attacks and to treat early. Through our gold standard design clinical trials and our many publications of the data, we've established a strong position as a patient-focused organization that is dedicated to improving lives, and I expect our reputation will continue to strengthen based upon our early success and our most recent data updates. With strong execution, a clear strategic runway and fully funded path through profitability, we believe we are well on our way to establishing EKTERLY as a foundational therapy for HAE and to generating long-term growth for the company. With that, we'll open the call for questions. Operator?[Operator Instructions] Our first question coming from the line of Maury Raycroft with Jefferies.
Maurice Raycroft: Congrats on the great quarter. Maybe to start off, wondering if you could talk more about trends for types of patients who are switching to EKTERLY early on, particularly the high-burden patients? Are you putting percentages on how the 937 start forms break down? And how could these trends change over time?
Benjamin Palleiko: Maury, thanks for joining today, and thanks for the question. Nice to talk to you. I guess I'll start and maybe Nicole will add some other details. What was really important here when we launched EKTERLY was we always presumed that the most rapid adopters would be the people living with HAE who have a very high treatment burden. And we've talked about this for a long time, and I think there's been substantial questions in some quarters about whether that patient population exists and also how severe their attack rates are. What we found through the third quarter was that that actually those people do exist and they are transitioning just as we would have expected. Roughly half of all the patients who have switched to EKTERLY to date self-report an attack rate of 2 or more attacks per month, which we consider to be high burden. And that accounts for, obviously, a fair amount of prescriptions, but also those people refill at higher rates and in larger quantities as well. So clearly, the discovery we've made here is that, that group really does exist that they actually aren't well controlled on prophylaxis and that their needs are being met by EKTERLY. In the longer run, obviously, we expect that number to decline, right? That's a fairly small portion of the population. And as we broaden out EKTERLY's reach, all those items will go down, the refill rates will decline and the number of cartons per refill will also go down. But for now, that group seems to be getting a lot of benefit from EKTERLY

just like we anticipated.
Nicole Sweeny: Yes. And just to add some further color on the patient base. As Ben was describing, these are patients with a high burden of disease who are also on prophylaxis and continue to have unmanaged HAE. In terms of the product that they've been switching from, we see broad adoption or broad switching across all of the on-demand therapies. The vast majority of patients are switching from Berinert to icatibant, which is very much in line with our expectations as in advance of approval, we often heard about the shortcomings of a subcu injectable. But again, very exciting and encouraging to see just the broad adoption across all of the different on-demand treatments.
Maurice Raycroft: Got it. Helpful perspective there. And then maybe one follow-up. Just for the 937 new starts, are you seeing more on what proportion is converting to drug? And are you breaking down paid versus free drug at this time?
Nicole Sweeny: Yes. So from an access standpoint, we are very encouraged by the continued increase in paid. Week-to-week, we see the paid rate continue to grow. And we've seen successful use of the medical exception, both in terms of consistency over time, as well as I should add more recently as the EKTERLY policies have started to come into play, we're seeing clarity in terms of path forward for patients to gain access to EKTERLY. So overall, at this point in time, certainly, our paid and the access dynamics are unfolding as we'd expect.
Benjamin Palleiko: And Maury, for perfect clarity because I don't know if this is where we're going, all those start forms reflect prescriptions. Those are people who are actually switching to EKTERLY. A start form is inherently tied to a prescription for that person to switch.
Operator: Our next question coming from the line of Stacy Ku with TD Cowen.
Stacy Ku: Congrats on a great quarter. So the first is just a follow-up. Are you willing to talk a little bit more about these refill rates or maybe disclose on average number of doses for these high-burden patients? And maybe help us compare that to where you would expect things to normalize, especially given your work with claims data? And of course, as it relates to payer willingness to treat these high-burden patients, maybe talk about the quantity limits that you're seeing for chronic use of EKTERLY? So that's the first question. And then the second question is just maybe as we look to the commentary, you're kind of trying to highlight for us around those patient bolus dynamics that you're seeing. Just help us understand what that means for the remainder of the year versus what we've seen in Q3? And of course, I'm putting you a little bit on the spot here. As we look to next year, again, still really early days, we totally understand that. But just your level of comfort around consensus as we think about the 937 patient start forms that you've already grabbed in '25?
Benjamin Palleiko: Thanks, Stacy, for all the questions. We'll work our way around the room here to answer them. So on the first one, you asked about refill rates. Our presumption going into this when you look at claims data is that the average person with HAE is refilling about once every 3 to 4 months. And that will normally be with FIRAZYR or icatibant is typically sold in pack of 3s. So, that will typically be at least 3 doses and maybe multiple packs because actually, I think the average rate of refill is higher than that. What we've seen to date, driven again by this high-burden population has been refill frequencies of probably kind of 1/3 that off frequent, maybe once a month or even more frequently than that. So, these people are very high or have, in some cases, very high-attack rates and so they're refilling quite frequently. And they are, when they refill, typically refilling with multiple cartons at a time. So it's many more doses than we would expect on average. As I said in the last answer, that's because of the subpopulation that has come to EKTERLY early. As we go over time, certainly, we'd expect those rates to normalize more towards what you see in the icatibant type marketplace where you've got refills that are multiple months apart and probably, on average, volumes will be lower. In terms of quantity limits, actually, you don't you take it from here, Nicole?
Nicole Sweeny: Sure. I'm glad to step in. Quantity limits are certainly the norm for the current branded on-demand treatment. And it is something that we're seeing and expected to see with EKTERLY. Having said that, to date, the quantity limits that we're facing with EKTERLY, again, very consistent with the other products and have not created impediment to a patient continuing to gain access to EKTERLY. And historically, there are means to overcome quantity limits should we end up in that situation on a patient basis. Also, just to transition to your question regarding demand for the remainder of the year, certainly, we recognize going into the holiday season, there are time out of office for

physicians and for staff as well as just a very busy time for all of us. So, we do anticipate potential disruption to demand in the remainder of 2025.
Benjamin Palleiko: And then do you want to talk to some of the financials?
Brian Piekos: Yes. On consensus, Stacy, what we see, there's quite a range in the consensus. I think over a three-fold gap, we understand the challenges of modeling this new prescription that is an on-demand therapy. It is challenging. It's far more complicated as we change our fiscal year now to a calendar year basis, and I'm not sure all the estimates have caught up to that. And so I think that dispersion in estimates is warranted as we kind of really figure out what utilization will look like over the long term.
Stacy Ku: Yes. Understood. And then just to confirm, a carton is 2 doses, correct?
Benjamin Palleiko: Yes.
Operator: Our next question coming from the line of Paul Matteis with Stifel.
Matthew Ryan Tan: This is Matthew on for Paul. Congrats on all the progress. I guess I just wanted to better understand with the multiple cartons per shipment, do you think there's any stockpiling behavior within the patients just given how convenient it is to have this oral and the storage is easier? And I guess, how do you see that evolving in the future?
Benjamin Palleiko: Actually, we don't know. Actually, we don't know. We got put on mute by accident for a second there. People don't have to tell us what's happening. Given that the self-reported attack rate among these folks is quite high, we do think there's obviously a high level of utilization there. But I don't know that we could allocate between how much they're storing it up like as they probably should really to have in places where they can access it when they have attacks versus actually using it. Again, stepping back a little bit, whether it's because of initial -- some kind of initial stockpile, although again, these refill rates have been pretty consistent or usage. Like I said, as we expand further into the population, we do expect the overall attack rates to normalize more towards what you see in the population as a whole. That means that, again, usage will probably be less on average. Refills will be less frequent on average, and the volumes per refill will come down to some extent. But even people that don't really have high attack rates, when they do refill, seem to be refilling at higher levels than we expected, that's probably maybe more indicative of stockpile than I think the really high-attack rate folks. I don't know if you have anything to add?
Nicole Sweeny: Yes. Just a reminder that the treatment guidelines do -- that physicians have developed both in the U.S. and around the world do encourage that patients keep product on hand to treat multiple attacks, 2 to 3 attacks. And so that is something that is fairly common in terms of practice here with patients in the U.S.
Operator: Our next question coming from the line of Joe Schwartz with Leerink Partners.
Joseph Schwartz: It's great to see that according to our math, the rate of PSF has stayed fairly constant through your first couple of updates so far. Do you expect this relatively linear PSF growth rate to continue? At what point, either months into the launch or overall penetration-wise, do you expect PSF growth to taper off? And then ex-U.S., it was great to see the German launch is underway. What is the price you agreed upon in Germany, and how does that compare to the U.S.?
Benjamin Palleiko: Yes. Thanks for the questions. So the PSF rates have been quite consistent as we've indicated through the first, now 4 months of the launch. As Nicole said a few minutes ago, we do -- the fourth quarter here, especially the November, December as we get to the holidays is definitely a time when we wouldn't be surprised if the numbers slow a bit, right? I mean, people just are not going to be going to their physicians for this type of thing over the holidays. So, we would expect that there will be some slowing in the fourth quarter, really just driven by the kind of seasonality of the thing. As we get into 2026, again, we think the fundamentals on demand are really good, right? People seem to be still getting these appointments at a quite a consistent clip. Inexorably, over time, the rate of start forms will slow down to some extent just as we get deeper into the patient population. But at this point, we really don't have enough information to give an indication of whether that's earlier or later in 2026. But the clip we are on now, while we're quite happy with it, certainly, we wouldn't really expect it to be this fast paced all 2026. So, that's the first part.
Nicole Sweeny: Certainly, German price, that's something that is not disclosed at this time. We're early in the days of launch there, and we'll be in ongoing negotiations and discussions with German

authorities. So, that's something certainly we could revisit in the new year.
Joseph Schwartz: Okay. What about other European countries in '26? What are the plans there?
Nicole Sweeny: Certainly. We certainly have approval in the U.K., and so that is something we're in active discussions with NICE and planning for a launch in the first half of 2026 as well as moving out to some of the other larger countries in Europe towards the end of 2026.
Operator: Our next question coming from the line of Jon Wolleben with Citizens Bank.
Jonathan Wolleben: Congrats on the progress. When you guys talk about kind of normalization of these rates, wondering if you could talk a little bit about your expectations for how many patients do you expect to ultimately be trialing EKTERLY because the high burden makes sense now, but do you think that this is going to be broad across people with low burden as well? Or is it going to be a majority of these high-burden patients over time? And then in the prepared remarks, you mentioned that gross net towards the low end of your expected range. I was hoping you could just remind us of what that expected range is.
Benjamin Palleiko: Sure. I'll do the first part. Again, Jon, we do fundamentally expect oral therapies to displace the injectables. I think we've fairly conclusively shown that EKTERLY offers all the benefits of the existing HAE therapies with much better equivalent efficacy in all likelihood, right? We haven't -- it has been shown head-to-head, but I think people generally accept that the safety has been pristine so far. There's really no advantage to anyone using -- continue to use an injectable or an IV therapy. So on a fundamental level, we do expect orals to overtake the injectables over time. And so there's a sort of high level how the market evolves in our viewpoint. That does -- to your point about whether the rate slows as you move into lower usage people, that's certainly likely. There's definitely just like there's a very high burden population, we presume a commensurate very low burden population that may be less inclined to move over time. To date, we have seen people across the board switching to EKTERLY. I mean, again, we said -- we've seen certainly the high population be through the third quarter, half of those folks. But the other half are much more of a distribution of attack rates. So the urgency may not be as high as we move deeper into the market, but we do think the fundamentals are that people will switch over time. I mean, a lot -- there's certainly a lot of folks who we believe are still a little bit and see how it's working for someone they know before they switch. Some of these folks will have tried ORLADEYO before and maybe not have a satisfactory response. And so we do anticipate there could be a little bit of initial caution about another oral therapy. But again, given the anecdotal reports we've seen so far and just the commentary we've heard from physicians who've talked to their patients, we think people are exceedingly satisfied right now. And we do believe that, that will play through over time, and that will bring these people who may be less motivated for whatever reason, right, initially to move, to switch over to EKTERLY in a timely fashion. I don't know if you want to add anything on that.
Nicole Sweeny: Yes, I would just offer that building upon Ben's point, anecdotal feedback as well as market research we've conducted with patients, we see very high satisfaction ratings, both with patients who have a high burden of disease as well as patients with a more moderate or lower burden of disease. And that satisfaction relates specifically to EKTERLY as well as with our patient support services that received high marks in terms of supporting patients to gain access.
Brian Piekos: And with respect to gross to net, Jon, like other specialty medicines, we expect to see gross to net to be on average, upper teens, low-20s.
Operator: Our next question coming from the line of Serge Belanger with Needham & Company.
Serge Belanger: Congrats on the quarter. First question, I wanted to go back to your initial focus on high-burden patients. Is that just a function of the market or the docs that you -- prescribers that you have initially targeted? And are they using these higher burden patients as leveraging them to get experience with the product and familiarity? Secondly, when prescribers are writing patient start forms or prescriptions, are these PRNs or are they limiting them to a certain number of boxes or cartons?
Nicole Sweeny: Sure. So in terms of the high-burden patients, these are the patients that spend most of their time in with their physician. So, these are individuals that are typically on prophylaxis and have HAE that is largely uncontrolled. And so given the high need that they have, they're very much on the physician's radar. Having said that, these are also the patients who are most informed. So in advance of approval, they're actively seeking new treatments. And with the approval of EKTERLY, we know that

they made appointments and went into their physicians' offices to discuss. So, I will say that it's a bit of the patient demand due to the burden of the disease as well as certainly significant awareness on the physician side that they need to support those patients. And yes, I think to some extent, your point, it enables them to test EKTERLY in some of the most difficult cases to really validate that what the profile we saw in the clinical trials really playing out in the real world, which we know has increased confidence of physicians as we see the majority of start forms that are coming from repeat prescribers. Just in terms of how they write the prescription, typically, a prescription is written for PRN, so that, that allows the flexibility for the patients to gain access to refills at the frequency and the magnitude of which they need. That's historically how it's been done with the other on-demand treatments and what we see with EKTERLY today.

Serge Belanger: Okay. Great. One quick one for Brian, just on inventory. Out of the $13.7 million that was reported this quarter, how much of that was inventory? And did you exit the quarter at steady state on that front?

Brian Piekos: Yes. We're seeing, obviously, with the first 2 months of launch, inventory build coming in by the specialty pharmacies, particularly as they add additional locations as the launch gained momentum. We think our specialty pharmacy partners are performing in a disciplined manner with a view of growth. It's not steady state. It's going to continue building in front of expected demand.

Operator: Our next question coming from the line of Debanjana Chatterjee with JonesTrading.

Debanjana Chatterjee: Congrats on the quarter. So, can you talk a little bit more about how your insurance negotiations are progressing and how we should think about the cadence of payers coming online in the first half of next year?

Nicole Sweeny: Sure. Absolutely. Leading into launch, we anticipated that it would take roughly 6 months to both drive demand and for payers to assess EKTERLY and establish policies. What we're seeing at this point in time is that, yes, we are leveraging medical exception on a consistent basis to gain access, but we're also seeing some of the regional and national payers create policies for EKTERLY that are largely favorable. Looking towards the end of this year and into the early part of next year, we are planning to, I would say, wrap up discussions with some of the larger payers and PBMs with an aim to have policies in place again, early in 2026.

Debanjana Chatterjee: Sure. And a quick follow-up. So, you've also mentioned that in the early quarters, revenues can be a bit bumpy as refill rates stabilize. So, can you talk about how we should think about revenue trajectory in the immediate like next couple of quarters?

Brian Piekos: I mean, it's a hard question as we just talked about. We continue to expect initial fills to come through. We've talked about that as adoption expands, the burden of disease on patients will, on average, go down. That will impact both initial fill amounts as well as refill rates. This is an on-demand therapy. We're going through a holiday period. It's really hard to understand exactly kind of the nature of the revenue to kind of comment on what trajectory should look like.

Operator: And there are no further questions in the queue at this time. Ladies and gentlemen, this concludes today's conference call. Thank you for participating, and you may now disconnect.