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# Skye Bioscience, Inc.

## Second Quarter 2025 Earnings

# Skye Bioscience, Inc.

**Second Quarter 2025 Financial Results & Update Call Transcript**

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## CORPORATE SPEAKERS:

## SKYE TEAM:

**Bernie Hertel**
*Head of Investor Relations*
**Punit Dhillon**
*President, Chief Executive Officer*
**Kaitlyn Arsenault**
*Chief Financial Officer*
**Puneet Arora**
*Chief Medical Officer*
**Tu Diep**
*Chief Operating Officer*

## PARTICIPANTS:

**Ted Tenthoff**
*Piper Sandler; Analyst*
**Matthew Hershenhorn**
*Oppenheimer; Analyst*
**Jonathan Wolleben**
*Citizens; Analyst*
**Unidentified Participant**
*Cantor Fitzgerald; Analyst*
**Albert Lowe**
*Craig-Hallum; Analyst*

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# Skye Bioscience, Inc.

## Second Quarter 2025 Financial Results & Update Call Transcript

## PRESENTATION:

Operator^ Ladies and gentlemen, thank you for standing by. (Operator Instructions)

At this time I would like to welcome everyone to the Skye Bioscience Second Quarter 2025 Financial Results and Business Update Call. (Operator Instructions)

I would now like to turn the conference over to Bernie Hertel, Head of Investor Relations.

Please go ahead.

Bernie Hertel^ Hello. And thank you all for participating in today's call.

Before we begin, I'd like to caution that comments made during this conference call will contain forward-looking statements under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995 including statements about Skye's expectations regarding its development activities, timelines and milestones.

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and adversely. And reported results should not be considered as an indication of future performance.

These forward-looking statements speak only as of today's date. And the company undertakes no obligation to revise or update any statements made today.

I encourage you to review all the company's filings with the Securities and Exchange Commission concerning these and other matters.

I'll now turn the call over to Punit Dhillon, Skye's President and CEO.

Punit Dhillon^ Good afternoon, everyone.

Today we have most of our executive team participating in our financial results and operations update through prepared comments, or they're available to address questions during the Q&A.

As we often say, we've managed the course with discipline, and we're now approaching the point where preparation becomes proof. This quarter marks a notable prelude to our reporting of our Phase IIa data for nimacimab, Skye's differentiated peripheral CB1 inhibitor in terms of

execution as well as the clarity arising from the convergence of key activities including the progress of our Phase IIa study, understanding of the mechanism of nimacimab, and planning for next steps relating to our clinical development thesis.

On today's call we'll walk through the progress we've made, the data that we've generated and the path we're charting forward.

We'll cover three key areas: one, clinical progress, where we stand on our Phase IIa program and the top line timing; two, R&D foundation, how we believe our antibody approach to CB1 inhibition is mechanistically distinct and supported by reproducible preclinical data; and three, where nimacimab fits, positioning our asset within the evolving obesity treatment landscape including gaps we believe are overlooked and not readily fulfillable with other mechanisms.

Let's begin with the clinical progress. The Phase IIa CBeyond is advancing as planned, on budget and ahead of schedule. Enrollment was completed in February, ahead of schedule and the 26-week visit for the last patient is projected to occur very shortly. The 26-week extension study is also now underway with both the monotherapy and combination arms enrolling.

Approximately, 50% of the patients from the original study are eligible for enrollment, and we're optimistic that a majority of the eligible patients will choose to participate in the extension study. The Data Safety Monitoring Committee has now reviewed the study four times and issued no recommendations for changes. This has been an effectively managed program from timeline management and data capture on various endpoints to regulatory coordination from the initial IND to the recent protocol updates to facilitate the 26-week extension.

We look forward to completing treatment of our final enrolled patient for this first segment of CBeyond and then stepping into the data analysis.

We remain on track to deliver top line results by late Q3, early Q4.

Next, let's discuss R&D.

As a reminder, nimacimab is a fully humanized, peripherally restricted CB1 antibody designed to target a well-established metabolic pathway, but to do so without the central toxicity that has historically limited CB1 inhibitors.

We differentiate from non-antibody CB1 inhibitors in two fundamental ways: one, from a distribution standpoint; and two, mechanism, both advantages that support a broader therapeutic window and target engagement in the periphery.

Let's focus in on peripheral restriction. Nimacimab shows negligible brain penetration across many different species.

It's confirmed through PET imaging, cerebral spinal fluid analysis and postmortem tissue assessments. Even at high and repeated doses, the molecule remains peripherally compartmentalized. Next, let's talk about mechanism, allosteric noncompetitive inhibition. Nimacimab binds at the allosteric site of CB1, retaining potency even in the presence of elevated endocannabinoids, which is commonly associated with the obese state. This is in contrast to small molecules that bind to the orthosteric site of the CB1 receptor, which may face increasing competition to bind to the receptor and can lose efficacy in the presence of high concentration of endocannabinoids.

We've evaluated this molecule through multiple preclinical studies using our human CB1 knock-in DIO mouse model. Based on these DIO mouse studies, we believe there are at least four distinct yet converging mechanisms that define nimacimab's action and form our platform's scientific core.

One, caloric restriction via peripheral hormonal coordination. Nimacimab reduces food intake by acting on adipose and gastrointestinal tissues to modulate appetite regulating hormones such as GLP-1, leptin and resistin. This enables a peripherally-mediated reduction in central appetite signaling without requiring brain exposure.

Two, improvement and restoration of glycemic control.

We see consistent improvements in fasting glucose and insulin with significant improvements in glucose tolerance in DIO models, supporting nimacimab's relevance for patients with prediabetes or insulin resistance. Three, enhancement of lipid metabolism. Nimacimab reduces steatosis and circulating cholesterol levels, a direct benefit for patients with obesity-linked metabolic comorbidities like NAFLD or dyslipidemia. Four, reduction of obesity-induced inflammation.

Nimacimab reduces the level of key serum inflammatory mediators and macrophage infiltration in liver and adipose tissue, pointing to a disease-modifying role of nimacimab related to comorbidities of obesity. These effects seen in our DIO models are robust, reproducible and mechanistically distinct from, though complementary to, incretin-based agents. That gives us potential optionality across monotherapy, combination and maintenance strategies.

Okay.

Let's dive into that last point and touch on the new preclinical data that was shared today.

To test how nimacimab could perform in real-world settings, we recently conducted a preclinical DIO study asking three key questions: one, can nimacimab enhance the efficacy of a suboptimal dose of tirzepatide? This is highlighted by the yellow part of the study schematic. Two, does nimacimab offer a more durable weight loss profile post treatment? This is highlighted by comparing the yellow to the blue part of the study schematic. And three, can nimacimab act as a maintenance or rescue therapy after incretin discontinuation?

This is comparing the yellow to the pink color as a clear control. Here's what we found.

First, the combination efficacy. The preclinical DIO study findings demonstrated that at day 25, the combination of nimacimab and a suboptimal tirzepatide dose of three nanomoles per kilogram daily yielded 44% vehicle-adjusted weight loss. The combination outperformed either agent alone with nimacimab demonstrating 21.5% vehicle-adjusted weight loss and tirzepatide demonstrating 29.7% vehicle-adjusted weight loss.

The combination efficacy also exceeded an optimal dose of tirzepatide of 10 nanomoles per kilogram daily, which resulted in 38.9% vehicle-adjusted weight loss. This highlights a meaningful opportunity to develop combination strategies that achieve greater efficacy at lower doses, potentially improving tolerability, reducing cost, and expanding treatment accessibility.

Now point number two, nimacimab demonstrated durable posttreatment weight loss compared to incretin therapy after the therapy stopped.

In comparison of nimacimab and tirzepatide following cessation of treatment in the preclinical DIO mouse model, nimacimab demonstrated superior durability of weight loss.

Specifically, the low-dose tirzepatide group regained most of their original weight back eight days after coming off therapy, regaining 29.7% of weight by day 24 post treatment.

In comparison, the nimacimab treated group maintained their post-treatment weight for approximately 20 days, regaining only 7.4% by day 24. This "rebound effect" has been well documented in animal models and clinical data and represents a major issue for patients who come off incretin-based therapies. Nimacimab's durability after cessation of therapy represents a potentially clinically beneficial and distinct outcome relative to incretin-based therapies.

Let's move to the third point and now add back nimacimab. Here, we're looking at maintenance of weight loss using nimacimab alone post incretin treatment.

When nimacimab alone was used after an initial tirzepatide or combination treatment in the preclinical DIO mouse model, it greatly reduced rebound weight gain in these bottom three groups of mice, the suboptimal TRZ and nima combo in purple, the optimal TRZ dose in red, and the one we're going to zoom into is the suboptimal TRZ following nimacimab, which is in pink. The key takeaway, no matter which of these line graphs you're looking at, is that the data show nimacimab reinforcing its potential role as a post-incretin weight loss maintenance therapy.

And specifically, when nimacimab was added following treatment with low-dose tirzepatide, the pink line, nimacimab reduced rebound weight gain from 29.7% to 12.8%. Taken together, these data suggest nimacimab has utility across a broad continuum of care, not just initiating weight loss, but also sustaining it. This continues to strengthen our thesis and bring us to the real-world setting and answering where nimacimab fits and understanding the real-world therapeutic gap.

Again, we're not trying to displace GLP-1s.

We believe they are foundational and they're backbone, but they also have well-recognized limitations. 58% of patients discontinue before 12 weeks, 80% by year 2, up to 40% of weight loss can come from lean mass, and GI side effects remain a major driver of treatment discontinuation and patient dissatisfaction.

This ultimately creates a significant therapeutic gap and one that nimacimab is designed to address. There's three market opportunities: one, as a monotherapy for patients who can't tolerate or don't respond to incretin therapeutics; two, as a combination partner to amplify efficacy or reduce incretin dose burden; and three, as a maintenance therapy to sustain weight loss after a desired weight is achieved with better tolerability.

As developers are racing to optimize potency, dosing and formulation, the field is now bumping up against a real-world ceiling, tolerability. And despite their clinical efficacy, incretin-based drugs are facing significant discontinuation rates, up to 50% within the first year and nausea is the most frequently cited reason.

As illustrated here, many of the late-stage programs cluster in the high nausea, high dropout zone, trading gastrointestinal burden for marginal weight loss gains. This has created a therapeutic paradox. There are actually stronger agents, but they have a weaker persistence.

We believe that this is not just a side effect problem.

We believe it's a structural vulnerability in the current obesity treatment paradigm, and it's leaving a growing population of patients without sustainable options. That's where nimacimab comes in. Rather than replicate what's already been done, nimacimab is designed to potentially expand the therapeutic options in obesity treatment, not only as a well-tolerated and effective monotherapy, but as a differentiated and essential combination where the current incretin saturated market does not provide such options.

Its mechanism offers alignment to GLP-1s, unlocking the combination potential without compounding the GI burden.

This positions nimacimab to potentially meet the needs of patients who discontinue using the drug due to side effects, who fail to sustain weight loss or who require multi-pathway intervention for broader metabolic impact.

For us at Skye, the opportunity is clear. Nimacimab is not just an alternative.

We believe it's a next-generation backbone candidate for durable, combinable and more accessible obesity care, and it's a platform that can potentially extend beyond monotherapy to life cycle expansion across lines of therapy and patient segments that are currently underserved by

today's options. And this is a key area to zoom in on, and we've been working on how best to frame it within the broader obesity treatment landscape.

We believe we're entering the fourth wave of obesity pharmacotherapy, a new phase that's driven by scientific innovation still, but needs to address real-world complexity in patient care. The FDA has now approved six drugs for long-term obesity treatment, each marking a step forward in the standard-of-care, from short-term stimulants to safer agents like Orlistat to the rise of GLP-1-based therapies such as semaglutide and tirzepatide, which have brought us closer to disease resolution, but a new chapter is unfolding.

Today's obesity market is evolving beyond the singular goal of caloric restriction. The next generation of anti-obesity medications such as the peripheral approach is being shaped by the need for broader metabolic impact, targeting pathways related to insulin sensitivity, lipid regulation, inflammation, and central reward signaling. This reflects a shift from weight loss alone to true disease modification, sustainable weight loss, and even addressing the other related comorbidities.

With the top line data ahead, we're preparing to potentially demonstrate how nimacimab delivers on the core needs of the evolving obesity treatment paradigm that, in our opinion, fit the definition of the fourth wave by improving quality and durability of weight loss through alternative metabolic pathways, better tolerability, and strategic combinability. Thank you, again, for listening to our update, and I'll wrap by emphasizing that the next 90 days will be busy, and Kate's going to walk you through a few of our upcoming milestones in her remarks.

Overall, for us, finishing Q2 and heading into Q3 isn't just a checkpoint.

It's a culmination of disciplined execution, scientific clarity and focused investment in a differentiated mechanism.

We appreciate your continued support, and now I'll turn the call to Kate, our CFO.

Kaitlyn Arsenault^  Thanks, Punit. After the market closed today, we issued a press release and filed Skye's Form 10-Q with the Securities and Exchange Commission, outlining our quarterly financial results.

We encourage you to reference our filings for the details of our financials and the risk factors described therein.

I will now provide a brief overview of key financial results for the second quarter ended June 30, 2025.

We ended the second quarter with cash and cash equivalents and short-term investments totaling $48.6 million.

Our cash flow guidance remains intact, with the expectation that our current capital is projected to fund operations and key clinical milestones through at least Q1 2027. This includes the completion of our Phase IIa study for nimacimab and certain Phase IIb manufacturing and preparatory clinical activities including the initial manufacturing runs needed to start the Phase IIb dose-ranging study and clinical feasibility activities.

In addition, our runway also includes a modest discovery research and development budget and the formulation and development work expected to support later-stage studies for nimacimab. Research and development expenses for the three months ended June 30, 2025, were $14.3 million as compared to $4.1 million for the same period in 2024. The increase was primarily due to contract manufacturing, clinical trial costs associated with our clinical study for nimacimab, discovery, research, and development expenses and salaries and stock-based compensation expense.

General and administrative expenses for the three months ended June 30, 2025, were $3.9 million as compared to $4.3 million for the same period in 2024. The decrease was primarily related to decreases in general business expenses and legal and professional fees, offset by increases in salaries and stock-based compensation expenses, consulting and advisory fees, along with investor relation costs.

Our net loss for the three months ended June 30, 2025, totaled $17.6 million including noncash share-based compensation expense of $4.2 million. This compared to $7.9 million for the same period in 2024 with noncash share-based compensation expense of $4.3 million.

In Q2, we maintained our track record of execution, hitting clinical milestones while managing capital with precision.

We continued to build internal cadence and operational rigor including the strategic expansion of our team to 20 employees.

We made key hires in regulatory affairs, quality, clinical operations and CMC. Notably, we welcomed a Vice President of CMC to directly support our advancing development activities. This deliberate scaling is intended to allow us to minimize downtime between clinical trials and stay positioned to move quickly following upcoming data readouts.

As we enter the second half of 2025, we remain focused on disciplined execution and are well positioned to advance nimacimab through its next development phase.

We are entering what is arguably the most crucial execution period in Skye's history. To outline what you can expect in the coming months: on September 4, we will host a KOL event at NASDAQ, which will be webcast live focused on the mechanism, CBeyond Phase IIa clinical data expectations and market positioning.

In addition, in the fall, we are participating in multiple investor conferences where we look forward to engaging directly with many of you.

Finally, ahead of our top line data, we are presenting the Phase I SAD/MAD NAFLD data at EASD on September 19, reinforcing hepatic and metabolic benefits.

In late Q3, early Q4, we expect our top line clinical readout from CBeyond.

As we have previously stated, this will be data from both the monotherapy and combo arms with placebo-adjusted weight loss, safety, body composition and mechanistic biomarkers.

With the top line data in hand in Q4, we expect to finalize the Phase IIb protocol, further advance CMC, initiate regulatory engagement and external planning for next phase studies. This concludes our prepared comments for today. Thank you very much for joining us, and we'll now open the call for questions from our covering sell-side analysts Operator, over to you.

## QUESTION & ANSWER:

Operator^ (Operator Instructions) Your first question comes from the line of Ted Tenthoff of Piper Sandler.

Ted Tenthoff^ Getting excited for data.

I had just a little bit of a housekeeping question, but with a specific angle on it.

So R&D was higher.

I saw that you've made some progress on the manufacturing lines. Did that account for a big part of it?

And in the press release you mentioned this Arecor, A-R-E-C-O-R, and a potentially higher concentration nimacimab formulation.

Can you tell us a little bit about what the goal is from that and when you may be able to use that higher concentration nimacimab?

Punit Dhillon^ Ted, thanks for joining the call.

I'll take the first -- this is Punit here.

I'll take the first -- or I'll let Kate take the financial questions relating to R&D.

I can jump in and just explain the Arecor relationship.

So at the moment, we have a concentration of 200 mgs per two ml or 100 mg per ml is our current concentration, and that's what we're using in the clinic.

Our goal here from a target product profile is to increase that concentration to allow for a longer dosing period or less frequent dosing. And ideally, it would mean even considering 200 mg per ml.

So we're basically looking to increase our concentration to go higher than 100 mg per ml and Arecor is supporting that effort. And just so we are clear about that, that's a separate kind of R&D track.

It doesn't interfere with our clinical development strategy.

So as you know our clinical development strategy and CMC efforts continue on track to support the advancement of nimacimab.

But as we consider additional life cycle management, that's where we are looking for ways that we can improve concentration. Kate, do you want to answer the financial piece?

Ted Tenthoff^ Kate is probably on mute. And the question really is just with the step-up in R&D to $14 million in the second quarter, was that largely due to this manufacturing line or more clinical trial expense?

Kaitlyn Arsenault^ Yes. Sure.

So there was approximately $9.1 million that we spent during the six months ended on contract manufacturing costs, and that related primarily to the Phase IIa resupply for the extension study and the supply for the Phase IIb trial as well.

Operator^ Your next question comes from the line of Jay Olson of Oppenheimer.

Matthew Hershenhorn^ This is Matt on for Jay. Congrats on all the progress.

So as we near CBeyond data, just curious, I guess, what you're thinking for nimacimab's weight loss efficacy potential at week 26.

Should we expect to see something around 8% or if it's slightly below that, would the range of around 5% to 8% be potentially compelling? And then I guess, additionally, beyond weight loss and obviously safety, what other key metrics will you be paying attention to?

And what biomarkers do you believe could be informative as well? Really appreciate it.

Punit Dhillon^ Matt, thanks for joining and taking the call on behalf of Jay. Yes. So we are looking at Phase II, the CBeyond trial, the Phase IIa really as a proof of mechanism study.

It was originally designed to detect an 8% placebo-adjusted difference in weight loss with 80% power over 26 weeks.

So our goal here is to demonstrate a really clear clinically meaningful weight loss separation from placebo. And as you alluded to, we believe that if we're seeing 5% to 8% range placebo adjusted, that's really a strong signal of biological activity of nimacimab.

Importantly, the study was not powered really to detect a smaller difference with any statistical significance.

So that's an intentional component because otherwise we would have required a way larger study.

So the objective here is to validate the mechanism, establish a really strong safety and tolerability profile, and really proceed to a definitive dose-ranging study to identify the optimal dose and then the ultimate regimen for nimacimab in a Phase III setting. And our goal here is to deliver obviously consistent weight loss, improve GI tolerability profile.

I think we alluded to that today in terms of where there's a lot of white space in the market, and that's where we feel we have really the upper hand.

And obviously a clear safety signal without any neuropsychiatric side effects.

So all of those three parameters, we would consider CBeyond a success, and it really puts a strong foundation to move forward with Phase IIb for us.

Matthew Hershenhorn^ Okay. Got it. That makes sense to me. Really appreciate it. And just a quick follow-up.

If you have any expectations on the potential discontinuation rate within 26 weeks and also how, based on your expectations, you believe that could translate into an advantage versus GLP-1s in the real-world setting? And also just to clarify, as you previously said you expect about 50% of patients from the original study to be eligible for the extension study.

If you could just walk us through your thinking there, that would be great.

Punit Dhillon^ Yes.

So Dr. Arora, you can take the 50% approximate on the extension study.

Let me walk you through the other pieces of your question.

So in terms of discontinuation, we're expecting the similar trends we're seeing in most obesity studies.

Now keep in mind, in the last two years, I think overall across all obesity studies, we've seen probably about 25% to 30% discontinuation. And I don't think that's a factor of always the drugs.

It's also a factor of a very competitive landscape and the accessibility of just commercial drugs and access to new modalities. And a lot of patients are looking for that access.

So we haven't seen any unusual trend in terms of discontinuation in our study and definitely not seeing anything related to safety.

But in terms of the real-world situation, as I alluded to in the presentation, there's a really large opportunity here where we're seeing 50% of patients not continuing incretin therapy after a year, right? And that's where this maintenance data really showcases. And here, we can essentially capture those patients and continue on with drug and allowing patients to have that long-term sustainable weight loss.

So I think there's a really clear market opportunity there where nimacimab's not really competing for that initial weight loss that incretins do, but it's designed to really lock in those losses that once the incretin therapies do their work, then we can see that there's an application there in a really large market. And obviously there's still an opportunity there in the monotherapy setting, too, because there's patients that don't respond.

I hope I answered those two questions.

I'll turn it over to Dr. Arora to just talk about extension study and those expectations.

Puneet Arora^  Yes.

So thank you. The extension study enrollment has started.

I think I'll just start with the good news.

We've been enrolling for the last month or so patients in the combination arms, and we are also now enrolling patients in monotherapy.

Just between the logistics of starting the extension and allowing patients to roll in.

As you know we didn't initially plan for an extension, but we've been able to execute on it. Between that and the natural early terminations that you get in an obesity study, we still believe that about approximately 50% of our original patient target will be eligible to roll over into extension. And it's just started.

So I can't give you any precise numbers.

But just based on the enthusiasm at the sites and from what we hear, we are very optimistic that a majority of these patients are going to roll over because we see a lot of interest in it.

Operator^ Your next question comes from the line of Jon Wolleben of Citizens.

Jonathan Wolleben^ Punit, you laid out a nice optionality between maintenance, monotherapy combo. How do you think about what we'll see in CBeyond and how that might guide development and the different utility in those three different modalities for nimacimab?

Punit Dhillon^ Yes.

So it's a great question. Thanks, Jon.

Look, I think there's a significant opportunity for a broader maintenance franchise really taking place, and that's probably really underappreciated in the market because, let's face it, we're dealing with a very rapidly moving market. And just this week, we've seen some highlights from other obesity drug developers and everyone is adjusting to what -- where does everything shake out.

I think that there's a clear opportunity for nimacimab in all three settings.

In the monotherapy, we've quoted about 10% to 15% of patients, based on our primary research, that don't respond to GLP-1 therapy.

So there's a pretty large capture rate of those patients.

In the maintenance setting, we've pointed to some really important stats there, about 50% discontinuing after one year, 80% discontinuing after two years.

So there's really a clear need for a drug that can capture that patient population with minimal GI side effects, and we're not expecting to add on to any of the tolerability concerns that we're seeing with incretins.

And then the third opportunity is in terms of combination, I think that's really going to come down to evidence-based data.

So far, this data that we pointed to today really is another important development because now we've shown with a suboptimal dose of tirzepatide in combination with nimacimab that we actually get a deeper weight loss.

So apply that to the real world, then we expect that a patient may be able to take a more tolerable dose of an incretin therapy, and we can make up that delta in terms of weight loss with another

modality. And it really points to a separation of the different biology here and pathway that CB1 is acting on versus GLP-1. Tu has been doing a lot of the market access research.

So I want to give him a few minutes here to just maybe elaborate on anything I've said.

Tu Diep^ Yes. No. I think -- thanks, Punit.

I think you've hit all the highlights.

I think what's important is when we speak to KOLs, they make it pretty clear that they are very excited at the prospects of new modalities that are beyond just incretins.

I think they want the option to be able to provide their patients with additional mechanisms of action that may be more tolerable, may provide different benefit and may provide different options for patients that may not need to lose significant amounts of weight, but may need to manage other areas of their health.

So these are important things that I think the market needs to understand and is beginning to understand that weight loss as a bottom line number is no longer going to be the most important endpoint as these new drugs, new therapies, in particular, these non-incretin drugs new data is coming to the fore and that these other complementary mechanisms and other endpoints are going to be important.

Punit Dhillon^ Yes. And just to add to that, looking at the orforglipron data today, there's still a clear opportunity here that orals are not necessarily going to save the day in a maintenance setting. They don't necessarily add any more substantial weight loss.

But here, we've now pointed to a completely different biology, a peripheral mechanism may be enhancing that weight loss.

So I think from a competitive positioning snapshot perspective, there's clearly room from an efficacy standpoint.

We'll see what that data looks like in the clinical setting now. There's a maintenance franchise, which we're starting to, I think, understand better. And there's a really clear safety moat, right, with the peripheral exclusion on the neuropsychiatric side, as well as the tolerability profile to date.

So those three things, I think, really stand out from a competitive positioning perspective.

Jonathan Wolleben^ That's really helpful color, guys. Appreciate it. And looking forward to the event in September.

Operator^ Your next question comes from the line of Kristen Kluska of Cantor Fitzgerald.

Unidentified Participant^  Hi, this is [Ayan] on Kristin's line. Congrats on the progress here.

First, regarding the independent board that oversees the trial for safety, could you just remind us what the protocol is here? What types of adverse events would they report? And then second, I know you touched on this already, but I just wanted to get some clarification around the enrollment eligibility in the extension study and how about 50% of the patients from the original study made the cut.

Punit Dhillon^  Sure. Thanks for joining today. And I'm going to let Dr. Arora, Chief Medical Officer, take both of those questions.

Puneet Arora^  Yes. Thank you, [Ayan].

As far as the DMC is concerned, on a routine basis, they meet quarterly, and we actually provide them all of the data -- safety data of the study.

So we give them the complete listing of all adverse events, all serious adverse events, and any AESIs that are reported. And they also have complete information on all of those patients, any narratives, all the labs.

So actually, they have a complete store of unblinded information with which they work when they review the data for the study. They are in a position to come back and ask us for clarifications, to ask us if they want us to monitor anything, what they want to know about an individual patient.

At this point, frankly, we've had four reviews completed. The last one was on July 18. Barring some minor clarifications and some questions where they wanted to know about an individual patient and were curious about certain things, there really hasn't been anything too significant.

And after each meeting, they have indicated that they are comfortable with the study continuing exactly as it is.

Unidentified Participant^  And then the second question on just a clarification around the enrollment eligibility in the extension study.

Puneet Arora^  Yes.

So the enrollment eligibility, and we were talking about this earlier, so patients who complete their dosing for 26 weeks are eligible for enrollment into the extension study.

So anyone who does not complete 26 weeks of dosing is not.

But primarily, what's happened here is that because we designed the extension study somewhat belatedly after the original study was started, it's taken us a while to get it going, to get all the approvals to get all the sites set up.

So we did lose a certain number of patients who would be otherwise eligible to roll over into the study.

So when we say 50%, it doesn't mean that 50% would not -- the remaining 50% would not necessarily have been eligible. A lot of those patients are not eligible simply because they had already completed the study before the time for rollover came. And of course, there is a certain amount -- yes, there is a certain amount of dropouts as well as you know as we've been seeing them with all of these three studies and ours seem to be in line with what you see. When you combine those two things, what we are looking at now is that we think it will be about 50% -- about 50% are eligible.

Operator^ Your last question comes from the line of Albert Lowe of Craig-Hallum.

Albert Lowe^ Just a quick one for me.

I know the original study design had this 13-week follow-up period to track for durability of weight loss. And I was wondering if the follow-up period after the extension study still has this follow-up period to look for durability and rebound weight gain? And in either case, when might we see data from either portion of CBeyond?

Punit Dhillon^ Hi Albert, thanks for joining the call today. Yes. That's a great question.

We're going to continue to have that 13-week follow-up, but that probably won't be available until the first half of 2026 in terms of that part of the data readout.

So now with the extension, we will finish the 52 weeks and then all those patients will be tracked for a follow-up 13 weeks and then that data would be available.

So that's more of a 2026 event now.

Operator^ Thank you. There are no further questions at this time. This concludes today's conference call.

We thank you for your participation.

You may now disconnect.