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Immunovant, Inc. (IMVT) Q2 2025 Earnings Call Transcript

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Q2: 2025-11-10 Earnings Summary

EPS of -$0.65 beats by $0.08 | Revenue of $0.00 beats by $0.00

Immunovant, Inc. (IMVT) Q2 2025 Earnings Call November 10, 2025 8:00 AM EST

Company Participants

Conference Call Participants

Stephanie Lee Griffin - Roivant Sciences Ltd.
Matthew Gline - Roivant Sciences Ltd.
David Risinger - Leerink Partners LLC, Research Division
Lut Ming Cheng - JPMorgan Chase & Co, Research Division
Samantha Semenkow - Citigroup Inc., Research Division
Yaron Werber - TD Cowen, Research Division
Prakhar Agrawal - Cantor Fitzgerald & Co., Research Division
Corinne Jenkins - Goldman Sachs Group, Inc., Research Division
Yuchen Ding - Jefferies LLC, Research Division
Douglas Tsao - H.C. Wainwright & Co, LLC, Research Division
Hao Shen - Wells Fargo Securities, LLC, Research Division
Thomas Smith - Leerink Partners LLC, Research Division
Brandon Frith - Wolfe Research, LLC
Gaurav Maini - LifeSci Capital, LLC, Research Division

Presentation

Operator

Thank you for standing by. Welcome to the Roivant Second Quarter 2025 Earnings Call. [Operator Instructions] Please note that today's conference is being recorded.

I will now hand the conference over to your first speaker, Stephanie Lee. You may begin.

Stephanie Lee Griffin
Roivant Sciences Ltd.

Good morning, and thanks for joining today's call to review Roivant's financial results for the second quarter ended September 30, 2025. I'm Stephanie Lee with Roivant. Presenting today, we have Matt Gline, CEO of Roivant. For those dialing in via conference call, you can find the slides being presented today as well as the press release announcing these updates on our IR website at www.investor.roivant.com. We'll also be providing the current slide numbers as we present to help you follow along.

I'd like to remind you that we will be making certain forward-looking statements during today's presentation. We strongly encourage you to review the information that we filed with the SEC for more information regarding these forward-looking statements and related risks and uncertainties.

And with that, I'll turn it over to Matt.

Matthew Gline
Roivant Sciences Ltd.

Thank you, Steph, and good morning, everybody, and thank you for listening. I appreciate all you dialing in. So not at all a quiet quarter for us and that we put out both the Graves' data and obviously, the Phase III data for brepocitinib in DM. So obviously a tremendous moment of transformation for the business, but a relatively quiet earnings call as we're looking forward to getting everybody together in December for a more fulsome telling of where we are as a business, more about the future on our Investor Day on December 11. That registration link is live on our website. So look forward to seeing you all there. Today will be more of a review of what's happened in the recent quarter, and then we'll talk much more about the future when we get together in December. So we're looking forward to that.

I want to start out on Slide 5, just by taking a short victory lap because it's been a pretty wild year for us. Obviously, starting with and probably most notably, the VALOR data for brepocitinib in DM, which hit on all 10 ranked endpoints and just a phenomenal data set that we think is going to transform the lives of DM patients. So that NDA filing remains on track planned for the first half of next year, and it will be the first novel oral therapeutic in DM, if approved.

We also put out data in this quarter from the durable remission sort of portion of the Graves' disease trial for batoclimab, which sets us up for the future there in our 1402 Graves' program. That demonstrated disease-modifying potential for 1402. And then we think -- earlier this year, we put out some data in MG and CIDP, and we can do a pretty nice job of validating the deeper is better idea for FcRns from an IgG suppression perspective. We also have initiated at Immunovant this year, potentially registrational trials in Graves', myasthenia gravis, CIDP, D2T RA and Sjögren’s as well as a POC trial in CLE. So some really exciting progress there with IMVT-1402, which we hope will take us to a first-in-class in many cases and best-in-class, we hope all -- in all indications potential.

We got a favorable marketing ruling this quarter for Genevant in the Pfizer case and just overall continued progress in the LNP litigation with the jury trial and the Moderna case scheduled for March of 2026. And our capital position remains very strong with $4.4 billion of cash and cash equivalents, which will get our current pipeline to profitability and support pipeline expansion and potential additional capital return, including the $500 million that we have currently authorized.

On Slide 6, and we've been showing this slide for a while, but it just -- it feels real and real with each passing quarter. Just a late-stage pipeline that we are really excited about with 11 potentially registrational trials and indications with blockbuster potential. Obviously, the first of those dermatomyositis now behind us, but many more to come. Setting us up for a slide that we've been showing since June on Slide 7, which is just a stacked 36 months ahead of us between multiple registrational data sets, first DM and NIU in brepo, and then the beginnings of a long list of them in 1402. Lining up for a series of launches, again, first DM in brepo and then NIU in brepo, and then very shortly thereafter, 1402 across multiple blockbuster indications, including Graves'.

So look, as I said, a moment of real change and transformation for the business. I think we recognize that. We're excited to talk more about it when we get together in December. It's something that the team internally is excited about. It's excitement that I hear from investigators, certainly and patients and docs in the DM landscape and from investors as well. So looking forward to the next leg of our journey here.

I'm going to do just a brief recap of the two major data sets from the quarter. So I won't spend a ton of time on either of these because we've talked about all of them in this setting before, but they bare re-mentioning just because of how exciting both of them are. Starting with the brepocitinib VALOR data on Page 9. Again, we've gone through this all before, but VALOR succeeded with really highly significant, robust and consistent data across the primary and all key secondary endpoints with a nice clear dose response that sets us up for 30 milligrams to be the optimal dose here. Responses were rapid, deep, broad and clinically meaningful across the board, a statistically meaningful and clinically important delta to placebo on mean TIS with deep responses occurring quickly and across a range of endpoints, including muscle and skin.

And as a reminder, on Slide 10, this is a patient population with very significant unmet need, and this is a story that has been underscored over and over again as our team has been out talking to physicians in the field after this data. This is a patient population that is significantly underserved by therapeutic options. 75% of these patients are on only either steroids or ISTs and are struggling to get well controlled. And many of them are requiring high doses of oral prednisone in order to be sort of be treated appropriately and are all looking for options or many of them are looking for options.

Only a relatively small percentage, only 1/4 of the market is currently on other therapies at all. And of the ones that are, some of them are on very demanding IVIg regimens, multiple days a month spent entirely in the infusion centers; and others are on a series of off-label therapies, many or most of which have failed DM programs before, but are used simply because there are no better options. So we're getting a predictably enthusiastic response from all of the physicians we've engaged with on this data already and are obviously looking forward to continuing that as we go through the registration process in the coming year.

Looking at Slide 11, again, a recap from before, but this is the primary endpoint. This is mean TIS. And this is a textbook picture from my perspective of positive clinical data, statistically significant at the high dose starting at the earliest time point, nice clear separation, nice clear dose response. And one thing that I was mentioning and we said this, we put the data out originally. We had originally been focused on a steroid taper as a risk mitigant in order to make sure we saw a clear benefit from the drug against the background of not really placebo, but actually actively managed background therapy. And we did that.

But the other thing we were able to show is a real dose response on steroid reduction. We were able to get a significantly greater portion of patients to lower steroid doses or off steroids on high-dose brepocitinib than on placebo. And I think that actually with the doc community has been enormously resident finding. It's something that the docs are really, really focused on getting these patients off high-dose steroids, and we are very excited that we were able to show this in the study, including as a part of at least one of the key secondary endpoints.

On Slide 12, more than 1/3 -- and this is the key secondary where we were able to really hit both the TIS improvement or the TIS, I should say, and a minimal or no steroid burden. More than 1/3 of brepo 30 patients were able to get to both major TIS responses and minimal or no steroid burden at week 52. So that's just a really exciting finding across the board. And more than 1/2 of patients were able to achieve a TIS40, a moderate TIS response, with very low dose of oral steroids at the same time. So just a phenomenal outcome there on the combination of endpoints.

On Slide 12, again, without going through them all, just a statistically robust data set, I'll say, with really low p-values across every secondary we tested benefit on muscle, benefit on skin, benefit on patient-reported outcomes like the HAQ-DI questionnaire on disability, just a terrific across-the-board outcome here.

In terms of what's next year, I think everyone is clear, the NDA submission, we're moving as fast as we can. The only real gating item here was drafting and it's ongoing right now. We expect to get it filed in the first half. Data readout from that proof-of-concept study in CS that we have ongoing will be next year. And the NIU study, which is enrolling very nicely, is currently anticipated to read out or say, guided to the first half of '27, around the same time as potential registration of brepo and launch in DM. And then we submit the sNDA for NIU shortly thereafter, with potential further indications and so on to come.

So that's brepocitinib. I'm sure we'll get some questions about it. And like I said, we'll talk more about that program and what it could represent commercially on the 11th. But suffice it to say, a tremendous quarter and something we're really excited to carry forward from here.

Next up, I'll just recap the Graves' disease remission data that we put out earlier this quarter as well. Starting on Slide 16, with just a reminder, this is a very large patient population with a significant unmet need. And there's been -- I think this is an important point as people are doing their work here, a shift away from ablation over time as patients don't want to go through the surgical procedure or the radioactive iodine, but really a lack of new medical therapies that's left. Something like 1/4 to 30% of Graves' disease patients who are relapsed, uncontrolled on or intolerant ATD. So just a very high proportion of patients who are unable to get well controlled.

As a reminder, on Slide 17, this is a bad disease. These patients are at much higher risk of cardiovascular events, much higher risk of preeclampsia, 4x higher risk of preeclampsia, and a 7x higher risk of thyroid cancer than the general population. So these patients are really sick or at a high risk of developing severe comorbidities. They often go on to develop thyroid eye disease. About 40% of patients go on to develop these eye symptoms, some of which get optic neuropathy and other issues that can be pretty significant for vision.

And then there's a bunch of other complications here. 16% are diagnosed with thyroid storm, which has a -- in patients who had hospitalized for Graves' disease, 16% are diagnosed with thyroid storm, which has a 20% mortality rate. So again, potentially sort of very sick patients and again, a relatively high risk of thyroid cancer, including a high risk of progressive thyroid cancer. So a disease that makes people quite sick. Again, more to come on the 11th, but just wanted to highlight that fact.

And then on Page 18, in addition to being a severe disease, it's a disease affecting a lot of people. And so you've got every year, call it, 65,000 newly diagnosed patients; of which 20,000 of those wind up in that sort of refractory bucket. And then there's 880,000 diagnosed U.S. patients, of which 330,000 in the prevalent population are walking around in that intolerant or unable to get well-controlled bucket. So there's just a huge patient population with a significant unmet medical need.

What we showed earlier this year in the batoclimab study is a pretty interesting result. We showed real disease-modifying benefit in these patients. Of the 25 patients who came in at baseline, as a reminder, the way the study worked, patients were treated for 12 weeks of high-dose batoclimab followed by another 12 weeks of low-dose batoclimab and were then followed for another 24 weeks off drug entirely. And what we saw is after that first 12 weeks, 20 out of 25 of those patients were responders to therapy. After dropping to low dose after another 12 weeks, 18 out of 25 of those patients were responders.

And truly remarkably, after being off drug for a further 6 months, 17 out of the 21 patients we were able to follow up with at week 48 were responders to therapy. So these are patients who were uncontrolled on standard of care at the beginning of the study, and 17 out of the 21 of them that we were able to follow up with remain responders to therapy, having been off drug for 6 months. So a pretty remarkable disease-modifying benefit.

Of the off-drug responders on page -- the off-drug responders on Slide 20, nearly half of them were fully off ATDs, and over 75% of them were on only the lowest doses of ATDs or off ATDs. So not only were we able to deliver disease-modifying benefit for patients who are uncontrolled on ATDs before, we were able to significantly reduce or eliminate ATD need for those patients. Now this was underscored on Slide 21, not just by the sort of clinical data on T3/T4 and so on, which is obviously always what's most important to the patients.

But you can also see it in the TRAb reductions on Slide 21. And as you can see, as you'd expect for FcRn therapy, these patients showed a rapid decline, both in general IgG and in TRAb levels, especially on high dose. The IgG levels came back a little bit as you'd expect during the lower dose period. And then what is maybe unique to Graves' disease or at least unusual among FcRn indications is while IgG bounces right back when you come off therapy and the only time points on this graph are week 24 and week 48. But by week 48, these patients were effectively back at baseline from IgG. The vast majority of these patients still had basically sort of reduced or no TRAbs. And that is a pretty remarkable finding around the durability of the benefit here.

On Slide 22, the next period is absolutely stacked for us in 1402 with data coming in a variety of indications. D2T RA and CLE next year. The second part of the D2T RA study as well as Graves' and MG in 2027. And then Sjögren''s and CIDP after. One small update just to flag for today, the TED study remains on track to conclude this year. Our last patient, last visit is very close to today. But we're going to hold off reporting the top line data from that first study in all likelihood until we see the top line data for the second study in the first half of next year. The evolving competitive landscape in TED and especially in Graves' disease has led us to take a more prudent path there. And so we're going to collect that data together and report it when we have it all.

Moving on to the -- briefly to just a reminder of where we are on the LNP litigation, which I know some people are following. In the Moderna case, we are in a pretrial process around the narrowing of claims and defenses and around summary judgment, which is happening now. The judge is reviewing summary judgment briefings and there's sort of a calendar on the docket that we're hoping will take us through trial in March. The trial is scheduled for March and the first international proceedings are also expected in the first half of 2026. The Pfizer case is ongoing in discovery, and there was a favorable market ruling issued in September that certainly sets us up nicely for what we think we need to do from there.

So I'll conclude before we go to Q&A with a brief financial update. Overall, a straightforward quarter from a financial perspective. Loss from continuing operations net of tax of $166 million. And cash, cash equivalents of $4.4 billion with no debt on the balance sheet. And obviously, a share count reflective of the significant share buybacks we've done over the last 18 months. So a strong position overall that, as I said, is expected to carry us through profitability. We've got more of our financials in here, and the catalyst sort of road map on Slide 28.

But again, just a really exciting 6 months or 12 months behind us and a really exciting 12 months or 36 months ahead of us. So feeling great about where the business is, feeling great about just the significant transformation in our profile that we've been through in the recent months and looking forward to carrying that forward from here.

Once again, as a reminder, we have an Investor Day in New York City for those that can make it in person on December 11, 2025, that registration link is live. It's in the presentation we put up as well as on our website. I hope to see many of you there to round out the year and talk about the future.

So with that, I'll say thank you again for listening. Again, a relatively quiet earnings call, but not at all a quiet quarter. And I will pass it back over to the operator for Q&A. Thank you, everybody.

Question-and-Answer Session

Operator

[Operator Instructions] Our first question coming from the line of Dave Risinger with Leerink Partners.

David Risinger
Leerink Partners LLC, Research Division

Congrats on all the progress, Matt, and looking forward to the event on the 11th. So my question is, could you please comment on what we should be watching next with respect to Pfizer litigation, so specifically in international markets and then in the U.S.?

Matthew Gline
Roivant Sciences Ltd.

Thanks, Dave. I appreciate the question. And obviously, it's something that a number of people are watching. It's tough, as always, to comment on ongoing litigation. I have nothing to say about any potential timing of any kind of international cases. Look, it's a busier moment coming up. I think there should be a sort of scheduling process for the Pfizer case underway, and we should learn more about the exact time line, including hopefully a trial date in the near future. And I think that's probably what I would be most watching out for in terms of what's public at this point is just getting that schedule together and progressing from here.

Operator

Our next question coming from the line of Brian Cheng with JPMorgan.

Lut Ming Cheng
JPMorgan Chase & Co, Research Division

Matt, just two quick ones from us. How do you feel about argenx stepping into Graves' and whether that has any impact on your strategy of 1402? And then we have a quick follow-up.

Matthew Gline
Roivant Sciences Ltd.

Thanks, Brian. It's a great question. And look, I think you heard my comment on the timing of the intended sort of production of the batoclimab TED data. Obviously, we're acutely aware of the competitive landscape in Graves' disease. And look, I think to make a gentle comment, whatever imitation is the finest form of flattery. I think it's great to see others recognizing the importance of Graves' as a disease. It's great to see more people working on treatment options for these patients. Obviously, in our Phase II study, we studied both high and low-dose batoclimab, and we saw a great benefit to the higher dose batoclimab in the study.

And then also, we reported in the past data breaking out the patients between that 70% cutoff below and -- above and below 70% IgG reduction. And we had 3x as many patients getting off ATDs at the above 70% group than in the below 70% group. So we think we should have quite a competitive profile there. But most importantly, to be honest, it's a big patient population, there's a lot of sick people. And I think a rising tide there will lift all boats.

And like I said, argenx is a formidable company with a wide following and has done a great job of execution. And I know there's at least some people out there who find it, although it might be frustrating to us validating of our strategy that they're following in our footsteps. And so we'll always take it. Thanks, Brian.

Lut Ming Cheng
JPMorgan Chase & Co, Research Division

Great. And just one quick one. So on the Investor Day next month, just curious if you can talk about what do you want investors to get out of the Investor Day? Is this more of a broader recap of your current strategy? Or do you think that there will be some unveiling of completely new data or a new strategic direction at Roivant?

Matthew Gline
Roivant Sciences Ltd.

Yes. Look, it wouldn't be a fun Investor Day if I reveal all of it now. But I think most importantly, this is just -- it's a moment of huge transformation for our business. I think the type of investors who are now along for the ride are different. And obviously, a lot of other things about the business are different. So I think we want to make sure we're telling that story fully that we're helping people see the course from a commercial perspective, from a patient need perspective in these indications so they can see at least the reasons why we are so excited about these indications about the certain nature of the blockbuster opportunity.

There might be some other new things we're able to share by then in terms of updates or other things, but we'll see where we're at in a few weeks here or a month. But I think it will be an exciting opportunity to get together and take stock of the business and to talk a lot about the future and the opportunities in front of us.

Operator

Our next question coming from the line of Samantha Semenkow with Citi.

Samantha Semenkow
Citigroup Inc., Research Division

Just for Graves', when thinking about the remission data, is there any way to tease out the impact of starting on the high-dose batoclimab in that study? And how much that actually contributed to the remission rates you saw? I'm just wondering if there's anything that you could share that you were able to tease out from the data when you analyzed it so as we think about the competitive landscape.

Matthew Gline
Roivant Sciences Ltd.

Yes. Look, thanks. That's a -- it's a great question. And I do think we're going to -- like I said, be a little bit careful about some of what we say here because of the evolving competitive landscape, and we're going to learn more about this from the hypothyroid TED patients and so on in that study as well. But look, I think in general, remission is about TRAbs getting normal for longer. And our view is that deeper IgG reductions are going to drive towards exactly that outcome. And so both in terms of the speed of responses that we saw in the VALOR trial and the depth of responses that we saw in the VALOR trial in terms of TRAb lowering, I think that's going to be a significant driver for us. So I think we feel good, put it this way, about our level of IgG suppression in that program at high dose. Thanks. It's a great question.

Operator

Our next question coming from the line of Yaron Werber with TD Cowen.

Yaron Werber
TD Cowen, Research Division

Great. Maybe a quick question. We've been getting a few questions about the ongoing preliminary -- the summary judgment against Moderna with respect to the U.S. government involvement in the EUP -- I'm sorry, EUA and whether the government ever took control of the vaccine for distribution and whether that made them a commercial party and whether that impacts their involvement and as a result, would potentially provide Moderna some venue to make an argument. Any thoughts about that, if you can comment at all would be great.

Matthew Gline
Roivant Sciences Ltd.

Yes. Thanks, Yaron. And again, as usual, it's difficult to comment in depth about an ongoing litigation, and it's ultimately going to be the judge's decision on the 1498 question. I'll point out that the two things that are worth keeping in mind. One is the Moderna case in the U.S. -- Moderna sales of COVID vaccines in the U.S. in total is a bit less than half of Moderna's total global COVID vaccine sales, and Moderna's total global COVID vaccine sales are a bit less than half of the total, inclusive of Pfizer.

And so -- and then what Moderna has claimed in their own briefings is that we asked for about $5 billion in damages in the U.S. case, and Moderna has claimed that a little bit less than half of those damages could be subject to 1498 in Moderna's view. And so I think you're talking about a little bit less than half of a little bit less than half of a little bit less than half of the total is the issue in summary judgment on 1498. Our position is pretty clearly laid out in our motions. And frankly, Moderna's position has also laid out in their motions. Obviously, we feel like we have a strong case to make here, but it's ultimately going to be up to the judge to determine. But I just wanted to sort of scope out the magnitude of the question as well.

Operator

And our next question coming from the line of Prakhar Agrawal with Cantor Fitzgerald.

Prakhar Agrawal
Cantor Fitzgerald & Co., Research Division

Congrats on the progress in the quarter. Maybe firstly, on Sjögren''s disease. Recently, there has been a lot of excitement around Sjögren''s market opportunity, especially with the recent data from Novartis' [indiscernible] drug, ianalumab. Maybe you can contextualize how FcRns can differentiate on ESSDAI scores of other specific endpoints? And do you think you could be first-in-class in this indication? And secondly, just quickly on brepo in DM, do you plan to apply for FDA's National Priority Voucher for brepo?

Matthew Gline
Roivant Sciences Ltd.

Thank you. Those are both great questions. Look, I think on Sjögren's, we are also excited about the market opportunity. It's a large patient population with a very significant unmet need. And just a lot of people kind of going through it as it were. There have been a variety of therapeutic classes that have shown some benefit. Obviously, the in-class data was positive and the J&J data, in particular, showed that lower is better. So we think we have a real shot at best-in-class.

We are working to launch as close to first-in-class as possible. I don't think we're here to commit that we'll beat our competitors. We obviously got a little bit of a head start on us, but I think we're trying to be kind of within a window small enough such that it shouldn't matter who comes first, and we can differentiate based on our profile. And I'll just say, I think -- first of all, I think the Novartis data was positive, but probably left room for even better as I think have all of the Sjögren's data produced to date. And I think the FcRn data to date has sort of been competitive with other classes of drugs.

And so if our deeper IgG suppression yields a better benefit than other FcRns, I think we should have a truly important opportunity in the space. A lot of excitement about new therapies from KOLs and from our investigators. The unmet need is significant. The overall market is a significant number of patients. So it's a great place for us to be in our view.

And then sorry, you asked about the CNPV program for brepo. We haven't said. Look, this is an orphan population with high unmet need. So I think we're thinking through all of the different ways we can get through FDA and out to patients as quickly as possible, and thinking about the puts and takes of them all, but stay tuned.

Operator

Our next question coming from the line of Corinne Johnson with Goldman Sachs.

Corinne Jenkins
Goldman Sachs Group, Inc., Research Division

Maybe following up on an earlier question about competitive intensity in Graves' disease. I think it goes beyond argenx in terms of number of companies that have announced plans there. So how are you thinking about the kind of competitive clinical landscape that's evolving? And what do you expect to inform sequencing decisions in that space over time? And then maybe separately, just on business development. Curious if you could give an update on what you're seeing on that front.

Matthew Gline
Roivant Sciences Ltd.

Yes. Thanks, Corinne. Look, I think the first question -- and obviously, we see the competitive landscape. Similarly, there's a number of people trying different things which is exciting. It's exciting for Graves' space, it's exciting to be there. One comment about that is, I think we've watched the myasthenia gravis landscape play out, and there's a lot of competitive intensity and a lot of new mechanisms and also that FcRn has been: a, a pretty undisputed king so far; and b, that the first FcRn to launch with the quality of that data has been a tremendous head start. And we think we've built something similar in Graves' disease, which is a market obviously a multiple of the potential size of the MG market.

So we feel great about our position, both from a timing perspective as well as a mechanism. It's a well-understood mechanism, FcRn. And it's pretty exquisitely well suited to treating the biology of Graves' disease. So you think about some of the other mechanisms outside of FcRns have something in common with ATDs, which is that at high doses, they will cause patients to go hypothyroid, which is a miserable thing as well. And so I think one of the great things about FcRn biology is other than maybe for a very short period of time, because what you're really doing is getting at the root cause of the disease with these autoantibodies, you're not going to like cause the thyroid to react in the other direction sort of directly. It's not like a TSHR targeted mechanism or something like that. And so I think that will be a big benefit to FcRn.

The other thing that I think is maybe underappreciated in some communities about FcRns is just how safe and well tolerated they are. And I think in a Graves' patient population, that is going to be an important fact that I think will be great for FcRns as a mechanism. So I think that those will all be sort of good guides towards FcRns being important and early line therapy for these patients who can't manage it with standard of care today.

In general, as I said, I think lots of activity in the space is actually going to be good for everybody. These are docs who haven't run a lot of clinical trials. These are docs who haven't had a lot of new treatment options. And I think the more voices there are out there talking about this stuff, the better we'll be able to get out to the patient population. So thanks. It's a great question.

And then you asked for BD update. Look, we remain extremely well capitalized. We remain very excited about the opportunities for pipeline expansion. We are incredibly excited about the things we currently have in our pipeline. And obviously, you hear that in our voice. You see that in the way that we're talking about our data. Obviously, we're thinking about indication expansion for those programs and then always looking in the world for programs, especially programs that are of a size and scale that can move the needle against the backdrop of our existing pipeline. And I think we've got some exciting ideas.

Operator

Our next question coming from the line of Dennis Ding with Jefferies.

Yuchen Ding
Jefferies LLC, Research Division

We have two, if we may. Number one is on Pulmovant. So you guys will have Phase II PH-ILD data in the second half of next year. I guess, how confident are you about the translatability from PH to PH-ILD? And how should we think about that update and what's the positive delta on PVR? And secondly, on the LNP litigation, I'm curious if you've done any work on what percentage of the U.S. doses were given to actual federal government employees as we think about a middle scenario for summary judgment.

Matthew Gline
Roivant Sciences Ltd.

Thanks, Dennis. I appreciate it. Both great questions. Thanks for the question about Pulmovant. We're obviously super excited about mosli. Look, I think you have correctly identified the risk that exists in the mosli data that is we don't have data in the PH-ILD patient population, and that's sort of the nature of this study. In general, PVRs have translated well. And so I think that's an important backdrop fact between these indications. And where they haven't, it's mostly been, for example, because of these V/Q mismatch issues associated with vasodilation in lung disease patients. And we think the format of mosli addresses that issue.

So we are, I'd say, cautiously optimistic about that translation, but obviously, I feel a lot better when that Phase IIb data is in hand. And my hope is that we see pretty significant PVR reductions and pretty significant clinical benefit in those patients. So looking forward to that data in the second half of next year. That's another area where there's quite a lot of enthusiasm for the program and for new opportunities, especially with the overall growth from the prostacyclins in PH-ILD, leaving plenty of room for additional mechanisms.

The other thing I'll point out is just the 38% PVR reduction we saw in pulmonary hypertension. Even if PVR reductions are for some reason a little bit lower in PH-ILD, obviously, there's still a lot of room for a very significant amount of benefit for these patients. Your second question, what percent of doses given to federal employees. I don't think our best estimates of that are in any of our motions. But I think you can imagine, as you think about the number of federal employees that it's a relatively small percentage.

Yuchen Ding
Jefferies LLC, Research Division

Got it. And if I can sneak one more in about the LNP litigation. Maybe remind us what's the status in terms of the OUS trials. We're not that familiar with the OUS process. So I guess, can you remind us how many cases you filed, which one is the furthest along? And can you get an initial decision in 2026?

Matthew Gline
Roivant Sciences Ltd.

Yes. So thanks, it's a great question. In the case of Moderna, we filed a number of OUS actions, including in the UPC in Europe as well as in Canada and Japan and a couple of other places. Those litigations are all ongoing. There are important hearings in 2026. And the nice thing about some of these European jurisdictions is they can move quickly. So it is possible that we would get outcomes of various kinds within 2026 in some of those jurisdictions and obviously look forward to saying more when there's more to say.

Operator

And our next question coming from the line of Yasmeen Rahimi with Piper Sandler.

Unknown Analyst

Congrats on a great quarter. This is Dominic on for Yasmeen Rahimi. We just had a question going into the TED data. Could you help us understand what you're thinking about with the expectations for the studies that are reading out here soon? And what do you hope to see to consider development considering the competitive landscape?

Matthew Gline
Roivant Sciences Ltd.

Yes. Thanks. It's a great question. We're looking forward to having that data relatively shortly for sharing it next year. Look, I think the competitive bar in TED is relatively high with IGF-1Rs being pretty efficacious. That said, they certainly leave room from a safety perspective, et cetera. And so I think we're looking to see data that makes sense in the context of the competitive landscape there. The other thing that I think -- and this is part of the reason why we're focused on the sort of competition in Graves' disease, I think we'll learn a lot about hyperthyroid Graves' patients from this study as well as the possible ways in which Graves' and TED might interact with one another. And so I think we're looking forward to the data from that perspective as well. We'll obviously make a final decision on a launch in batoclimab once we've got the TED data in hand and in consultation with our partner.

Operator

And our next question coming from the line of Douglas Tsao with H.C. Wainwright.

Douglas Tsao
H.C. Wainwright & Co, LLC, Research Division

I guess, Matt, maybe as another follow-up on Graves' and TED. As you referenced, the two diseases are obviously sort of very interrelated with interplay. And I guess when we think about argenx, they will potentially come to market with VYVGART being both Graves' and TED hypothetically. Obviously, you have a big head start with 1402 in Graves'. So I'm just curious how you're thinking about potentially pursuing TED with 1402 versus, as you just noted, potentially thinking about batoclimab and the sort of disadvantage of maybe sort of coming at those dual markets with two different molecules.

Matthew Gline
Roivant Sciences Ltd.

Yes. Look, thanks. It's a great question. And a couple of comments about this. One is it's -- we'll be speaking in the abstract now. We're going to know a lot more about the TED data that will inform the answer to this exact question, and we will be in possession of more information than anybody else will have at this moment in time on the sort of overall treatment landscape and on what FcRns can deliver. And so I think that will set us up really nicely to think about the possible options.

They're totally different call point in terms of the physicians who treat these things and there are different stages of disease. And so I think they get treated at different times in different ways. And I think being able to talk to endos who are treating Graves' patients about the benefit in forestalling TED, for example, is an important potential thing to be able to discuss when we get to it.

In terms of thinking about the sort of TED versus Graves' market dynamics, I'd say let's just wait and see what the TED data looks like, and then we can talk more about it. As a reminder, the Graves' population is meaningfully bigger and it's upstream of the TED population. And so I think there's a reason that was our first focus once we got into the clinic with 1402. Great question.

Douglas Tsao
H.C. Wainwright & Co, LLC, Research Division

Okay. Great. And Matt, if I can, on a follow-up with brepo. Obviously, incredibly impressive results in DM. I'm just curious if you have given thought just given sort of somebody alluded to sort of the competitiveness in Sjögren's, have you ever thought of that as an indication because I think there is a mechanistic rationale and obviously, an oral option would be very attractive.

Matthew Gline
Roivant Sciences Ltd.

Yes, thanks. I appreciate the question. Look, I think the short answer is we have thought pretty exhaustively about possible indications for brepo. We have a number that we think are exciting beyond what we've talked about. I think if you look at the indications we've chosen so far, they've been indications where we can really chart a market-defining course. And I think there are maybe more to do in that story. But the short answer is there's an embarrassment of riches in terms of the indication set available for brepo, and we feel very privileged with the data we have in hand for what we've got. As a reminder, it has worked almost everywhere it has been tested. And so I think we feel like it's a great molecule and with a lot of great places to go. Thanks for the question.

Operator

Our next question coming from the line of Derek Archila with Wells Fargo.

Hao Shen
Wells Fargo Securities, LLC, Research Division

This is Hao calling in for Derek Archila from Wells Fargo. I guess we have a question on brepo. We were at AACR. So very positive feedback from all the KOLs. So question is about really the competitive landscape. I guess we've seen VYVGART having data next year and the CAR-T is also starting their pivotal trials. How do you see the kind of the treatment paradigm evolve over the years? And brepo, do you have also plan to explore in other subtypes of myositis like IMM, [ASMS]?

Matthew Gline
Roivant Sciences Ltd.

Yes, perfect. So look, I think on the competitive landscape, similar comment to, frankly, my comment in Graves', which is that I think it's a great opportunity to be able to get out in front of it. And obviously, first and foremost, the easiest and oral is always going to have a huge place. The majority of these patients are on oral therapy now. And so I think just like the overall profile that makes us unique.

I'll say the CAR-Ts, that's not, in my opinion, going to play for the same patients mostly that we are. That's obviously a much different sort of intervention. And there's still plenty of open questions about benefit there. Look, I think that's also sort of a little bit about that landscape. FcRn could be a compelling option. Obviously, IVIg is used. But I'd say, first of all, it's good to have what we think of as a multiyear head start in DM. And we think the patient population that we have access to, given the nature of our therapy is really basically the entire DM patient population, which gives us a lot of room to go.

So we think, again, similar to VYVGART and MG, we think we get to define that market and be the heart of it. And so I think that's all great. We also suspect that the data we have in DM specifically may be just the best overall, and that's the biggest part of the myositis market. Obviously, argenx is studying in other subtypes of myositis as well, and some of those may be more directly appropriate for an FcRn.

As to your question about other subtypes of myositis for us, I'll just say again, we thought about a whole bunch of different places to go. There's a lot of exciting places to go, and we have an embarrassment of riches in terms of where we can take the molecule from here.

Operator

Our next question coming from the line of Thomas Smith with Leerink Partners.

Thomas Smith
Leerink Partners LLC, Research Division

Congrats on the progress. Just with respect to the TED program and the competitive landscape, could you comment on some of the data we recently saw from the IL-6 class, whether you think [indiscernible] is approvable with that data set and sort of your expectations for batoclimab relative to those results? And then secondly, is there any update you could provide from the overseas study that you're running with 1402? And any sort of timing guidance for when we might see data from additional indications from that study?

Matthew Gline
Roivant Sciences Ltd.

Thanks. Those are, look, obviously, great questions. I'll say obviously not our place to make comments on the feasibility of other mechanisms. There was a notably high placebo response in the IL-6 study, which is something we've paid attention to. But overall, no specific comments on where that program goes from here. From a competitive landscape perspective, I think the competitive intensity in TED is real, as I said earlier. And the IGF-1Rs are efficacious, although they have safety and tolerability concerns associated with them. And so I think we're sort of focused on where we could play in TED. And then as we said a minute ago, thinking about Graves' an opportunity to impact the disease much earlier in its course. And I think that's an important thing the way that we are approaching that with 1402.

On the sort of second overseas study, look, I think we, obviously, at this point, have a number of large registrational programs running in 1402 that are big global studies. We continue to like the option of small, fast POCs overseas and feeding that information into bigger studies. If and when we have anything to share from those ongoing efforts, we'll share it. But mostly, it's being used to inform either indication selection or design decisions of the bigger studies.

Operator

And our next question coming from the line of Brandon Frith with Wolfe Research.

Brandon Frith
Wolfe Research, LLC

This is Brandon on for Andy. Have you provided any analogs for the DM launch? And we're curious to know what to expect for the cadence out of the gate in longer term?

Matthew Gline
Roivant Sciences Ltd.

Yes, perfect. Look, I think DM is an area with high unmet need, but also not a lot of novel therapies recently launched. So first of all, there aren't great analogs to look at, specifically in DM. And second of all, I think the appropriate course for any public company is to guide cautiously on launch speed and to say that we're going to do everything we can to get this drug out there and to get docs excited about it. And the thing that we're most confident in is that the overall market opportunity is large, that there is high unmet patient need and that when we get to peak penetration, there's a really big and exciting opportunity.

Exactly how long it takes to get there, I think we're going to see is the answer, and we're going to do everything we can to make it as successful as we can. Obviously, the real value add is the stuff to get the long-term trajectory here right. So that's probably how I think about the launch.

Operator

Our next question coming from the line of Sam Slutsky with LifeSci Capital.

Gaurav Maini
LifeSci Capital, LLC, Research Division

Congrats on the quarter. This is Gaurav on for Sam for LifeSci. So just a question on Graves' here. Based on all the market research done to date, as you compare the uncontrolled Graves' disease opportunity versus what FcRns have shown in the MG market, I guess, how do you size these up? How are you thinking about the opportunity? Is it bigger, smaller, similar as we think about MG for FcRns?

Matthew Gline
Roivant Sciences Ltd.

I mean, look, it's hard to -- the MG market has been tremendous. And so I think it's hard to call it one way or another. But obviously, there's a lot of uncontrolled Graves' patients, and it's an exciting place to be. And I think we have a real opportunity to build something big. There's just lots and lots and lots of uncontrolled patients is the answer.

The other thing I'll say is we'll talk more about the commercial opportunity in Graves' disease on December 11. And I think we're excited with what we see. And I think we can make -- I think the most important thing is there are hundreds of thousands of patients for whom we could make a meaningful difference. and a lot of different ways for us to get into that market and establish different toeholds in places. And so we're looking forward to all of that. We're also learning, and I want to highlight this as an important advantage that we have from being first, so much about the Graves' opportunity by being out there with these docs enrolling patients in the study, looking out at what we're finding. And I think that competitive benefit is going to set us up really well to make sure we've got the right product on the market as well.

Operator

There are no further questions at this time. I will now turn the call back over to Mr. Matthew Gline for any closing remarks.

Matthew Gline
Roivant Sciences Ltd.

Thank you. Thank you, everybody, for listening this morning. Once again, a phenomenal quarter for us in terms of the results we delivered. And super importantly, looking forward to getting together on the 11th to talk about the future and address in further detail some of the very same questions we got on today's call. So I hope to see many of you there. And I hope you all have a great end to your year apart from that. Thanks very much, and have a good day.

Operator

This concludes today's conference call. Thank you for your participation, and you may now disconnect. Goodbye.