# EDITED TRANSCRIPT

## MYOV – Myovant Sciences, Inc. at 41st Annual Cowen Healthcare Conference

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OVERVIEW:
Myovant Sciences presents at the Cowen Healthcare Conference 2021

## CORPORATE PARTICIPANTS

**David C. Marek, Myovant Sciences Ltd.** - Principal Executive Officer & Director

**Frank L. Karbe, Myovant Sciences Ltd.** - Principal Financial & Accounting Officer

## OTHER PARTICIPANTS

**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

## PRESENTATION

**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

Good morning. My name is Laura Christianson, and I'm a Biotech Equity Research Vice President at Cowen. This morning, it's my pleasure to host Myovant for a fireside chat. I have with me CEO, David Marek; and President and CFO, Frank Karbe. Thank you for joining us, Dave and Frank.

To begin, Dave, could you give a brief state of the company? What are Myovant's biggest strengths and challenges and what needs to happen to drive outperformance over the next 12 to 24 months?

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**David C. Marek, Myovant Sciences Ltd. -** Principal Executive Officer & Director

Sure. And thank you for having us today. Laura, we're really happy to be here and with your audience.

So I think if we look at, first of all, kind of what are the biggest strengths for Myovant. I've been CEO now at Myovant for all of two months. And I can tell you that one of the reasons why I was so excited to join Myovant really starts with the culture and how that culture is really strengthened by the people and the employees that we have at Myovant.

Our mission is to redefine care and while that sounds like a great tagline, I think the difference at Myovant is how we pull that through, through our employees day in and day out. And the first area of evidence of that is really the effective and efficient success that we've had with our clinical development engine. So if you look at our ability to execute five Phase 3 trials in two products across three indications and then getting two of those clinical programs published in the *New England Journal of Medicine*, leading to one product approval and all of that within just the first five years of the company. I think there are a few companies that can match that kind of success that Myovant has had. So we clearly have a strength in our clinical development team and that engine that we built.

When we look at the opportunity areas, the first area, I think, is really to take that clinical development success and potentiate it. And that's with life cycle management opportunities with relugolix, but also really building our pipeline through business development opportunities. So that would be the first opportunity area.

And then the second one is right here in front of us now. We are right in the midst of demonstrating our commercialization capabilities as we launch ORGOVYX. And we know that, that is really a high priority for us and for the marketplace, to really get our therapies in the hands of the patients, who deserve it.

And that's the opportunity that we're going to continue to push now with ORGOVYX. And then FDA willing, in the middle of the year, with our action date for uterine fibroids on June 1.

So in the short term, I think it's really delivering on the opportunities with our launch performance and then in the mid and longer term opportunity, it's really the pipeline that will help build sustainable value for shareholders.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

Perfect. Yes. Let's talk a little bit more about ORGOVYX. Could you give us a brief update on its launch? And if you're satisfied with the pace of the uptake and the level of reimbursement access that you've gotten so far?

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**David C. Marek, Myovant Sciences Ltd.** - Principal Executive Officer & Director

Well, certainly, Laura, I think we are very enthusiastic about the interest that we are receiving from ORGOVYX. And we're not surprised because we did research prelaunch, and we saw over 60% of physicians who said they were very or extremely interested in prescribing ORGOVYX. So we're seeing that play out in terms of the clinical excitement around ORGOVYX. We know that a large percentage of the patients reside within these large group practices. And the feedback we've received from those group practices, again, extremely excited about the clinical profile.

We know that it takes time in those practices for them to assess the other considerations, such as the economic impact if they have in-office dispensing, the operational implementation of switching from one therapy to another. And we're very pleased with the progress that we're making in those large practices. We know it takes more time but we're seeing really good progress there.

As a matter of fact, the vast majority of, what we've identified as our top accounts, have already ordered at least once and many of them have already reordered. So we're very pleased with the momentum that we're seeing there. As far as coverage, you mentioned commercial and Part D. We are having very positive discussions with the commercial payors as well as the Part D payors, and we're right on track. We think that we're going to see some of those agreements come into place in the next few months, certainly on the commercial side.

And then Part D, of course, decisions mid-year, we'll see some of that start to peak through towards the end of the year and then with the majority of that in Part D flipping over really at the beginning of 2022.

So overall, a lot of positive momentum, and we have every confidence in our vision for ORGOVYX that we're on track to eventually become the standard of care in ADT.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

Yes. You mentioned some patient switching happening, wanting to become the new standard of care. How do you perceive the competition from existing GnRH agonists and antagonists in the prostate cancer market? And how do you go about taking share from that entrenched standard of care?

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**David C. Marek, Myovant Sciences Ltd.** - Principal Executive Officer & Director

Well, Laura, any time you come into a therapeutic area and there are decades of entrenched prescribing, we know that it takes time to start to break those habits. So we go in very clear-eyed in what we have in front of us. But what gives us optimism that is consistent with the feedback we're hearing. And that's really how we're moving with where the marketplace is going and how ORGOVYX fits within that.

So the first area where there's momentum in the marketplace is the clinical profile. What we're hearing providers are looking for, are therapies with an ADT that have a fast on and a fast off. So when we look at the initiation of ORGOVYX and the fact that we quickly lower testosterone levels without that hormonal flare, we're receiving a lot of positive feedback on that. When discontinuation of therapy, the ability to bring – to have the reversal of testosterone suppression, we can get over half of the patients there in only 90 days. And so that clinical profile is moving with where the marketplace is going.

And the second area is really the safety profile. More and more we're hearing physicians are very interested in assessing cardiovascular risk. And when you look at the safety profile that we conducted, certainly what we saw in our HERO trial and what's represented on our label, physicians are very motivated by the safety profile they're seeing and the data that we have around major adverse cardiovascular events.

And then the third area where there's momentum in the market is really towards oral therapies, more and more prostate cancer is being treated with oral therapies and ORGOVYX falls right in line with that. So when we think about competing, we really feel like in those three areas, that's what the market is telling us that they want and that's what ORGOVYX is delivering.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

You mentioned the cardiovascular benefit. And I think that's been something that is particularly compelling to investors. There's an ongoing Phase 3 trial investigating a different GnRH antagonist, the subQ degarelix and whether it can reduce the risk of cardiovascular complications relative to Lupron in prostate cancer patients with cardiovascular risk factors. Those data are anticipated in the second quarter. If they're positive, how might ORGOVYX benefit from that data?

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**David C. Marek, Myovant Sciences Ltd.** - Principal Executive Officer & Director

Well, Laura, I mean, you have struck upon a very important topic. We know that patients with prostate cancer, that more of those patients actually die of cardiovascular disease rather than prostate cancer itself. So understandably, there has been increased attention from the urology and the oncology communities regarding the cardiotoxicity of treatments in APC. So I believe that when you look at the body of data, as it continues to amount regarding the cardiovascular risk associated with the older LHRH agonist, and you look at what we're seeing with the newer GnRH antagonist, the data continues to really look positive.

And when we look specifically at ORGOVYX, we have great data from our HERO trial that was published in the *New England Journal of Medicine*, in which we showed in a prespecified safety analysis that relugolix had a low incidence of major adverse cardiovascular events observed in those patients treated with ORGOVYX. So we know that this is a very motivating factor that we're hearing from clinicians out there and we believe our data stacks up extremely well in that consideration set.

Particular to that study, look, any evidence that raises the discussion around cardiovascular risk as it relates to prostate cancer is good for patients, but it's also good for ORGOVYX.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

Great. So current Bloomberg consensus, I believe calls for ORGOVYX's revenue of $55 million in fiscal year 2022, $568 million in fiscal year 2023, and $932 million in 2024. How do you feel about those estimates? Do they seem reasonable to you?

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**David C. Marek, Myovant Sciences Ltd.** - Principal Executive Officer & Director

Well, I'll let Frank weigh in on that. As you know, we're not providing guidance at this time. But Frank, why don't you address, if you would, please, the current consensus?

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**Frank L. Karbe, Myovant Sciences Ltd.** - Principal Financial & Accounting Officer

Sure. There's maybe a few points to note here. The first one is that the numbers you're citing on Bloomberg do not capture the entire pool of analysts that cover us. So it's a somewhat incomplete picture. Then secondly, I believe these estimates on Bloomberg do not differentiate between ORGOVYX and relugolix combination tablet. I believe those are actually combined numbers for the combined relugolix franchise. And then thirdly, if you look at those estimates in detail, you will find that they cover a very broad range, which leads to the fact that many variables at play, which are difficult to estimate this early in the launch.

Keep in mind that we are only a few short weeks into the ORGOVYX launch. And the launch for relugolix combination tablet is, of course, yet still to come, hopefully following approval, in June. So as Dave said, we're not providing revenue guidance at this stage. But what we can tell, I'll tie back to what Dave said earlier, we are hearing a lot of enthusiasm from both prescribers and patients. And we are optimistic about the long-term prospects for ORGOVYX, and its potential to become the standard of care for ADT.

We can also tell you that we are making good progress on the market access front in establishing coverage for ORGOVYX. But at the same time, I also always want to caution everyone that it does take time for practices, basically these large group practices, to incorporate a new product into that practice setting. And so that's just something to keep in mind, but long-term, we're very bullish.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

Great. That's helpful. Maybe moving to uterine fibroids, which women would be most appropriate for relugolix? And how many of them are there in the U.S.? And just what's your strategy for growing the market for oral GnRH inhibitors?

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**David C. Marek, Myovant Sciences Ltd.** - Principal Executive Officer & Director

Well, Laura, when we think of uterine fibroids, there's a tremendous opportunity there. We're looking at five million women with uterine fibroids and about three million, who are inadequately controlled on their

current therapies. And so when you look at that patient population, it's tremendously underserved. We know that most women are not satisfied with the current first-line treatment.

So now we look at what is the marketplace looking for in terms of the next uterine fibroids treatment. And it's really three areas that gynecologists tell us that they continue to focus in terms of serving their patients, and the first is just efficacy, symptom relief. And we have tremendous data in terms of reducing bleeding associated with uterine fibroids that we've seen in our LIBERTY program.

So efficacy is the first area that we know they're looking for. The second is safety. And safety as it relates, of course, to – or tolerability and safety as it relates to hot flashes but also bone mineral density. And when you look at the one-year data that we've had demonstrated with our LIBERTY program and soon, we'll be releasing two-year data with – in uterine fibroids around BMD. Again we feel like we stack up very well to provide that confidence that prescribers are looking for.

But the third area that's really specific to this category with gynecologists is really around simplicity. Simplicity of dosing, not only for them, but for their patients. And so when you think about relugolix combination therapy as a one tablet once-a-day solution, not only in uterine fibroids, but even eventually carrying it over to endometriosis. We're hearing from the provider community that, that's very motivating to them. So when you look at how we stack up against what the marketplace is telling us that they're looking for, then we see a broad range of patients post first treatment, that would be appropriate, if approved, with relugolix combination tablet.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

You mentioned the bone mineral density loss. What is your current thinking on how long women might stay on therapy, given the safety profile that you're seeing and patient need for chronic treatment?

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**David C. Marek, Myovant Sciences Ltd.** - Principal Executive Officer & Director

Well, you mentioned it. I mean the need is for chronic treatment. We fully expect that with treatment, that we would expect to see symptoms subside. But we also expect that upon discontinuation of treatment that symptoms would resume. So when we designed relugolix combination tablet, we designed it with longer-term treatment in mind. Now of course, we're in discussions with FDA right now, so I can't comment on the regulatory status, but we have provided the BMD data that we have to date. And as I mentioned, we have additional BMD data that's coming. So we certainly understand that this is – these are long-term diseases that require long-term treatment. And we've really felt like the design of relugolix combination tablet plays to that dynamic.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

How important is reduction in fibroid volume to women with uterine fibroids? Do you expect physicians to prescribe maybe a short course of Lupron to get that reduction in fibroid volume and then switch to relugolix for long-term treatment to try to maintain that reduction? Or should we think about it less in terms of fibroid volume and more in terms of the blood loss?

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**David C. Marek, Myovant Sciences Ltd.** - Principal Executive Officer & Director

Well, I think what clinicians tell us they're looking for is symptom relief. So let's play that out. The first area that they're looking for in symptom relief is blood loss and the reduction of that. And our data is very strong there. So when we look at fibroid volume, what is the downstream impact of that and it really impacts pain. And so I think when you look at the pain scales that we've measured and the reduction in pain in uterine fibroids, that's what we feel like gives clinicians motivation with our clinical profile. So it's really the pain as part of the symptomatology that many times they're managing. And so we feel like for that reason, or – I'm sorry, relugolix combination tablet would be still an ideal therapy, and that's what we're hearing from clinicians as well.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

Okay. Got it. And then how are you thinking about the launch relative to AbbVie's therapy, ORIAHNN? And why might your launch be different?

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**David C. Marek, Myovant Sciences Ltd. -** Principal Executive Officer & Director

Well, first, it starts with an understanding of the marketplace. And when you understand what the marketplace is asking for, I mentioned the three areas that we feel like our product profile really aligns ideally with what the gynecologists are telling us that they're looking for. That's in the symptom relief or the efficacy, in the safety and tolerability as well as kind of the simplicity of dosing and the convenience.

So that – it starts with the clinical profile, but it's also how we enter the marketplace. And I think one of the things that we want to make sure is that when we are looking at patients, we know that it's not taking share from other therapies that may not even have significant share. It's more how do we activate a marketplace and get the appropriate therapies to women who need those.

And so therefore, we're really going to look at how do we activate the appropriate women to talk to their physicians about treatment and what's important to them. And we know in our relationship now with Pfizer, that we have a partner, who is at the top of the game in terms of reaching patients, and making sure that they connect with patients or that we connect with patients to drive them to have the appropriate discussion with their physician at the right time, once we've established the brand and once coverage is there. And we think that, that – those will be key differentiators in terms of connecting with women and encouraging them to have the right discussion with providers, who will then look at relugolix combination therapy as an ideal solution to what those patients are looking for.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

What about on pricing? Do you expect to price relugolix at a discount to ORIAHNN? I know you're probably not going to want to give too much detail there, but I'm going to ask anyway.

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**David C. Marek, Myovant Sciences Ltd. -** Principal Executive Officer & Director

Yeah, Laura, you saw my smile before you finished the question. But you know what, look, it's a fair question. I think when we consider pricing, of course, we know that we're going to have benchmarks that

we're going to be compared against. And you're right, we're not at a point where we have landed on what the price will be and certainly an announcement of that.

But what I would say is that innovation has value. And when we look at our product profile against the current available options and other options that may come, we think that innovation is going to deliver a differentiated experience for patients. And we'll take that into consideration when we think about pricing.

So we haven't landed on what that price is, but there's certainly permission to believe that we have a differentiated profile, and that profile should add value.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

Great. So let's move to endometriosis, which women with endometriosis would be most appropriate for relugolix? And how many of those women are there in the U.S.?

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**David C. Marek, Myovant Sciences Ltd. -** Principal Executive Officer & Director

Yeah. Certainly, Laura, we're looking at a patient population of about 8 million women and about 6 million of those women experience really debilitating symptoms. And when we look at who fails first-line therapy or let me just say that differently, who are failed by their first-line therapies, it's about 1 million women, where first-line therapy does not address what they needed to address. So substantial patient population that we're looking at.

And once again, when you look at the same providers that are treating uterine fibroids and the same request that they have for an innovative therapy, they fall into the same categories. So you're looking at symptom reduction. Now we're talking about pain reduction. You're looking at the same areas of safety and tolerability. Our data on things like hot flashes, et cetera, comparable to placebo, but we also have the BMD data in endometriosis as well, that looks very favorable.

And then once again, the convenience of having one tablet once a day, same brand name in uterine fibroids and endometriosis, and the same dosing, we think that simplicity, not only for providers, but ultimately for patients, will be something that will matter to them as well.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

Yeah. In endometriosis, I'm curious how you think about the competition from AbbVie and whether you see that as any different in this indication? And again, what you believe might be the barriers limiting uptake there? I mean you've mentioned the importance of convenience and the once-daily pill. Anything else that's unique to the endometriosis indication?

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**David C. Marek, Myovant Sciences Ltd. -** Principal Executive Officer & Director

Well, Laura, I'll say again, I think our biggest competitor is practice patterns. It's apathy to the marketplace. It's getting women, who deserve a better treatment, to have the right discussion and to have a chance to have a different therapy. And so our focus is really how do we serve those patients and how do we serve the providers. And we believe that, yes, our clinical profile stacks up extremely well against what the marketplace is looking for. So we have strong permission to believe that if the right conversation

happens, that relugolix combination therapy is going to be, ultimately, we believe, has the potential to be the standard of care in not only uterine fibroids, but also endometriosis.

But it's also how we go to market, how we engage with providers, how we engage with patients and how we connect them as well as even our advocacy efforts to help draw more attention to things like social stigma and gaps in care and other areas. So we'll have a broader – more broad approach to how we look at the therapeutic area and where we can have points of value along the way in addition to our differentiated clinical profile.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

Great. And then in terms of duration of therapy, I'm curious if you have a sense of what proportion of endometriosis patients taking ORILISSA, AbbVie's drug are on the six month course at a high dose versus 24 month course at a low dose, and what your sense is on the average treatment duration with those regimens? And kind of what women ideally would be looking for that those regimens either are or are not addressing?

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**David C. Marek, Myovant Sciences Ltd. -** Principal Executive Officer & Director

Yeah. I think your question speaks volumes. Because the very discussion around which patient is on which dose for how long, that speaks to one of the areas that relugolix combination therapy gets to address. Because you don't have to have the discussions around which patient, which dose, which duration.

We'll see where our discussions ultimately land with the FDA. However, that's the very problem that we're solving for with relugolix combination therapy, to keep it simple and straightforward. So while AbbVie will have much better information on which patient falls into which dose and for how long, what I'm pleased about is we don't have to have that discussion on our end, and that's what we're excited about. And that's what our providers are telling us is exciting about the prospects for relugolix combination therapy.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

I know ORILISSA is also in a Phase IIIB trial in endometriosis with add back therapy. And that's completed and AbbVie intends to add add-back therapy to ORILISSA's label. How might this change the average duration of therapy with ORILISSA's product and then relugolix's competitive position? I think I know some of what you'll say, but curious to hear it anyway.

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**David C. Marek, Myovant Sciences Ltd. -** Principal Executive Officer & Director

Well, Laura, and you're right, because I think I've characterized a little bit about what the marketplace is looking for and how we consistently – when we talk about these different topics, it really reinforces that we've designed relugolix combination tablet in the right way, because we don't have to continue to go back to all these different dimensions. And if you're one of the providers right now and you're trying to sort through all of this, again, which patient, which dose, add-back therapy, not, et cetera, wouldn't it be great if you had one therapy for uterine fibroids and the same therapy for endometriosis, and you had one dose, and it was once-a-day and that would take care of the patients that you're trying to serve. And

I think – so these questions just reinforce our conviction around why we're bringing a very differentiated offering to the marketplace, that is still remain – wanting for a therapy like relugolix combination tablets.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

Perfect. I'll just finish with a couple of quick questions on the Pfizer collaboration. I guess first, what factors do you believe Pfizer will consider in determining whether to commercialize ORGOVYX in Europe? And then secondly, how achievable are the sales milestones? And what's the likelihood you might receive all $3.5 billion?

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**David C. Marek, Myovant Sciences Ltd. -** Principal Executive Officer & Director

Yeah. Laura, I'll let Frank weigh in on this. Just as kind of an intro, we could not be happier with the fit and the partnership that we've already had with Pfizer. The ideal partner for prostate cancer, ideal partner for women's health. And I can tell you that in the first few months, our partnership has been very strong, and we've made a lot of progress. So I'd just say that as a little bit of an intro, but I'll turn it over to Frank to answer your questions more specifically. Frank?

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**Frank L. Karbe, Myovant Sciences Ltd.** - Principal Financial & Accounting Officer

Yeah. On your first question, I mean that's – what factors might factor into Pfizer's opt-in decision. That's really a question to them. But I do want to remind everyone that we're in the final stages of finalizing our MAA submission. We've said that we intend to submit later this month. And we also expect that we will have a decision from Pfizer on whether or not they opt in, in the first half of this year. And by the way, their right to opt-in covers more than just Europe. I just want to clarify. There's sometimes some confusion around this.

In fact, [it] covers all territories outside the U.S. and Canada, which under – which are sort of the co-promotion territories under the collaboration and outside of Asia, because Asia is owned by Takeda. So covers all other rest of world territories. And then I think you had a second question. Remind me of about what that was?

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

Yeah. Just on the sales milestones?

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**Frank L. Karbe, Myovant Sciences Ltd.** - Principal Financial & Accounting Officer
Yeah, the sales milestones, yeah, sorry. Yes. So the first thing to note is sales milestones, there are separate sales milestones for prostate cancer and for the women's health indications. In both cases, the milestones are tiered. And while we have not disclosed what the tiering is, I would say it's sort of typical with what you might have seen in other arrangements of this kind. We believe that many of the milestones are readily achievable for us and then maybe some – at the higher end of the range are perhaps a bit more ambitious. And they're there really to ensure that Myovant is adequately compensated in the event that the relugolix franchise reaches the potential that both Pfizer and us believe it has.

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**Laura Christianson, Cowen and Company, LLC**, Research Division - Research Associate

I think we're on our countdown for wrapping up this chat. So I think we'll close it there, and I just want to thank all of the people who have listened in. And then also you, Dave and Frank, for your commentary and for participating in our conference, it has been great to see you both, albeit virtually. And yes, looking forward to next time.

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**David C. Marek, Myovant Sciences Ltd. -** Principal Executive Officer & Director

Thank you for the opportunity, Laura, and thank you to everyone who joined us virtually.

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**Frank L. Karbe, Myovant Sciences Ltd.** - Principal Financial & Accounting Officer

Bye-bye.

**DISCLAIMER**



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