

# EDITED TRANSCRIPT

## MYOV – Myovant Sciences, Inc. at Baird Global Healthcare Conference

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### OVERVIEW:

Myovant Sciences presents at the Baird Global Healthcare Conference

## CORPORATE PARTICIPANTS

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

**Juan Camilo Arjona Ferreira**, Myovant Sciences Ltd. - Chief Medical Officer

**Lauren Merendino**, Myovant Sciences Ltd. - Interim Chief Commercial Officer & Director

## OTHER PARTICIPANTS

**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

## PRESENTATION

**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

All right, good afternoon, everyone. Welcome back to the Baird Healthcare Conference. I'm Brian Skorney, one of the Senior Biotech Analyst here at Baird. Very glad to have with me as the next fireside chat presentation, the management team from Myovant Sciences. It's a name that I do currently have under coverage. They are focused on developing a number of opportunities, most notably a program that straddles between prostate cancer and women's health, the drug ORGOVYX in various indications.

So I'll let the management team to take a couple of minutes here to provide a brief intro of the opportunities by the consumers before we get to Q&A. If anyone has any questions, there is a button on the upper right hand corner of your screen, feel free to click that and it will send an email for me and I'll ask a question on your behalf. So without further ado, David and team, thanks so much for joining us today. Really happy to have you here as I said. Maybe you could just kind of kick it off, give us a little bit of an overview as to what you guys are focused on right now.

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

Well, thanks, Brian. We really appreciate the opportunity to speak with you and the audience today. We're at an exciting time with Myovant. We were founded and IPO'd back in 2016 as an independent company. We set our mission to really redefine care for women and for men. And we wanted to do that through really cutting edge science as well as highly differentiated therapies, but importantly also regarding transformative advocacy. So those are the three pillars in which we operate.

Our lead molecule is relugolix and around that we built a strong development capabilities as well as regulatory capabilities while conducting our five successful Phase 3 programs across three different indications. So we now sit with two FDA approvals since December of 2020, ORGOVYX for advanced prostate cancer and MYFEMBREE for uterine fibroids.

And so for ORGOVYX, we're very proud that that is the first and only oral GnRH antagonist available for the treatment of advanced prostate cancer and we feel like we really have an opportunity to disrupt the marketplace, which is really dominated by the older injectable GnRH agonists. And then for MYFEMBREE, that also has a place of distinction as the first and only once daily oral GnRH combination that's available for the treatment of uterine fibroids. And there again we have a tremendous opportunity to help many women who were impacted by uterine fibroids today and then over time, we hope for endometriosis down the road as well, both very large markets with high unmet needs.

So we've recently evolved from a development organization to a very strong commercial organization and that's also been fueled by partnerships with Gedeon Richter outside the U.S. and currently partnering with Pfizer on commercial and development capabilities here in the U.S. So very exciting time for Myovant.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Great. That's a wonderful overview to start. Maybe, we can begin talking with ORGOVYX, it seems like it's the primary investor focus right now. There are lot of things that investors are focused with you guys. So for those of us who are less familiar, maybe just getting a brief overview of the product, the GnRH pathway and how ORGOVYX is really amenable to treating prostate cancer? And how it compares with other available androgen deprivation therapies?

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

Yeah, certainly, Brian. I'll start and maybe I'll turn it over to Juan Camilo to add, but prostate cancer is the most common cancer diagnosis, second most common cause of cancer death in men in the U.S. Today there is about 3 million men in the U.S. living with prostate cancer. About 300,000 of those men are treated with androgen deprivation therapy or ADT with 100,000 men that will initiate ADT therapy this month -- or I'm sorry, this year. And so the unmet need really remains high in this therapeutic area and we're very proud with the therapy that we've been able to bring forward with ORGOVYX. And for that, I'll turn it over to Juan Camilo to really describe the unmet need and how ORGOVYX we feel can really help fill that opportunity. Juan Camilo?

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Juan Camilo, I think you're on mute.

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**Juan Camilo Arjona Ferreira**, Myovant Sciences Ltd. - Chief Medical Officer

Yeah, I think I got muted when we transitioned to this room, sorry.

As I was saying, prostate cancer is sensitive to testosterone, it's actually fueled by testosterone. So for a long time, the initial therapy has been to reduce testosterone that's been done in many ways by the most common way it is done today with LHRH agonists that are injectable. What we're bringing with ORGOVYX as a GnRH antagonist that is slightly different mechanism that had some benefits. So the issue with LHRH agonists, or the standard of care today, is that they stimulate this testosterone first. So you will get a surge of testosterone before you desensitize the system and then get to suppression of testosterone which is the intended goal. Because of that, you had -- it takes longer to suppress testosterone. There are patients that get worse symptoms because of their testosterone going up. And then the PSA, which is a marker of the treatment of the disease, it takes longer to be reduced.

And then because they are injectable depot formulations what is today, after the patient -- some patients may be able to stop their treatment, their testosterone will not recover for a long, long time. So when you talk about an antagonist that directly inhibits production of testosterone the reduction is very rapid, very profound, which is what you want to see for the treatment of the disease. And then because

it's oral in ORGOVYX than you can get a rapid return off of a testosterone when the patients can have it, which can have a significant impact in the quality of life of these men.

In addition to that, the LHRH agonist had multiple warnings and precautions in their label, cardiovascular disease, diabetes, glucose metabolism issues, convulsions, and I think that also makes a difference. We've shown with the data from our HERO program -- HERO study, the Phase 3 study that supported registration that the -- not only the efficacy, but also the safety profile with low incidence of cardiovascular disease and a well tolerated safety profile.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Okay. So now with the launch of ORGOVYX now underway, still in the early days, but what sort of metrics are you really looking at to evaluate the early part of the curve here and determine success?

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

Yeah, Brian, for us it always starts with patients and delivering for patients, but I'll let Lauren provide a little more color around that. Lauren?

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**Lauren Merendino**, Myovant Sciences Ltd. - Interim Chief Commercial Officer & Director

Sure. So, of course, we're monitoring a lot of metrics at this point launch, but the three most important are, as Dave was mentioning number one, the number of patients. And through the end of June, we've estimated that over 4,500 men have been treated with ORGOVYX. Now keep in mind that includes both commercial patients as well as those who have received free drug, which is about a third of those patients. And more importantly, the patient volume continues to grow steadily month-over-month.

The second metric we look at is the breadth of the customer base. So in the first six months of launch, we were able to reach 88% of our Tier 1 prescribers and that's led to over 1,150 treatment centers utilizing ORGOVYX as of the end of June. And 80% of them have reordered. And in general, we see these accounts growing in their use over time.

And then the third metric that's really important at this stage of our launch is the expansion of payer coverage. So as of July, we had over 150 million total lives covered and that breaks down to 63% of lives covered on the commercial side and 78% on the Part D Medicare side. And so, ultimately, the success of our launch is going to be defined by the net revenues that we generate, but we believe the foundation we're laying today will support a significant revenue opportunity over time.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Great. So, Pfizer is clearly a very strong player in the prostate cancer space, maybe you can talk a little bit about what that partnership adds in terms of your ability to commercialize ORGOVYX?

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

Yeah, absolutely, Brian. Just to frame the relationship with Pfizer that we cast at the end of December, this is really a transformative relationship for us. What it does first and foremost, we really believe that Pfizer was the ideal partner because of their presence not only in prostate cancer, but also in women's health. So when we looked at our two core therapeutic areas, they have clear strengths and history of success in both of these areas. So our collaboration covers ORGOVYX and MYFEMBREE in U.S. and Canada and it's broad in scope. It covers not only the commercial aspects, so sales force -- we have our sales force, they have their sales force for each of those therapeutic areas, the marketing aspects as well as support for payer. But it also covers medical affairs, it also covers our development of relugolix across both of those areas. So it's very broad and we've had a tremendous early relationship with Pfizer.

Importantly, it also helps us with our balance sheet because now resources that we would have been solely dedicated towards commercialization, for example, now we can look at broadening our view of the relugolix pipeline, what can we do in terms of lifecycle management and also frees up resources to be able to build our pipeline outside of relugolix as we look to business development and other means to extend our pipeline.

So the collaboration is very broad in nature and we're off to a great start. Specific to ORGOVYX, how does that -- well, when we think of our field force, they have an existing field force that's calling in the prostate cancer markets, we're able to leverage those relationships and experiences in addition to what we have built for Myovant with an equal size sales team and then, of course, with their XTANDI experience, an oral prostate cancer regimen that's co-administered with an ADT like ORGOVYX, it makes for a highly efficient and effective sales call for their team. So we're off to a great start in the collaboration from the sales efforts, from the marketing and payer efforts, but also from medical affairs and development as well.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Great. So I think there is an upcoming opt-in decision from Pfizer, I think it's for the end of October, I guess can you remind the audience a little bit of a context around the opt-in and why the decision deadline was extended?

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

Yeah. So thank you, Brian. What I referenced was the collaboration in the U.S. and Canada. Outside the U.S., we have a partnership in women's health with Gedeon Richter. And the opt-in decision for Pfizer was they really wanted the right of first refusal for oncology outside the U.S. and Canada and certain Asian markets. As we approach the mid-year, which is when we were planning on kind of a landing the decision there, we talked about some of the business assessment that was occurring at Pfizer and the need for to really extend that timeline to allow that assessment to continue. As I mentioned, we have a great relationship with Pfizer, we've been having very good discussions and so it felt that it just made sense for both sides to say, hey, why not go ahead and extend this.

We're very pleased with how the U.S. has been progressing in terms of ORGOVYX and the success we've had early on. What they were very clear is that this is not about any concerns around safety or efficacy related to ORGOVYX or the EU regulatory approval process, et cetera. It's just really time for

them to conduct the diligence that they need and that extra time felt warranted. So now we look to the end of October for that decision.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Great. Then switching back to kind of the commercial progress with ORGOVYX. Can you give any color in terms of how commercial access and insurance coverage is going, how you're working through insurance plans and any kind of path on how secured Medicare reimbursement goes?

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

Yeah, certainly. Lauren, do you want to take that one?

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**Lauren Merendino**, Myovant Sciences Ltd. - Chief Commercial Officer & Director

Absolutely. So, we've been very pleased with the progress we've been able to make on access. And through June, as I mentioned, we had -- we have over 150 million lives covered. For commercial, that's about 63% of lives and for Part D it's about 78%. And to your question about Part D, in particular, we continue to work with the remaining plans that have not yet made a decision. Some of them will make decisions by the end of this year, but we anticipate that many will wait for the new year to implement.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Great. And then what if anything I guess would be the next quarter about? Why should we paying an attention to on the next quarter data wise to sort of assess where you are in the launch?

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

Yeah, Lauren?

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**Lauren Merendino**, Myovant Sciences Ltd. - Chief Commercial Officer & Director

So those same three parameters that we talked about earlier, so the number of patients, the breadth of the customer base and then we'll continue to update you on the progress we've made on the payer coverage.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Okay. Maybe moving onto women's health for a little bit, we can jump into that franchise. So maybe talk a little bit about the combination tablet approach here and providing some additional context to those who are familiar with the way in which relugolix acts in sort of the endometriosis uterine fibroid landscape.

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

Yeah, I'll let Juan Camilo address that. Just as an intro, at Myovant, we're very focused on understanding what the market need is and making sure that we are developing differentiated therapies that can meet the needs. And certainly there is a high unmet need in both uterine fibroids and endometriosis. So drug design was very important in terms of fulfilling what we believe the market was really looking for. So Juan Camilo?

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**Juan Camilo Arjona Ferreira**, Myovant Sciences Ltd. - Chief Medical Officer

Yeah. And in a little bit of a parallel to what we just discussed for prostate cancer, uterine fibroids and endometriosis are both driven by estrogen, the hormone in women. So you can use relugolix to reduce the levels of estradiol that -- to improve the symptoms of these two conditions. The approach that we took was different, which is that combination approach. In the past drugs that reduce estrogen have been used, but that leads to a lot of hot flush and other symptoms as well as loss of bone density, which have limited the duration of treatment. So we designed our combination in a way that brings estradiol levels to a predictable range that improves the symptoms of uterine fibroids or endometriosis, but without the hot flashes and the significant bone loss that would allow for a longer duration of treatment, which is what is needed for these conditions that are mostly treated surgically, but many women do not want surgery and have been waiting for an oral option.

And what we've learned from -- I'm a gynecologist by training -- and we've learned from my experience but also talking with other gynecologists is they want a simple solution, a solution that provides predictable efficacy, that provides also a predictable safety profile that is well tolerated by their patients and that is simple for them and their patients in terms of the prescription and use. And we believe that our commission in MYFEMBREE is -- provides that as a single, like once daily oral drug that treats the symptoms with a good safety profile. And that, if approved by the FDA, will be the same brand, same dose and dosing regimen for both uterine fibroids and endometriosis.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

So I think you commented on a little bit on it, but I love to dig in a little bit on some of the competitive landscape and differentiation here. Obviously there is a product out there ORLISSA -- or elagolix -- compared to MYFEMBREE and relugolix that has really kind of sputtered and I would say it's kind of disappointed in terms of its commercial launch. I mean, how do you kind of see the commercial impact of that drug and where do you guys think you can really improve on that profile and do better?

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

Yeah, Lauren?

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**Lauren Merendino**, Myovant Sciences Ltd. - Chief Commercial Officer & Director

Yes, so there's really three ways that we will be differentiating our launch from predecessors. And first of all, our product profile as Juan Camilo mentioned, we received a lot of positive feedback from our customers on MYFEMBREE, both on the compelling and consistent efficacy data and equally attractive safety and tolerability profile including low incidence of hot flush and our BMD data. And then, of

course, the simplicity of the one pill once a day. So, we believe in the strength of our product profile as a differentiator.

The second way that we will differentiate is on providing an optimal first experience. So very early in our launch. We provided starter packs for physicians to start to get trial with our drug. We also have co-pay card and other patient support programs available because, as you know, early in launch, it takes time to establish payer coverage. And so we want that process to be smooth and simple for the physicians. And so we believe that the programs that we put together will deliver a positive first experience for both patients and prescribers.

And then the third way is really through our field execution. So, in partnership with Pfizer, we have two experienced women's health teams that can be deployed strategically and there is a broad base of prescribers for uterine fibroids. And so it allows us to be strategic and how we activate those prescribers effectively by having two separate teams that we can flex.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Got it. And when you kind of think about securing reimbursement insurance coverage, what sort of a value proposition that you're taking to payers to try to get them to allow reimbursement for patients with heavy menstrual bleeding and uterine fibroids?

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

Yeah, Lauren?

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**Lauren Merendino**, Myovant Sciences Ltd. - Chief Commercial Officer & Director

So the response from payers has been very positive and it's primarily driven by our clinical profile as I -- as Juan Camilo and I just mentioned. And so that's really been the driver of those conversations and we're making great progress there.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

But I think, you've noted before there's about \$250,000 -- 250,000 hysterectomies a year due to uterine fibroids in the U.S. I'm just wondering how you kind of position MYFEMBREE as a bridge -- I guess, not a bridge, but an option instead of a hysterectomy is obviously pretty costly to payers and not the ideal intervention from probably most women's standpoint. So how do you kind of contextualize surgical intervention with medical treatment here?

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

Yeah, Juan Camilo, maybe you could take that one.

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**Juan Camilo Arjona Ferreira**, Myovant Sciences Ltd. - Chief Medical Officer

Yeah, I think that -- we think about it in a way broader way, Brian. Of course, there is that subset of women that are getting to basically at the end of their options and choose even if they don't want to to have a hysterectomy. What we know is the majority of women that are offered a hysterectomy wouldn't want to have one. But there is a larger pool of women with uterine fibroids and symptomatic -- that are symptomatic. There is around 5 million women in the United States that have uterine fibroids and symptoms of whom 3 million have been failed by first line therapy.

So we think that, yes we want to get to those patients that may prevent or delay or prevent fully the need for hysterectomy, but we also want to get to those women that are suffering in silence that believe that their only option is hysterectomy, so they declined to go to the physician. And with this option -- with their profile that we just described, Lauren and I, I think that they will be interested in hearing more about what they can do to manage their symptoms, which are pretty debilitating for many.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Great, great. So you're now up and running with the launch in uterine fibroids, you also have an PDUFA in endometriosis, congrats on that. Maybe you could just kind of compare and contrast the two indications and where you kind of see the opportunity for endometriosis medical intervention versus UF.

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

Sure, Juan Camilo?

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**Juan Camilo Arjona Ferreira**, Myovant Sciences Ltd. - Chief Medical Officer

Yeah. I think that the number of women with endometriosis is a little smaller, but still a significant opportunity. There is around 6 million women with endometriosis in the United States and around 1 million have failed first-line therapy. And the issue with endometriosis is that the diagnosis is usually delayed since it may start very early in life. But for many reasons, normalization of symptoms and patients are cycled through different therapies, anti-inflammatories, non-steroidal anti-inflammatories, contraceptives, multiple rounds of that and the diagnosis can be delayed by 7 to 10 years, but then after that, surgery becomes the option.

So we believe that having a profile like the one we described before and we have shown with our data that it has a similar profile of endometriosis, it's predictable efficacy, a good safety profile and same simplicity is going to be appealing to women and to the gynecologist that, as I mentioned before, they want simplicity. So we're very excited about what we will be able to do to help these women if we're approved by the FDA for that indication.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Great. And then another indication you're pursuing is via the SERENE study. I was hoping to get a little context for that study. I think there was a -- I think, hopefully, very temporary clinical hold there, but we'd love to kind of hear any updates on resolution there.

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**Juan Camilo Arjona Ferreira**, Myovant Sciences Ltd. - Chief Medical Officer

Yeah, I'll take that one too. I'm happy to report that as we had said during our earnings call that in August the FDA has lifted the hold, so we are back on going with the study. Part of the discussion we had with the FDA led to an update on the study population before we were aiming for healthy women in search for contraception. Now we will be studying women with uterine fibroids and heavy bleeding or endometriosis and pain that are seeking for contraception, which is the population that ultimately will benefit from this indication. We've also increased a little bit the sample size from 900 patients before to around 1,020 patients. And then we are reactivating all our sites and we're going to expand all that in number of sites. And we've already screened our first patient and look forward to reporting when we have our first patient dose, so we're back on with the study ongoing.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Great. And now I know you guys are probably almost always bombarded with relugolix questions all the time, but you do have another asset MVT-602, an oligopeptide kisspeptin-1 receptor agonist. Maybe you could just give us a high level overview of the Phase 2 study there and what the next steps are for that program?

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

Sure, Juan Camilo?

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**Juan Camilo Arjona Ferreira**, Myovant Sciences Ltd. - Chief Medical Officer

Yeah. We're excited about that program, not only because of what we've seen already in the Phase 2 study that we conducted in the IVF setting, but because it has a multi-indication possibilities like relugolix does. So we are -- we've spend last few months looking at all the options that we have in our hands and we are finalizing our plans for how we're going to take this forward and including the -- what we're going to do with the fertility part of the program, but also where else we can take it so that we can maximize that asset and help more patients. We look forward to reporting that soon to everyone.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Great. I do have a question from an investor here. What is the outlook for partnering with a companion diagnostic in the area of endometriosis with companies like Aspira who are working on with the FDA for fast-tracking EndoCheck test? That'd be interesting, are there any efforts collaboration to try to more broadly identify patients with endometriosis?

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

Yeah. I mean, I can just say from a broad perspective, I think one of the benefits of our relationship with Pfizer as it does really help us put a spotlight on our business development efforts even more broadly. And certainly we are looking at a broad definition around business development and certainly partnerships, such as the one mentioned would certainly be within our scope of consideration.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Got it. I think we're running up against time here and so I'll throw my last question. To just say, it's lot we've discussed here. There could be a lot more that we could discuss, but if there's anything that you really love to highlight that we haven't discussed here that you think investors should focus on with Myovant, please we'd love to hear that now.

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

Yeah. Thank you, Brian. Look, we're off to a great start with our two launches that we mentioned. I think we're certainly getting prescriber uptake and we're pulling through payer coverage on ORGOVYX. On MYFEMBREE, we're seeing a lot of early signals of momentum with the starter pack, hub enrollments and even the discussions that we're having about extending payer coverage.

And we have some important milestones through the remainder of this year. We're looking at the Pfizer opt-in decision that we mentioned. We didn't really talk about Europe for women's health, but RYEQO, which is the European name for MYFEMBREE, we've got the EMA submission for endometriosis that will be managed by our partner Gedeon Richter.

Later this year, we anticipate the FDA submission of our randomized withdrawal study results for MYFEMBREE in uterine fibroids that includes our two-year bone mineral density data, which is very differentiating in the space. And then when we look to early 2022, we anticipate reading out the SPIRIT two-year long-term extension results for endometriosis. In May of 2022, we also anticipate the FDA decision regarding our sNDA filing for endometriosis. And then, we anticipate the EC decision for advanced prostate cancer somewhere around mid-2022.

So we have a lot of upcoming milestones that we're very excited about. We remain at a very strong financial position, which gives us a lot of flexibility to fund our product launches while also building our pipeline. So very exciting time for Myovant with a lot going on and a lot of opportunities ahead.

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**Brian Peter Skorney**, Robert W. Baird Research Division – Senior Research Analyst

Great. I really appreciate the time today, fascinating discussion. As always, I look forward to speaking with you all very soon. Everyone on the line, thanks so much for joining and hope to see some of you in the next session. Take care, everyone.

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

Thank you Brian.

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