EDITED TRANSCRIPT

MYOV – Q1 2021 Myovant Sciences, Inc. Earnings Call

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OVERVIEW:
Co. reported fiscal first quarter 2021 financial results and provided a general business update.

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PRESENTATION

Operator

Good day, everyone, and welcome to Myovant Sciences' First Quarter of Fiscal Year 2021 Earnings Conference Call. Today's call is being recorded.

At this time, I would like to turn the call over to Ryan Crowe, Vice President of Investor Relations at Myovant. Please go ahead.

Ryan Crowe, Myovant Sciences Ltd. - Vice President of Investor Relations

Thank you, operator. Good morning, and thanks for joining us today to review the financial results of Myovant's first quarter of fiscal year 2021 and to discuss other corporate and business updates. Joining me for today's call are Dave Marek, Myovant's Chief Executive Officer; Frank Karbe, President and Chief Financial Officer; Lauren Merendino, Chief Commercial Officer; and Dr. Juan Camilo Arjona, Chief Medical Officer.

In addition to the press release issued earlier today, the slides that will be presented during today's webcast are available on our Investor Relations website, investors.myovant.com. Today, we will be referring to our fiscal first quarter, which ended on June 30, 2021, as our first quarter or Q1 throughout this presentation.

During the course of this conference call, we will be making forward-looking statements. These include plans and expectations with respect to our products, product candidates, strategies, opportunities and financials, all of which involve certain assumptions of risks and uncertainties that are beyond our control and could cause actual results to differ materially from these statements.

A discussion of these risks can be found in our SEC disclosure documents. In addition, Myovant does not undertake any obligation to update any forward-looking statements made during this call.

I'll now turn the call over to Dave Marek Myovant's Chief Executive Officer. Dave?

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

Thank you, Ryan, and good morning, everyone.

Myovant's 2021 fiscal year is off to a strong start, marked by accelerating commercial momentum in the U.S. and significant regulatory achievements that will enable us to bring our differentiated therapies to more and more patients. In our first quarter, Myovant recorded $41.1 million of total revenue, including $11.6 million of product revenue and $29.5 million of Pfizer collaboration revenue.

During its second quarter on the market, ORGOVYX achieved revenues of $10.5 million, reflecting strong sequential growth quarter-to-quarter. This continued growth reflects increasing enthusiasm from clinicians regarding the differentiated clinical profile of ORGOVYX as well as increased payer coverage. We're also pleased with the FDA approval and June launch of MYFEMBREE as the first and only once-daily oral treatment for women with uterine fibroids.

We achieved revenues of $1.1 million, reflecting initial inventory stocking by distributors. We and Pfizer conducted a simultaneous launch and remain excited to bring this differentiated profile to the millions of women battling uterine fibroids, where high unmet need remains.

From a regulatory standpoint, we've achieved several significant milestones over the past few months. In addition to the FDA approval of MYFEMBREE, the European Commission also approved RYEQO, the European brand name for relugolix combination tablet. The commercial launch of RYEQO is expected to begin in the second half of this calendar year and will be executed by Gedeon Richter, Myovant's commercialization partner for RYEQO in Europe.

The approval of RYEQO is notable for a couple of reasons. Not only is it the first once-daily oral treatment for women with uterine fibroids approved in Europe, it's also the first treatment that does not have a limitation on duration of use. Recall that our European regulatory submission included 2-year bone mineral density data from a Phase 3 LIBERTY randomized withdrawal study, whereas those data were not available at the time of our FDA submission. We do intend to submit the two-year BMD data to the FDA later this year for potential inclusion in the MYFEMBREE label.

Also, for MYFEMBREE in early July, we submitted a supplemental NDA in the U.S. seeking approval for the management of moderate to severe pain associated with endometriosis. And finally, in response to the FDA partial clinical hold regarding the Phase III SERENE study for MYFEMBREE to evaluate the prevention of pregnancy, in July, we provided the FDA with an amended study protocol, where we're incorporating BMD monitoring as well as modifying the study population, per their guidance, to better support the prevention of pregnancy claim in women for whom MYFEMBREE's indicated. Following further discussions with FDA, we expect the partial clinical hold to be lifted next month.

Turning to business development and intellectual property updates. Myovant and Pfizer recently agreed to extend the time line for Pfizer's decision regarding its option to acquire development and commercialization rights to relugolix in oncology in Europe and other international markets through the end of October.

In June, we also took another step in protecting our intellectual property as we were issued a new methods of treatment patent, which could expand the exclusivity period for MYFEMBREE and uterine fibroids. This patent joins 2 other methods patents previously granted for ORGOVYX for treating advanced prostate cancer, all of which are now listed in the FDA Orange Book with expirations in September of 2037.

And finally, we continue to be in an excellent financial position with cash and committed financing of over $600 million as of June 30, excluding $115 million of recently triggered regulatory milestone payments from Pfizer and Richter.

We're excited about the opportunity that we have with MYFEMBREE to redefine care for women with uterine fibroids. And we continue to be encouraged by the continued launch momentum for ORGOVYX.

Now for a more in-depth review of our commercial performance, I'll turn the call over to Lauren. Lauren?

Lauren Merendino, Myovant Sciences Ltd. - Chief Commercial Officer

Thanks, Dave. Today, I'll provide an update on the early progress we have made in the launch of MYFEMBREE followed by an update on the ORGOVYX launch.

MYFEMBREE was approved by the FDA in late May and is the first and only once-daily oral treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women.

We believe MYFEMBREE has the potential to be a truly meaningful advance in women's health and could become the standard of care medical treatment for women with uterine fibroids. The unmet need in urine fibroids is enormous. Approximately 5 million women in the U.S. has sought treatment for symptoms of their uterine fibroids. Of these women, 60% are failed by first-line therapy, typically oral contraceptives, which are unable to control their most challenging symptoms. Even though 2 out of 3 women prefer a medical option versus surgery, approximately 250,000 women per year in the U.S. make the difficult choice to undergo a hysterectomy for relief from their uterine fibroids. Myovant and Pfizer are united in our goal to provide these women with an effective, well-tolerated and convenient medical option.

We believe MYFEMBREE aligns well with physicians stated treatment goals of meaningfully improving heavy menstrual bleeding and other challenging symptoms with minimal side effects in an easy and convenient dosing regimen.

MYFEMBREE has the potential to redefine care for women with uterine fibroids because it meets the treatment needs for this market. In the LIBERTY clinical trial program, MYFEMBREE demonstrated sustained and meaningful reduction in menstrual blood loss. Hot flush, a particularly bothersome side effects, occurred in less than 11% of MYFEMBREE patients, not meaningfully different than the approximately 7% of patients treated with placebo.

In the LIBERTY clinical program, the average decline in lumbar spine bone mineral density at 12 months was under 1%. However, due to the risk of continued bone loss, the duration of use in FDA label is limited to 24 months. Finally, MYFEMBREE achieved all of this in one small pill taken just once a day.

The Myovant and Pfizer commercial teams have worked collaboratively to meet the operational milestones required to position MYFEMBREE for a differentiated launch. Before launch, we initiated engagement with key payers to support timely access. And we've accomplished a lot within the first few weeks following approval, including activation of the MYFEMBREE website, fully stocking the distribution channel, activating patient support services and beginning in-person field force engagement.

More recently, in July, we began offering starter packs to certain prescribers who have identified

patients to initiate on MYFEMBREE therapy. All of these steps were taken with the intent of ensuring a positive first experience for providers, patients and payers, the hallmark of our launch strategy.

The Myovant and Pfizer sales teams have already conducted more than 20,000 sales calls in the first 5 weeks since our launch. With nearly 90% of these interactions being in person, reaching over 60% of our high and medium priority target prescribers. This activity has improved aided awareness among potential prescribers from approximately 30% pre-launch to nearly 50% as of July.

This early in launch, patient experience is just beginning, and we are encouraged by the approximately 100 patients that have enrolled in MYFEMBREE patient support services. Additionally, over 150 patients have been identified by prescribers as candidates for starter packs in just the first 2 weeks since launching the starter program.

Obtaining payer coverage for MYFEMBREE is among our top launch priorities. We anticipate that approximately 85% of patients that could be prescribed MYFEMBREE are commercially insured. The remaining 15% of potential patients primarily include Medicaid or cash patients.

As of July 1, 37% of commercial lives were eligible for pre-review coverage for MYFEMBREE. We believe MYFEMBREE is well-positioned to establish access that supports prescriber choice and minimizes out-of-pocket costs for patients. With certain payers, we have already made significant progress and believe some initial coverage decisions could be implemented as early as August.

We believe MYFEMBREE addresses the needs of providers and patients with its clinical profile and convenient one pill once-a-day dosing. We are excited about the progress that we've been able to make in the early days of launch and to be bringing a new and differentiated treatment option to women with uterine fibroids.

I'd now like to discuss the continued progress we've made on the ORGOVYX launch.

ORGOVYX launch momentum continues to build as we and Pfizer work toward redefining care for men with advanced prostate cancer. Six months following our launch we estimate that over 4,500 men have been treated with ORGOVYX, reflecting steadily increasing adoption. We recorded $10.5 million of ORGOVYX net product revenues in fiscal Q1, reflecting substantial demand-driven growth compared to fiscal Q4 2020.

Monthly estimated cumulative patients on therapy, which includes both patients on free and commercial drug, have increased every month since launch, culminating in June, where we estimate that over 4,500 men have been treated with ORGOVYX.

In May and June, we estimate that approximately 1,000 patients initiated ORGOVYX therapy in each month, reflecting a consistent and gradual trajectory that we've seen since launch. It's important to note that since launch, approximately 1/3 of patients treated with ORGOVYX received free drug, utilizing either our free trial, bridge or patient assistance programs. Although our visibility into patient level data is incomplete, we estimate that approximately 60% of patients that started ORGOVYX were previously naive to androgen deprivation therapy. Additionally, we believe that ORGOVYX is being utilized to treat patients across the spectrum of advanced prostate cancer, reflecting our broad FDA label and the therapeutic appeal of the ORGOVYX clinical profile regardless of patient types.

As we have discussed before, there are clinical, economic and operational considerations that can play a role in ADT treatment decisions. Since launch, we have been actively engaging with prescribers to drive ORGOVYX awareness and build recognition of its differentiated clinical profile. In the first 6 months of launch, Myovant and Pfizer have conducted over 42,000 sales calls with over 13,000 providers, including reaching nearly 90% of our highest priority target prescribers.

As the launch has progressed and COVID restrictions on in-person detailing have eased, the volume and quality of our engagements with health care providers and other practice personnel has increased significantly. In June, 75% of Myovant and Pfizer sales engagements were in person, which is up from 38% in February. We remain optimistic that we can maintain or increase this level of in-person detailing in the second half of 2021.

These sales efforts are delivering results. ORGOVYX shared voice continues to dominate the GnRH class and was nearly 50% in June. Our recent market research indicates near universal aided awareness amongst target prescribers with 82% indicating that they are knowledgeable about the ORGOVYX clinical profile.

We have also successfully broadened the base of prescribers to approximately 1,150 treatment centers through June, an increase of approximately 350 in just the last 2 months. The re-order rate also remains high with 80% of practices re-ordering ORGOVYX at least once, up from 75% at the end of April.

Finally, our market access team has worked diligently to enable e-prescribing. And as of early July, ORGOVYX was available across all of the EMR systems utilized in practices that we are actively targeting, up from approximately 60% at the end of April.

Utilizing data from our patient support hub and specialty pharmacy network, we estimate that approximately 56% of ORGOVYX prescriptions have been written by urologists and 40% by oncologists. This early trend is in line with the 2020 patient claims data for the ADT class. And as expected, the vast majority, 75% of the ORGOVYX commercial volumes has been shipped via the specialty distributor channel, which serves practices and institutions with dispensing capabilities such as large urology group practices, hospitals, academic centers and integrated delivery networks. The specialty pharmacy channel, which serves patients of practices that do not have in-office pharmacy capabilities, distributed the other 25% of ORGOVYX commercial volumes and is expected to remain the smaller channel for ORGOVYX going forward.

We have also made notable progress in building commercial and Part D coverage for ORGOVYX. As of July 1, we have coverage for over 150 million total lives, an increase of 49 million lives since May 1. Let's take a look at the progress we've made since May.

On the commercial side, ORGOVYX coverage expanded by 20 percentage points to 63%, adding 36 million incremental covered lives since May 1st. Plans that cover 28% of commercial lines have yet to make a 2021 coverage decision, but are expected to do so in the coming months.

We have made even greater progress with Medicare Part D, where we achieved coverage for ORGOVYX for 78% of lives as of July 1, an increase of 27 percentage points or 13 million lives since the beginning of May.

Plans that cover the remaining 22% of Part D lives may implement coverage decisions later this year with some of these plans potentially deferring ORGOVYX coverage implementation to early next year. Importantly, all payers contracted to date have agreed to cover ORGOVYX according to our FDA-approved prescribing information.

In closing, we continue to make tremendous progress across all areas of ORGOVYX launch and have built great momentum in the prostate cancer community. As we look forward, with in-person engagement increasing the impact of clinician engagement, and improved commercial and Part D coverage for patients, we believe that prescribing momentum will continue to steadily build and ORGOVYX will make a difference in the lives of many more men battling advanced prostate cancer.
I will now turn the call over to Frank to review our financial results.

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

Thank you, Lauren. As usual, I will focus my comments on the highlights of our financial performance in the quarter and refer you to our press release and Form 10-Q issued earlier today for additional information.

Let's begin with revenue. Myovant recorded $41.1 million of total revenue for the first fiscal quarter ending June 30, 2021, composed of $10.5 million and $1.1 million of net product revenue from ORGOVYX and MYFEMBREE, respectively, as well as $29.5 million of Pfizer collaboration revenue consisting of $21 million related to the partial recognition of the upfront payment Myovant received from Pfizer in December 2020 and $8.5 million related to the partial recognition of a $100 million regulatory milestone payment that was triggered upon FDA approval of MYFEMBREE.

In future quarters, the Pfizer upfront payment will continue to be amortized at a rate of $21 million per quarter. In the MYFEMBREE uterine fibroid FDA approval milestone will be amortized at $4 million per quarter through the end of calendar year 2026 when the amortization period is scheduled to end.

For fiscal Q2 2021, we also expect to recognize approximately $31.7 million of license and milestone revenue from our collaboration with Gedeon Richter, comprised of a $15 million regulatory milestone for the July 2021 European Commission approval of RYEQO for uterine fibroids, and $16.7 million related to the remaining portion of the upfront and initial milestone payments.

Moving on to other highlights of our income statement. Cost of product revenue for the quarter was $1 million and largely comprised of the high single-digit royalty on net sales of ORGOVYX payable to Takeda and to a lesser extent, expenses related to the cost of goods sold for ORGOVYX and MYFEMBREE.

Collaboration expense was $5.3 million, reflecting Pfizer's 50% share of net profits from the sale of ORGOVYX and MYFEMBREE in the U.S. during Q1.

R&D expenses in the first quarter were $30.9 million compared to $44.2 million for the comparable prior year period. The decrease in R&D expenses was mainly driven by cost share reimbursements from Pfizer as well as a reduction in clinical study costs resulting from the completion and wind down of Myovant's Phase 3 LIBERTY, HERO and SPIRIT studies. The decrease also reflects lower regulatory expenses in Q1 2021 as the prior year period included NDA submission fees for ORGOVYX and MYFEMBREE. These decreases were partially offset primarily by higher expenses incurred by Myovant's medical affairs organization, which was built out in recent quarters to support the ORGOVYX and MYFEMBREE launches as well as increased study costs related to relugolix's life cycle management activities.

SG&A expenses in the quarter were $61.2 million compared to $22.8 million for the comparable prior year period. The increase was primarily due to higher expenses related to commercial activities to support the U.S. launches of ORGOVYX and MYFEMBREE and higher personnel-related costs in connection with the hiring of Myovant's commercial operations, marketing and market access teams as well as the oncology and women's health sales forces.

Myovant generated a net loss of $61.7 million or $0.67 per share in the first quarter of 2021 compared to a net loss of $32.9 million or $0.37 per share in the prior year quarter.

Looking ahead, R&D expenses for the remaining fiscal 2021 quarters are projected to be modestly lower than Q1 actual spend. SG&A expenses for the remaining fiscal 2021 quarters are expected to

increase modestly from Q1 actual spend.

We ended fiscal Q1 with total cash and committed financing of $611.1 million comprised of $569.8 million of cash, cash equivalents and marketable securities and $41.3 million of capacity remaining under the low-cost loan facility extended to us by Sumitomo Dainippon Pharma, our majority shareholder.

This balance does not include $115 million of recently triggered milestone payments from the regulatory approvals of MYFEMBREE and RYEQO. We received the $100 million milestone payment from Pfizer in July 2021, and expect to receive a $15 million milestone payment from Richter in second fiscal quarter 2021.

Our cash position and potential future milestone payments over the next 12 months coupled with the sharing of certain expenses with Pfizer and the anticipated increase in ORGOVYX and MYFEMBREE revenue puts Myovant in an excellent position to execute our commercial strategies while at the same time, expanding our pipeline through future relugolix life cycle programs and business development.

I would like to wrap up with a bit more color on the recent developments pertaining to our intellectual property associated with relugolix, which we believe could extend U.S. marketing exclusivity for both ORGOVYX and MYFEMBREE into late 2037, significantly expanding the value of the relugolix franchise.

Depicted here is a subset of the patents listed on the FDA Orange Book for each product. Each product has 3 listed patents relating to the composition of matter case, which we have highlighted previously. The gray bar on the first composition case indicates that we have applied for a patent term extension which is currently pending a decision from the FDA and USPTO. We expect to receive the full 5-year term extending the relugolix species patent to January 2029.

The more recent development pertain to methods of treatment patents, which represent the culmination of years of research and innovation. All 3 of these patents expire in September of 2037, potentially extending the U.S. marketing exclusivity for these products. The 2 methods cases for ORGOVYX cover among other aspects, the particular dosing regimen for ORGOVYX. The methods patent for MYFEMBREE was issued last month and covers the use of our unique relugolix combination tablet to treat the FDA-approved use relating to urine fibroids. Among others, we have also filed the patent application, which is currently pending on our next anticipated indication for MYFEMBREE relating to the treatment of endometriosis.

Now with that, I'll turn it over to Dave for some closing remarks. Dave?

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

Thank you, Frank, and Lauren. The approval and launch of MYFEMBREE represents a significant milestone in expanding the treatment options for women with uterine fibroids to include for the first time a one pill, once-a-day regimen with the clinical profile that prescribers and patients have long desired. We're encouraged by the early progress that we've made with [the] MYFEMBREE launch and look forward to delivering this important new medicine to patients.

We're also excited about the launch momentum that we've been able to generate for ORGOVYX through our strengthened prescriber educational efforts and increased payer coverage that we achieved over the past few months.

In addition to continuing to execute on the ORGOVYX and MYFEMBREE launches, the remainder of

2021 will bring several other important milestones. By the end of October, we expect Pfizer's decision regarding its international option for relugolix rights in oncology. In the second half of the calendar year, we expect Gedeon Richter to launch RYEQO in Europe and to submit the European filing for endometriosis. We also expect to submit our randomized withdrawal study results to the FDA by the end of the calendar year, which will include 2-year bone mineral density data. And looking further ahead into the calendar year 2022, we expect a European Commission decision on our advanced prostate cancer filing.

As Frank highlighted, we continue to operate from a position of financial strength, which gives us the flexibility to sufficiently fund our U.S. product launches while simultaneously expanding our pipeline through relugolix life cycle opportunities and business development opportunities.

I'm extremely proud of the passion and the work done by our Myovant team to enable us to deliver on our mission to positively impact the lives of so many men and women. Thank you for your attention.

And I'll turn the call over to Ryan to begin the Q&A session.

Ryan Crowe, Myovant Sciences Ltd. - Vice President of Investor Relations

Thank you, Dave. Operator, can we now please poll for questions?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

We have a question from the line of Jason Butler with JMP Securities.

Jason Nicholas Butler, JMP Securities LLC, Research Division - Equity Research Analyst

Congrats on the progress. First one for me, just in terms of the MYFEMBREE launch. Can you just give us a sense -- I know it's early -- of what number of prescribers or your target prescribers are actually already writing prescriptions? And what's the feedback you're getting from the initial interactions in terms of what docs would need to start writing prescriptions? Is it reimbursement access? Or is there anything else that physicians are looking for? And then I have a follow-up.

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

Thank you, Jason. I'll let Lauren address some of those. Just as a bit of an intro. Of course, it's early going, as you know. And we also have a number of -- we're looking at kind of triangulating a number of just different areas of demand. So we see the audited data, but we also have activity within our hub services. And then we're starting to take a request for samples for -- from physicians that have yet to be distributed to the patients with a prescription or have a prescription involved. So let me let Lauren provide a little more color on that.

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

Yes. Thank you for the question, Jason. Yes, as Dave said, it's a little bit convoluted right now because of how early it is. So of course, we have prescription data that you see as well. But the other factors include the 100 patients we've seen come through our hub services as well as over 150 requests for samples for starters. So we have seen quite a bit of interest from prescribers to start patients even in these early weeks, although it may not all be in the data yet because they're receiving samples first.

And then as far as the anecdotal feedback from the field, we have been very pleasantly surprised with the positive feedback from prescribers. It's clear that they understand there is an unmet need here, with the treatment options that were previously available, and they understand the value that MYFEMBREE brings from a clinical perspective. As far as what may cause some hesitation, I think that they are very sensitive to payer coverage. And so we are actively in discussions with payers and hope to have some decisions relatively quickly that will help us to build confidence in the payer landscape and payer support for MYFEMBREE.

In the meantime, we do have our patient support services, and we've received positive feedback from our physicians on not just the services themselves, but also the hub and the level of support that they receive in going through the hub. So we believe we're doing everything we can at this point and are confident that we'll continue to build confidence as they get experience with the drug and also as we build that payer coverage.

Jason Nicholas Butler, JMP Securities LLC, Research Division - Equity Research Analyst

Great. And then, Dave, just as a follow-up, can you talk in any more color about the extension of the Pfizer opt-in. Was -- is this being driven by waiting for more commercial information or regulatory dynamics? Or any additional color you can give us there?

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

Sure. Look, we enjoy an excellent relationship with Pfizer. We have been in discussions regarding the opportunity in Europe. And really, we just felt that as we were going through some of these discussions that an extension was warranted just to allow Pfizer to complete its diligence and make a fully informed decision. So we feel very comfortable with the discussions that we're having, and we wanted to ensure that they had the right duration of time to fully explore the opportunity. So -- and we support that.

Jason Nicholas Butler, JMP Securities LLC, Research Division - Equity Research Analyst

Congrats again on the launches.

Operator

Our next question comes from Eric Joseph with JPMorgan.

Eric William Joseph, JPMorgan Chase & Co, Research Division – VP & Senior Analyst

Thanks for all the color on the ORGOVYX launch metrics. The 75% versus 25% breakdown of prescriptions coming from specialty distributors versus pharma -- pharmacies. Can you talk a little bit

about how that compares with the historical demand trend with ADT and AR blockers? Did it skew similarly? I'm just trying to get a sense of where you kind of see kind of the greater level of headroom in either of those segments?

And then perhaps just a follow-up also on the extended opt-in to Pfizer. Is there something particularly about this time frame to October as opposed to the end of the year? Would you rule out an additional extension of the opt-in deadline?

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

Well, thank you, Eric. I'll let Lauren address the first question regarding the breakdown of kind of source of demand, and then I'll take the Pfizer question, Lauren?

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

Yes. Thanks for the question. I can't speak to the comparison to other marketplaces. But what I can say is that this is playing out exactly as we expected. We knew from the beginning that it was important for us to remove any disincentive for using ORGOVYX from a financial perspective to support offices from an operational perspective and, of course, to build the confidence in our clinical profile. And so we fully expected that the majority of our business would be flowing through the specialty distributor channel. And we expect that for the foreseeable future that is our plan. And that's why we're continuing to bring on new accounts from a -- from the perspective of using ORGOVYX, many of which are dispensing. And so we would expect -- this is exactly as we expected, and we think the mix will stay similar to what it is today.

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

And then regarding the Pfizer opt-in decision, Eric, there really was no market or regulatory milestone that led to the specific 90-day or roughly 90-day extension. It was really the amount of time that we felt like was warranted to allow them to complete their diligence. So that was really the nature of it. We just sat down and thought that, that time frame would make sense. And it doesn't necessarily mean that they will take the full 90 days to get to a decision. We just felt like that was enough lead time to allow for the proper diligence to be done and for them to have conviction in their decision.

Operator

Our next question comes from Phil Nadeau with Cowen and Company.

Philip M. Nadeau, Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Let me add my congratulations on the 2 simultaneous launches. First, a question on ORGOVYX. Appreciate that's early days. Do you have a sense of how patients are using ORGOVYX? Is it being used as chronic therapy? Or are the men adopting it using in an intermittent fashion? Any sense of the role it's playing in the treatment?

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

Yes, Phil, I don't think we have the proportionality, but I think overall, we believe it's more chronic therapy. We know there is some intermittent use that we hear anecdotally. Of course, we don't have the data specific to that. But the vast majority of the feedback that we're getting is for chronic use. And I think as Lauren mentioned, a disproportionate share of those are new to ADT therapy.

Philip M. Nadeau, Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Perfect. And then second question, degarelix is supposed to have cardiovascular safety data come out, I think, any day. We've heard from physicians that, that could really spur the market towards the antagonists should show a benefit to degarelix. Do you have any sense when that data could be released? It seems like a kind of clinical trials like the trial completed some time ago?

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

Yes. I don't have particular insight in terms of the timing for their data. What I would say is that we certainly received very positive feedback around the data that we were able to generate through our HERO trial as it relates to cardiovascular risk. And we're very heartened to hear the feedback from clinicians as cardiovascular risk has really continued to become a consideration increasingly with the proper awareness of the cardiovascular risk that these patients have. So we're happy to see the increased attention on that. We think that's good for providers, and we think it's good for patients.

Philip M. Nadeau, Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Great. And then last question, in Lauren's prepared remarks, you mentioned the unmet need for the treatment of uterine fibroids. I'm curious if as you've been detailing to practices, if you have a better understanding of what is that AbbVie's kind of done wrong, why or hence launch hasn't gone better? And therefore, what ways could you improve with MYFEMBREE to get us uptake to be somewhat more rapid than what we've seen from the competitor.

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

Yes. I think it starts with a really deep understanding of the marketplace, and I'll let Lauren address there's kind of 3 key areas that we focus on leading up to the launch. And we think each of those provide a significant departure from what's occurred previously. So Lauren?

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

Yes. Thanks, Dave. We -- as you have, we have observed the competitive launches and the challenges that they face and learn from that. And I think the first thing that's most important is that our clinical profile is really unique and is uniquely meeting the specific needs that prescribers say that they have in this market as well as patients. And so we're bringing a unique offering to this market.

The second thing is that we are optimizing the first experience for patients. We've invested a great deal in making that first experience a positive one. And that's something that we learned was a challenge in previous launches. And then finally, we believe our field execution with having 2 teams, both of which have a lot of women's health experience and being able to flex those teams appropriately to reach the

breadth of targets in this market since it is very diffuse, but also being able to get the frequency where it's needed. And some of those ways, we believe that we'll be able to show up differently than our competitors have in the past.

Operator

And our next question is from Brian Skorney with Baird.

Brian Peter Skorney, Robert W. Baird – Sr. Research Analyst

Congrats on what looks to be a very solid launch so far. I guess to switch topics a little bit. I was just wondering if you could kind of give us some details on the protocol amendment, BMD monitoring in the SERENE study and just kind of how to think about that going forward? And just in terms of the role of relugolix in pregnancy prevention, how do we kind of think about the safety profile there versus proved oral contraceptives? I got sort of a substantial efficacy benefit over these in UF and endometriosis. But can you help understand what you see as the potential differentiation in pregnancy prevention here?

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

Yes, certainly, I'll let Juan Camilo address that. At the risk of saying that we don't typically comment on the FDA discussions back and forth. But Juan Camilo, what can you share with us?

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

Yes. I think that with regard to the amendment, we follow the advice that we received from the FDA, and we've submitted that the amendment protocol to them, we expect to hear back from them soon. And expect that to be with hopefully a removal of the hold and allowing us to restart the study. With regards to your -- the second part of your question about differentiation, I think that, as you know, women with uterine fibroids and in the future with endometriosis are premenopausal women and as they are considering their options for treatment for their diseases that they're talking about, they are also considering their reproductive decisions in that includes -- it includes contraception.

So the ability to have a product that treats their symptoms of uterine fibroids and endometriosis and provides prevention of pregnancy is something that we've heard loud and clear from gynecologists and from women to be a pretty important differentiating factor is something that they really care about.

I can tell you as a gynecologist that, that's something that I've had top of mind since we started developing relugolix combination tablet. Because I can't imagine those conversations happening in the clinic. So we feel very strongly that this is a pretty important component to the future of MYFEMBREE and the treatment of uterine fibroids and endometriosis.

Operator

Our next question comes from Paul Choi with Goldman Sachs. Paul, your line is open.

We cannot hear you, Paul. (Operator Instructions) We want to proceed with the next question from Josh Schimmer with Evercore ISI.

Gavin Clark-Gartner, Evercore ISI – Research Analyst

This is Gavin on for Josh. Nice quarter. Just have one. On the provider economics for ORGOVYX, that's dispensed through the provider-owned specialty pharmacies. I believe you had mentioned that the practice economics were pretty similar to the GnRH agonists. But given how eroded their ASP is and where ORGOVYX WAC is priced, it feels like there would be room to offer a little better economics. Could you just elaborate on this dynamic a bit?

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

Yes, certainly. Well, we have seen the change in ASP, Lauren, maybe you could address that.

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

Yes. And so as I believe you're already aware, we have contracted with the clinical accounts. And -- but when we did that, we did that to remove any disincentive from an economics perspective. Since then, the ASP dynamic for our competitors has changed. We are not affected by that. And at this point, it actually improves the economic dynamic in favor of ORGOVYX.

So we currently do not have any plans to change our contracting strategy. But the way that clinics determine how this plays out in their clinic and their decision-making is up to them. And it's unclear how much of a role that will play considering that shifting a patient, especially for some Medicare patients may change their co-pay. And so offices will have to consider both dynamics in making their treatment selection. Did that answer your question?

Gavin Clark-Gartner, Evercore ISI – Research Analyst

Yes, that’s helpful.

Operator

We have a question from the line of Paul Choi with Goldman Sachs. Please proceed.

Kyuwon (Paul) Choi, Goldman Sachs Group, Inc., Research Division - Equity Analyst

Sorry about earlier. Just 2 quick ones from our side, please. Just with regard to your other comments on forward demand for ORGOVYX here, can you maybe just sort of comment on how you're thinking about potential changes with regard to patient visit levels just given what seems to be the changing backdrop with regard to COVID? And any additional color you can say there? And then I had a follow-up question on MYFEMBREE.

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

Yes. I'll let Lauren address that. I think we're seeing certainly patient dynamics, I think, are different in the urologist office versus the oncology office. So Lauren, do you want to address that?

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

Yes. Thanks, Paul. So I think there's 2 elements to the COVID impact. One is what you were referencing, which is patients going into the clinic. And we've essentially seen that return almost to pre-COVID levels. So we're comfortable that, that dynamic is rebounding now. The second part is the access that we have to customers. And to Dave's point, that does vary between urologists and oncologists with oncologists managing immunosuppressed patients. They are a little more restricted at this point. However, in both cases, urologists and oncologists, that access has improved. And so that's why we're able now to have a higher percentage of in-person details, which is more valuable and allows us to have greater access to our customers, which is important to driving demand.

Kyuwon (Paul) Choi, Goldman Sachs Group, Inc., Research Division - Equity Analyst

Okay. And then on MYFEMBREE, I appreciate that the early sales were primarily stocking and inventory. I guess with regard to messaging in the market and having a sort of more fulsome presence in the market this quarter for either Dave or Lauren here, I guess. Can you maybe just sort of reframe for us, again, the learnings from the kind of competitors launch and just where you will primarily be focusing on addressing questions where there may have been resistance among potential prescribers for the GnRH class here and just what additional messaging you'll be bringing to market.

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

Well, thanks, Paul. I think one thing just for context. The real opportunity is not really for us to focus specifically on GnRH antagonist as a class. I think the real opportunity is to really look at those women who are still on oral contraceptives, who've been failed by their first-line therapy. We're looking at 3 million women who have been failed by their first-line therapy and another -- or a total of 5 million women who are seeking treatment. If we can step in and provide a better option for those patients with our clinical profile and then specifically with the -- with our administration of one tablet once-a-day, we think that's really where the opportunity is. And that is really where we think we can unlock the full potential of this marketplace.

I think our clinical profile, coupled with our one pill, once-a-day, it makes us really the ideal choice that physicians are telling us they're looking for. And we think now, coupled with the positive discussion that we're having with payers. We think that the payer environment will open for us as we hope. And in the interim, we certainly have all the patient support services to support the offices and the patients along the way. So we feel very good about the ability for MYFEMBREE to make a significant impact in the marketplace and really provide the treatment that both clinicians and patients have been waiting for.

Operator

And I'm not showing any further questions. I will turn it back to Dave for his final comments.

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

Okay. Thank you. Well, look, Myovant is at a very exciting time with 2 launches underway with differentiated therapies that can really make a meaningful difference for patients with advanced prostate cancer and with uterine fibroids. We are very well positioned, both operationally and financially to deliver strong commercial execution as well as build sustainable long-term value. So thank you all,

and I look forward to keeping you updated on our progress.

Operator

And ladies and gentlemen, this concludes Myovant Sciences' First Fiscal Quarter 2021 Earnings Conference Call. Thank you for your participation, and you may now disconnect.

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